Study on the evaluation of Regulation (EC) No 178/2002 ("the General Food Law Regulation")

Final Report

Dr Maria Christodoulou, Agra CEAS Consulting
October, 2015

fcec
food chain evaluation consortium
Civic Consulting - Agra CEAS Consulting - Arcadia International - Van Dijk Management Consultants

EUROPEAN COMMISSION

Directorate-General for Health and Food Safety
Directorate [Directorate letter] — [Directorate name *-see organigramme*]
Unit [Directorate letter.Unit number, *e.g. A.1*] — [Unit name *-see organigramme*]

Contact: [First name Last name]

E-mail: […]*@ec.europa.eu (functional e-mail if existing, or)*
[First name.Last name]*@ec.europa.eu*

European Commission
B-1049 Brussels

Study on the evaluation of Regulation (EC) No 178/2002 ("the General Food Law Regulation")

Final Report

Title	*Study on the evaluation of Regulation (EC) No 178/2002 ("the General Food Law Regulation")*
Conducted for	European Commission, Directorate-General for Health and Food Safety
By	Food Chain Evaluation Consortium (Civic Consulting - Agra CEAS Consulting - Arcadia International - Van Dijk Management Consultants)
Project leader	Agra CEAS Consulting
Author	*Dr. Maria Christodoulou (maria.christodoulou@ceasc.com)*
Reviewed by:	*Dr. Dylan Bradley*
Date	15.10.2015

Europe Direct is a service to help you find answers to your questions about the European Union.

Freephone number (*)**:**

00 800 6 7 8 9 10 11

(*) The information given is free, as are most calls (though some operators, phone boxes or hotels may charge you).

Luxembourg: Publications Office of the European Union, 2014

ISBN [number]
doi:[number]

PRINTED IN [Country]

PRINTED ON ELEMENTAL CHLORINE-FREE BLEACHED PAPER (ECF)

PRINTED ON TOTALLY CHLORINE-FREE BLEACHED PAPER (TCF)

PRINTED ON RECYCLED PAPER

PRINTED ON PROCESS CHLORINE-FREE RECYCLED PAPER (PCF)

Table of contents

List of Tables

List of Figures

List of Boxes

Acronyms

ABP	Animal by product
AGRI	Directorate General for Agriculture and Rural Development
AT	Austria
B2B	Business to business
B2C	Business to consumer
BE	Belgium
CA/s	Competent Authority/ies
CAP	Common Agricultural Policy
COM	European Commission
CZ	Czech Republic
DE	Germany
DG	Directorate General of the European Commission
EC	European Community
EE	Estonia
EEC	European Economic Community
EEN	Europe Enterprise Network
EFSA	European Food Safety Authority
ES	Spain
EU	European Union
EURL	European Union Reference Laboratory
EQ	Evaluation Question
FBO/s	Food Business Operator/s
FCEC	Food Chain Evaluation Consortium
FCM	Food Contact Materials
FI	Finland
FIC	Food Information to Consumers (Regulation (EU) No 1169/2011)
FR	France
FSG	Food for Specific Groups
FTA	Free Trade Agreement
FVO	Food and Veterinary Office (European Commission)
GAPs	Good Agricultural and Animal Husbandry Practices
GFL	General Food Law (Regulation (EC) No 178/2002)
GFSI	Global Food Safety Initiative
GM	Genetically Modified
GMPs	Good Manufacturing Practices
GROW	DG for Internal Market, Industry, Entrepreneurship and SMEs
GTPs	Good Trading Practices
HACCP	Hazard Analysis and Critical Control Point
HU	Hungary
IFS	International Featured Standards
IT	Italy
MANCP	Multi-Annual National Control Plan
ML/s	Maximum Limits
MOE	Measures of Effectiveness
MOS	Measures of Suitability
MRL/s	Maximum Residue Levels
MS	Member State/s
NGO	Non Governmental Organism
NL	Netherlands
NMS	New Member State
NRL	National Reference Laboratory
RASFF	Rapid Alert System for Food and Feed
REFIT	Regulatory Fitness and Performance Programme
PAFF	Standing Committee on Plants, Animals, Food and Feed (former SCOFCAH)
PCB	Polychlorinated Biphenyls
PP	Precautionary Principle
SANTE	European Commission's Directorate General for Health and Consumers

SCM	Standard Cost Model
SE	Sweden
SEC-GEN	Secretariat General of the European Commission
SG	Steering Group
SME/s	Small and Medium size Enterprise/s
SML	Specific migration limits
SMP	Skimmed milk powder
SK	Slovak Republic
SUD	EU Directive on the sustainable use of pesticides
TC/s	Third Country/ies
TFEU	Treaty on the Functioning of the European Union
ToR	Terms of Reference
TRADE	Directorate General for Trade
TTIP	Transatlantic Trade and Investment Partnership
UK	United Kingdom

Acknowledgements

This evaluation of Regulation (EC) No 178/2002, known as "the General Food Law (GFL) Regulation", was undertaken for the Directorate General for Health and Consumers (DG SANTE) of the European Commission. The study was led by Agra CEAS Consulting of the Food Chain Evaluation Consortium (FCEC).

The FCEC team would like to thank all authorities, stakeholders and independent experts[1] contacted during the project for their contribution to this study. We would also like to thank the members of the steering group and the various Commission services involved, as well as the third country authorities consulted, for their valuable assistance and support throughout the study.

The FCEC has appreciated the continuous and extensive exchanges with the relevant Commission services, members of the Steering Group, Expert Group (Member State Competent Authorities) on the GFL, and Working Group of the Advisory Group on the Food Chain (stakeholders) since the early stages and throughout this evaluation. In this process, every step of the methodological approach, including all data collection tools, have been fully validated and, in many cases, further refined to better reflect expert comments, opinions and guidance.

[1] The following independent experts were involved in the FCEC team on an advisory basis: Dr Alberto Alemanno; Dr Martin Holle; Dr David Jukes; Dr Mihalis Kritikos; and Dr Bernd van der Meulen.

Abstract

This evaluation of the General Food Law (GFL) assessed the effectiveness and efficiency of the GFL key provisions (Articles 1 to 21), and the potential for simplification and/or reduction of regulatory costs and burden. The performance of the GFL during 2002-2014 was assessed using evidence from: existing literature; online surveys of all 28 Member State (MS) Competent Authorities and of organisations representing the supply chain, NGOs and consumers; companies active in the supply chain (SME Panel); interviews (at EU and MS level), including selected third country authorities; and, case studies on four themes: traceability; allocation of responsibilities; risk analysis/precautionary principle; and, transparency (public information and public consultation). The analysis focused on establishing whether systemic failures could be identified in any areas of the GFL or in any other relevant secondary legislation (to the extent that problems/shortcomings raised issues related to the GFL provisions). The GFL was found fit for purpose, in terms of five key criteria (relevance; effectiveness; efficiency; EU added value; and coherence with wider EU policy priorities). Gaps/shortcomings were found to arise from interpretation, implementation and/or enforcement, mainly of other secondary legislation, at MS level. Thus the study identified some potential for legislative simplification and the reduction of regulatory costs/burden, in relation mainly to other secondary legislation.

Key Messages

- The General Food Law (GFL), for the most part, provides a framework of general principles and requirements on which further implementing provisions through other secondary legislation are based (with the exception of certain directly applicable provisions of the GFL e.g. on traceability and withdrawals/recalls)[2].
- Compared to the baseline situation prevailing prior to the adoption of the GFL, the GFL has made a positive contribution to the EU legislative *acquis* on food/feed, in line with the vision and expectations of the White Paper on Food Safety (COM(1999) 719 final).
- The GFL is fit for purpose, in terms of broadly fulfilling all five criteria on which it has been assessed (relevance; effectiveness; efficiency; EU added value; and coherence).
- The combined (overarching) effect of the GFL provisions has, for the most part, achieved the core GFL objectives, i.e. the protection of consumer health and interests and the effective functioning of the internal market (*effectiveness*).
- The GFL has facilitated implementation and enforcement of feed/food law across the EU, consistently allocated responsibilities among operators along the chain, and allowed simplification (*efficiency*).
- The original objectives of the GFL continue to correspond to current needs as driven by the evolving context within which the GFL operates (*relevance*).
- EU feed/food law/measures are particularly relevant to ensure both a harmonised and a more global approach across the EU, leading to a more uniform level of consumer protection and contributing to a level playing field (*EU added value*).
- With the introduction of definitions, overarching guiding principles and base requirements, on which other secondary legislation is built, the GFL has fostered coherence within EU feed/food law and across Member States (*coherence*).
- Despite the overall positive contribution of the GFL framework in fostering coherence when compared to the baseline, continuing gaps/shortcomings arise from differences in interpretation, implementation and/or enforcement, mainly of other secondary legislation, at Member State level.
- Such shortcomings affect the extent to which the integrated approach pursued by the GFL in ensuring 'chain responsibility' can be effectively and efficiently delivered.
- Further investigation of the identified problems and shortcomings has not revealed any link to systemic gaps or failures in the GFL principles and general requirements. On the contrary, the general non-prescriptive design of the GFL, defining broader principles and requirements rather than specific rules, is a strength, not only in the current context, but also making it 'future-proof' in an evolving global context.
- Thus, the study highlighted relatively limited further potential for legislative simplification and reduction of regulatory costs/burden in relation to the key obligations stemming from the GFL. On the other hand, more potential exists in relation to other secondary legislation. Recommendations are built on this basis.
- In terms of the GFL provisions, recommendations are mainly in the form of soft, non-legislative interventions, aiming to increase the harmonisation of implementation and enforcement. These relate to: the definitions (consolidated list; glossary); risk analysis and precautionary principle (guidelines; application of the precautionary principle; general principles of risk communication); feed/food safety requirements, allocation of responsibilities and withdrawals/recalls (training; review existing guidelines); and, transparency provisions (guidelines).
- In terms of other secondary legislation, recommendations include: review the application of exemptions/simplified rules for micro-enterprises; complete the harmonisation process in other secondary legislation (to address the problems related to incomplete harmonisation); develop/review EU guidelines; and, examine the feasibility of potentially laying down common principles and requirements regarding the different authorisation procedures that apply in sectoral legislation.

[2] The evaluation covered Chapters I and II (Articles 1 to 21) of the GFL; other secondary legislation was considered only to the extent that provisions systematically raise issues of consistency/coherence with the GFL that are relevant for this evaluation. The analysis focussed on establishing whether systemic failures could be identified in the implementation of the GFL and of other relevant secondary legislation.

EXECUTIVE SUMMARY

1.1. Introduction

The evaluation of Regulation (EC) No 178/2002 (the General Food Law - GFL) assessed the effectiveness and efficiency of the GFL, its relevance in delivering EU added value, its coherence with wider EU policy priorities as well as the potential for simplification and the reduction of regulatory costs and burden. The GFL is centrepiece and the foundation of the EU regulatory framework on food/feed. The GFL consists of several chapters which together establish common definitions and lay down overarching guiding principles for food/feed law, in order to ensure a high level of health protection and the effective functioning of the internal market. The fundamental principles enshrined in the GFL are reflected in other horizontal and/or sectoral legislation (referred to as 'other secondary legislation') that has been adopted or revised following the adoption of the GFL.

1.2. Methodology

The analysis in this study was produced using an evidence base comprising: a literature review; an online survey of all 28 Member State (MS) Competent Authorities (CAs); an online survey of organisations representing relevant sectors of the supply chain, NGOs and consumers; an SME Panel addressed to SME companies active in the supply chain; and, interviews with all of the above at EU and MS level, as well as interviews with selected third country authorities. In-depth analysis was carried out on the basis of case studies on four themes: traceability; the allocation of responsibilities; risk analysis and the precautionary principle; and, transparency (public information and public consultation). These case studies involved interviews with national authorities in ten MS: Austria, Estonia, Finland, France, Germany, Hungary, Italy, Netherlands, Slovakia, and the UK. Additional information and feedback came, *inter alia*, from a series of workshops organised at the start, interim and final phase of the study, in the context of: the MS Expert Group on the GFL; and, the Working Group of the Advisory Group on the Food Chain and Animal and Plant Health on the GFL. A triangulation process was used to validate all of the above evidence. Finally, the study benefited from a panel of independent experts who were involved in an advisory role.

The evaluation covers the key provisions stipulated in Chapters I and II (Articles 1 to 21) of the GFL as follows: definitions and scope; general principles and requirements of food law; principles of transparency; and, general obligations of food trade. Key challenges addressed in this study are that the GFL framework extends over a wide ranging policy area and sets out general principles implemented through other secondary, vertical or sector-specific legislation. Thus, the analysis focused on establishing whether systemic failures could be identified in any areas of the GFL or in any other relevant secondary legislation. Also, the consideration of other secondary legislation has been carried out only to the extent that provisions systematically raise issues of consistency/coherence with the GFL that are relevant for this evaluation.

1.3. Main findings: implementation and impacts of the core GFL provisions

GFL definitions and scope: The scope and general definitions of the GFL (Articles 2, 3 and 4.1) are sufficiently broad to ensure an integrated approach to food/feed safety management, and are relevant to address the core objectives of food law (EU/national). In particular, they have been instrumental in achieving a comprehensive, integrated approach for the management of food safety from 'farm to fork', which is demonstrated in the evaluation of the core requirements of the GFL (e.g. traceability and allocation of responsibilities). Despite the overall positive findings, shortcomings were identified in terms of a broader than intended interpretation of the definitions which can result in differences in practical approaches to enforcement. Although having in place sufficiently broad general definitions, in line with international definitions, ensures that the legal scope for control is wide enough, at the same time it creates the scope of such

differences in interpretation. This occurs even in cases where the scope and definitions are clarified in the Commission guidelines and/or in other secondary legislation: e.g., the definitions of 'food', 'retail', 'food business' and 'food business operator'. Other issues raised with regard to practical enforcement include cases where it is difficult to distinguish 'food' from 'feed' (e.g. borderline products or materials of potential multiple use), definitions/elements not explicitly stated in the GFL (e.g. 'consumer interest'; 'local' or 'craft'; e-commerce/distance selling; food contact materials, processing aids).

Core requirements for feed/food operators:

- **Traceability**: Article 18 has played a key role in achieving the generalised application of 'one step back-one step forward' traceability to cover the full supply chain. Its impact has been not only quantitative (from partial to complete application by all operators), but also qualitative (from fragmented/disjointed to full application along the chain), in line with the underlying "farm to fork" vision of the GFL. This has enabled the effective tracing of affected products throughout the supply chain, both in the event of food safety (e.g. dioxin, e-coli) and non-safety related incidents (e.g. horse meat fraud). Thus, Article 18 has proved to be a sufficient tool for food and feed tracing. In some cases, the more extended traceability currently in place is either justified by the specific objectives laid down in vertical legislation, or by business needs (e.g. internal traceability required by voluntary certification schemes and/or to minimise business losses in case of withdrawals/recalls). It is therefore not considered appropriate or justified for the general objectives of the GFL to extend the traceability requirement beyond one step back – one step forward, on a compulsory basis.
- **Allocation of responsibilities**: The rules laid down in Article 17 have largely ensured an effective and efficient allocation of responsibilities, both amongst operators and between operators and MS CAs, due to the non-prescriptive character of the provisions. Article 17.1 has led to the clarification/formalisation and more systematic application of measures and procedures that operators had in place prior to the GFL, to ensure their primary responsibility of compliance with the core requirements of EU/national food/feed law. This has established 'chain responsibility', a major novelty of EU feed/food law compared to the pre-GFL fragmented individual responsibility approach. Article 17.2 is implemented through the Official Controls Regulation (EC) 882/2004, which aims to create an integrated and uniform approach to official controls along the agri-food chain to ensure harmonised enforcement. There is evidence of efficiencies both at operator level (design of fit for purpose systems, integrated in quality management and certification schemes) and at authority level (in some cases, freed up resources to focus on enforcement). Despite the overall positive contribution of Article 17, in practice, key obstacles remain as follows: authorities in some MS do not consistently take into account operators' own-check/verification systems in determining risk profiling and the frequency of the audits carried out by MS CAs, although to some extent this also reflects differences in the reliability of operators' own checks; and, there are differences in understanding and implementation of the official controls carried out by national authorities between MS or even within MS (at regional/local level) although official control plans as such have benefitted from the harmonised requirements set out in Regulation (EC) 882/2004. The extent to which 'chain responsibility' can be ensured in a uniform manner across the EU, is also determined by the complexity of the supply chain, and incomplete harmonisation in other fields (including the allocation of liability which is based on the national legal order, as foreseen in Article 21, and in the specific infringed legislation). Although these shortcomings are not due to the GFL as such, they ultimately define the limits of the system in terms of its ability to deliver full 'chain responsibility'.
- **Determining food/feed safety, withdrawals and recalls of unsafe food/feed**: Operators have, for the most part, complied with the actions foreseen in the context of withdrawals and recalls when such actions were necessary, while the cooperation between operators and authorities is generally functioning well (as envisaged by Article 19: food; Article 20: feed). This has largely led to fit for purpose withdrawals/recalls and ensured a high level of protection of consumer's health. Compared to the situation prior to the GFL, the implementation of harmonised

provisions has led to more effective and efficient withdrawals and recalls, as also evidenced by the improvement both in the speed and costs of actions taken. Despite the overall positive findings, an important issue of concern remains the variable level of implementation of withdrawals/recalls between MS, including in terms of determining the course of action to be taken in similar cases, cooperation between authorities and operators, and informing consumers/transparency (Article 10). An underlying factor accounting for such differences relates to some inherent difficulties in interpreting and/or applying the legal provisions to determine the safety of feed/food, with regard both to Articles 14 and 15 and to secondary legislation. Particular problems have been encountered in areas of secondary legislation where the harmonisation of legislation is incomplete and in areas where there is no scientific basis for assessing safety risks or the balance between scientific assessments and other legitimate factors is not clear. In this context, the application of objective and transparent criteria to establish safety, such as in the approach currently applied to determine the safety of food products exceeding MRLs for pesticides residues, can improve the effectiveness of the legal provisions (GFL and secondary legislation) in protecting consumer health.

Application of risk assessment and risk management: Globally, since the entry into force of the GFL, EU measures managing microbiological, chemical and physical risks linked to food/feed have been adopted on the basis of risk analysis, in line with the general principles laid down in Article 6. Furthermore, most of the sectoral legislation (basic acts) laying down additional specific procedures (authorisation/setting of MLs) have been revised/modernised, including the design of harmonised procedures in most sectors, in line with the GFL risk analysis principles. The adjustment process has been gradual both at EU and at MS level over that past decade and this is still in progress today. The separation of the risk assessment and risk management functions at EU level has improved considerably over time and is generally functioning well in practice; risk assessment by EFSA is considered to be independent, objective and transparent. The implementation of the risk analysis principles has improved the scientific basis and transparency of measures adopted both at national and EU level, in all areas of feed/food law. It has also increased efficiency, in terms of: a) cost savings from the central approach followed at EFSA (thus reducing the need for national risk assessments, particularly in smaller MS that cannot afford to invest in the required scientific capacity); and, b) the pooling of scientific resources involved in EU/national assessment bodies. Where national and EU measures on feed/food have been adopted on the basis of a risk analysis, including consideration of other legitimate factors, positive outcomes have been achieved and measures have been effective and proportionate. Persisting problems/difficulties are partly linked to the complexity of the risk analysis process, but also to the complexity/diversity of the field of application, particularly in partially or non-harmonised areas. In particular, although both risk assessment and other legitimate factors consistently tend to be taken into account in EU/MS risk management process, in view of the diversity of issues/sectors, the exact range of factors varies on a case-by-case basis, according to needs. Although the case-by-case approach is considered inevitable, this contributes to a certain lack of 'certainty' in relation the outcome of the risk management process, particularly in the partially and non-harmonised areas; this constrains innovation, in view of the high costs involved (e.g. authorisation procedures).

Application of the precautionary principle (PP): There is considerable misperception both over the use of the PP and its potential impacts on innovation and trade. Although provisional risk management measures have been taken on the basis of Article 7 by most MS, there is lack of clarity on the actual basis of the measures, particularly in relation to the overlap/interface with the consideration of 'other legitimate factors' of Article 6. When assessed on the basis of objective criteria (duration of measures; whether reviewed; basis/trigger for adoption), national measures do not strictly speaking fulfil all three criteria. There is more limited use of the PP on the basis of Article 7 at the EU level; where it has been used, measures have been reviewed in most cases. A key continuing concern for failure/gap in the application of the PP is the scope for potential misunderstanding, in particular for wider interpretation of 'scientific uncertainty' than

originally intended, such as presumption of risk or uncertainty about the facts rather than the science, within a context where it is challenging to cover all areas of food safety and science. Although this is an inherent challenge of the PP across all policy areas, literature suggests that there is no single EU policy area, including in food law, where the PP has been misused. Despite these challenges, the application of the PP in food law has allowed prevention/earlier intervention; successful examples of the use of PP, according to consumers, include growth promoting hormones ractopamine and other beta-agonists (pre-GFL and post GFL), as well as GMOs. No evidence was provided of an adverse impact on innovation and trade, when the PP is correctly applied (as also supported by other literature). In this context, it is noted that a key constraint for the correct application of the PP, both at EU and at MS level, is that the reasonable time by which PP-based decisions should be reviewed - a key factor for the potential impact of PP measures on trade/innovation - depends on the availability of new scientific studies.

Transparency: As in the case of other adjustments by MS following the introduction of the GFL, those made to apply Articles 9 and 10 run concurrent to other parallel developments at national levels, in particular the considerable reorganisation of MS CA competences on food safety; these changes were accelerated by developments in the communications/media sector. In this sense, it is difficult to attribute impacts to the GFL as such, although the GFL was one of the factors contributing to greater harmonisation. Despite persisting national differences, these are progressively reducing, leading to an overall higher standard of transparency both at EU and national level, when compared to the situation prior to the GFL:

- **Public consultation**: this is applied more systematically, involves the wider spectrum of stakeholders/interest groups across the various legislative fields and an increase in general public consultation (facilitated also by the development of online consultation/survey tools and access to online information). These improvements contribute to: an increase in stakeholder confidence in the consultation process and the authorities, as documented by the results of public satisfaction surveys in MS where these exist; and, improving the evidence-base underpinning legislation and the feasibility of application/implementation. Nonetheless there is scope for further improvement, in particular in narrowing down persisting differences between MS approaches, as certain MS remain more advanced than others, with cultural differences an important underlying factor.
- **Public information**: the process of informing the public that a food/feed may present a risk has improved over time, in particular taking into account lessons learnt from poor communication and its impact during previous crises (e.g. dioxin, E.coli, etc.). Authorities tend to inform the general public in an order of priority that is generally defined and is proportionate to the level of the potential food/feed safety risk, and the type of information provided (in the case of recalls) is generally adequate/appropriate. Although this has had a positive impact in more effectively/efficiently managing emergencies, authorities highlight that there are no fixed rules on the best approach to take, particularly in balancing the need to provide additional information versus confidentiality requirements, which also depends on the circumstances and the case. Nonetheless, the development of public information mechanisms is dynamic, both at EU and MS level (e.g.: EU – establishment of RASFF Consumer Portal, 2014 and the pending proposal for a new Official Controls regulation; MS – ongoing development in some MS of mechanisms to inform the public of the results of official controls).

Trade and international aspects: The GFL has facilitated feed/food trade with third countries: the impacts that can be attributed to the GFL are qualitative, including the enhanced business/consumer trust and confidence and quality/safety aspects. The volume and pattern of trade are influenced mostly by market/economic factors, although harmonisation more generally both across the EU and in alignment to international standards (adopted at the level of Codex Alimentarius) exerts a positive impact on international trade: in setting the same requirements for both imported and EU food products, the GFL has led to harmonisation and the creation of a level playing field. For the most part, restrictions on trade (foreseen by Articles 11 and 12) are applied by MS when justified and the application of restrictions is generally transparent. Restrictions on

exports are usually implemented with measures taken under Articles 19-21 of Regulation (EC) 882/2004 and/or the non-issuance of health certificates for export, taking into account the specific rules applying in export destinations, rather than an export prohibition. This has achieved the intended objectives of the GFL in terms of avoiding the export to third countries of feed/food potentially injurious to health and no such incidents were reported by the consulted third countries. Nonetheless, EU exports to third countries of feed/food more generally are frequently hampered by differences in food law systems and/or the non-respect of international standards by some third countries. Although the EU is generally found to apply a high level of openness and transparency (including at Codex level) with regard to the applicable rules and principles on imports of feed/food from third countries, concerns remain over the lack of reciprocity in the transparency of the rules and principles applied by some third countries on their imports of feed and food from the EU (e.g. with regards to the pre-listing of establishments and the application of the regionalisation principle in trade restrictions).

1.4. Overall assessment of the GFL, conclusions and recommendations

Relevance: Taking into account the evolving context within which the GFL operates, the original objectives of the GFL, i.e. the protection of consumer health and interests and the effective functioning of the internal market continue to be the most relevant that the GFL needs to address, in that they correspond to current needs. Safety and non-safety related food incidents that have occurred over the evaluation period (e.g. 2011 E. Coli outbreak; 2013 horsemeat scandal) have impacted consumer health and interests, affected consumer confidence and led to costs and losses for the industry. The EU agricultural, feed, food and drink supply chain remains crucial to the wider EU economy. In the context of the economic downturn that has affected Europe since 2008, the GFL was generally found adequate to address innovation and competitiveness: by improving harmonisation in EU food law, it has enhanced predictability and ease of implementation and has streamlined processes for companies selling products within the internal market. Consuming healthier food/addressing the nutritional needs of the general population is currently embedded and adequately addressed in the GFL in the pursuit of a high level of human health: the provision of scientific advice on human nutrition is explicitly stated in relation to EFSA's remit; it is addressed through requirements in other secondary legislation covering nutrition labelling, health and nutrition claims. Similarly, the challenges posed by increasing globalisation are adequately addressed by the GFL: its provisions have contributed to the increasingly necessary global cooperation between all players and have played a key role in promoting international food chain governance by laying down an internationally recognised high level of food safety standards, and a general commitment of adherence to international standards.

Shortcomings in addressing current needs are due mainly to continuing failures and gaps with the completion and/or implementation of other secondary legislation and/or persisting national differences in areas that are not harmonised. For example, negative impacts on innovation mainly stem from shortcomings identified with the implementation of authorisation procedures foreseen in other secondary legislation, including in partially/non-harmonised areas (e.g. enriched food, food contact materials other than plastics). In terms of preventing/addressing fraudulent/deceptive practices, the broader current regulatory framework system is not considered sufficiently equipped to prevent, detect and sanction fraud in the food chain, despite relevant provisions foreseen in the GFL and the Regulation on Official Controls. Finally, in relation to the emerging trend of distance selling/e-commerce, the identified shortcomings do not relate to the relevance of the GFL objectives or scope which covers all food operators, but rather to the understanding and interpretation of the GFL definitions.

Effectiveness: The combined (overarching) effect of the GFL provisions has for the most part achieved the core GFL objectives. The evidence available from all major incidents over the past decade indicates that the core GFL provisions, such as traceability, withdrawals and recalls and their combined effects have played a major role in effectively addressing food safety risks, thereby raising the level of food safety in the

Union. More recently, these provisions have also shown their effectiveness to address non-safety related incidents such as in the case of the horsemeat scandal. Furthermore, the explicit inclusion of the protection of consumers' interests in the general objectives of the GFL (Article 5.1) has brought a change in approach in EU food law, as demonstrated by the Regulation on Food Information to Consumers (the FIC Regulation), which puts consumer interests at the heart of the legislation. The GFL has also largely contributed to achieving the free movement of food and feed in the internal market, which has grown by 72% over the evaluation period. The GFL has also played an important role in improving the effectiveness of feed/food law implementation in the MS with increased harmonisation: for example, in relation to risk analysis, where the GFL has enabled the achievement of a higher scientific standard throughout the EU. It has also contributed to more effective implementation for operators: by laying down principles and general requirements, the GFL has allowed its adaptability to best fit operational contexts and needs; other tools (private standards, guidelines, codes of good practice) have been effectively combined with the regulatory provisions, as observed for example in the context of traceability and operator responsibilities.

Any weaknesses identified are not linked to systemic problems with the GFL provisions. In particular, a number of tools/elements defined at MS level, that are essential to ensure harmonised and optimal implementation, are missing/incomplete and different approaches prevail in practice between MS. These include: variable national approaches to sanctions and liability; implementation of official controls by MS is not always risk-based; measures not always taken by MS and/or considerable differences in the approach and severity of measures to address fraudulent and/or misleading practices (Article 8). In some cases, inherent difficulties hinder harmonised implementation, such as the absence of objective/science-based criteria inevitably requires a case-by-case approach in practice: e.g., when considering other legitimate factors in the risk management decisions or when determining the safety of feed/food that is 'unfit for human consumption'. Considerable differences also persist in the approach and level of transparency between MS (although more harmonised compared to the baseline). This is an important shortcoming affecting consumer and business trust/confidence, as it creates perceptions and undermines the recognition of the facts in relation to the effectiveness of feed/food law. Moreover, the current level of cooperation between MS CAs in all of the above areas remains rather limited/*ad hoc* and does not allow the systematic and sufficient exchange of good/best practices.

Efficiency: The GFL has largely facilitated the implementation and enforcement of rules across the EU, consistently allocated responsibilities among operators along the chain, and allowed simplification. The benefits conferred by the provisions on traceability (Article 18) and operators' primary responsibilities (Article 17) outweigh the costs of setting up and operating the required systems. The low level of prescriptiveness, the combination of the legal requirements with self-regulation, and adaptability to national markets and cultures have acted as important cost-mitigating factors that allowed an efficient, fit for purpose implementation, tailored more closely to the specific operational, market and cultural needs of individual business operators within an extremely diverse EU feed and food supply chain. A key benefit of the core GFL provisions is the reduction in the costs of risk/crisis management, which *inter alia* can be attributed to the enhanced and harmonised traceability system in place. Similarly, the implementation of the risk analysis provisions of Article 6 has resulted in important efficiency gains in terms of cost savings from the central approach followed at EFSA and the pooling the scientific resources involved in EU and national assessment bodies.

Inefficiencies in practice stem from the same constraints and shortcomings that hinder effectiveness, rather than systemic gaps or failures in the GFL principles and general requirements. In particular, the burden for operators stemming from the GFL provisions is distorted by the impact of additional requirements posed by other secondary legislation, such as in the case of specific authorisation procedures, due to increased complexity and/or incomplete harmonisation (e.g. in the case of nutrition/health claims, and enriched food). Furthermore, differences in implementation by MS CAs, often due to

a non-uniform understanding and/or practical approach, do not allow the full achievement of a level playing field across the EU.

The current regulatory environment generally creates a relative cost advantage for larger-scale businesses which makes it harder for small and micro businesses to compete, all other factors being equal (size is not the only determinant factor). Furthermore, micro/small companies find it hard to understand and interpret requirements set by EU food law, do not know which authorities to approach and find that authorities are often unwilling to cooperate. Nonetheless, it is not the GFL but detailed requirements in other secondary legislation that contribute to the costs and burden. In this context, the concept of providing exemptions/simplified rules for micro-enterprises has not really worked in providing the intended benefits, except in a few best practice examples (notably, the exemption provided in the hygiene package to apply good manufacturing practices (GMPs) rather than fully-fledged HACCP systems and the exemptions for labelling of non-prepacked food under the FIC Regulation).

EU added value: EU feed/food law/measures are particularly relevant to ensure both a harmonised and a more global approach across the EU. When taken at EU level, they have the greatest effect, in terms of improving consistency/coherence in implementation and facilitating enforcement. This ultimately leads to a more uniform level of consumer protection across the EU and contributes to creating a level playing field.

Coherence: The GFL has fostered coherence both within the body of EU law of relevance to the food chain and across MS, *inter alia*, through the introduction of definitions, overarching guiding principles and base requirements, on which other secondary legislation is built. Complementarity with the Common Agricultural Policy (CAP) is inherent, as the CAP objectives include food safety policy goals; the food safety focus has gained momentum with the evolution of the CAP from price support towards increased market orientation.

Conclusions: The GFL is fit for purpose, in terms of broadly fulfilling all five criteria on the basis of which it has been assessed (relevance; effectiveness; efficiency; EU added value; and coherence). The GFL has made a positive contribution to the EU legislative acquis of relevance to the food and feed chain. This is in line with the vision and expectations outlined in the baseline context that led to the adoption of the GFL (White Paper on Food Safety (COM(1999) 719 final)). The GFL framework has established a new era in EU feed/food policy design and implementation. The observed fitness of the GFL to serve the purpose for which it has been set is a particularly important achievement given the difficulties of having a one size fits all framework legislation in this policy area. Considering the challenges of the diverse interests that the GFL aims to address, it has generally succeeded in providing a fit to purpose solution for the range of issues, sectors and affected stakeholders.

Despite the overall positive contribution of the GFL, a common finding of the evaluation, which runs across the assessment of the GFL provisions and all five criteria, is that gaps/shortcomings arise mainly from interpretation, implementation and/or enforcement of other secondary legislation, at MS level. These shortcomings have a bearing on the extent to which the integrated approach pursued by the GFL in terms of ensuring 'chain responsibility' can be effectively and efficiently delivered, which depends on whether there remain any weak points in the system. In this respect, the feed/food chain can be seen as any other system approach, which can only be as strong as its weakest part/link. In all cases, further investigation of the identified problems and shortcomings have not revealed any link to systemic gaps or failures in the GFL principles and general requirements. On the contrary, an overarching conclusion of the evaluation is that the general rather than specific design of the GFL, in the form of defining broader principles and requirements rather than specific rules, is its strength, not only in the current context, but also making it '*future-proof*' in an evolving global context.

Although the identified differences do not for the most part hinder the achievement of the GFL's core objectives, i.e. public health protection and the effective functioning of the internal market, a level playing field has not been fully achieved. Thus, the study highlighted some potential for simplification and reduction of regulatory costs/burden, although this is mainly in relation to other secondary legislation[3] rather than the key obligations stemming from the GFL. EU food law continues to evolve dynamically with a number of revisions to other secondary legislation recently concluded/currently ongoing, which aim *inter alia* to reduce the regulatory burden.

Recommendations: The recommendations below are drawn with a view, in particular, to the identified potential for simplification and/or reduction in administrative burden[4]:

- In the GFL, several areas were identified where differences in understanding and/or interpretation of some provisions prevail and can have important implications for the effectiveness and efficiency of implementation. Recommendations are provided mainly in the form of soft, non-legislative interventions, with a view to addressing these differences, thus aiming to more harmonised implementation/enforcement. In particular, these relate to: the definitions (consolidated list; glossary); risk analysis and precautionary principle (guidelines; application of the precautionary principle in the filed of food law; general principles of risk communication); feed/food safety requirements, allocation of responsibilities and withdrawals/recalls (training; update existing guidelines); and, transparency provisions (guidelines).
- Beyond the GFL, recommendations to address the shortcomings identified in other secondary legislation include[5]: review the application of exemptions/simplified rules for micro-enterprises; complete the harmonisation process in other secondary legislation (to address the problems related to incomplete harmonisation); develop/update EU guidelines; examine the feasibility of potentially laying down common principles and requirements regarding the different authorisation procedures that apply in sectoral legislation.

More generally, the review/development of guidelines, training, as well as encouraging more cooperation and exchange of best practices between MS CAs are complementary soft interventions that can help improve interpretation, implementation and enforcement of legislation. This applies both to the general principles and requirements of the GFL and to other secondary legislation.

[3] Furthermore, in the context of national measures adopted by MS in non-harmonised areas, the TRIS system for MS notifications is not currently used to its full benefit to prevent or follow up on potential trade barriers.
[4] It is noted that the potential for reduction of regulatory burden is bound by the wider objective of the GFL to ensure a high level of consumer protection (i.e. any potential reduction cannot risk undermining this objective).
[5] The recommendations provided here should be read in the context of the present study scope (the evaluation of the GFL), and are not an exhaustive list of all areas of EU feed/food law where the potential for simplification and/or reduction in administrative burden may exist.

I. DESCRIPTION OF THE STUDY

I.1 Economic and legal context

I.1.1 Food law, public health and the economic dimension of the EU food and feed supply chain

Food law has an important role both in terms of pursuing the protection of public health and for the operation of the food and feed supply chain[6]. The provision of safe, nutritious, high quality and affordable food to EU consumers is the central objective of the extensive EU policy and legislative framework, which covers all stages of the supply chain.

Although the **public health impacts** of food law cannot be fully monetarised, relevant literature, including the Fitness Check on the food chain Commission Staff Working Document, SWD(2013) 516 final), point out three major areas of impact:

1. **Direct costs and losses.** The BSE crisis (1988 and onwards) had 170 direct victims and interrupted a trade worth in excess of €800 million per year. The 2011 *E. Coli* outbreak from sprouting seeds cost more than 50 lives and losses for fruit and vegetable growers estimated to have exceeded €800 million, in addition to over €200 million of emergency payments on market support, and other costs/losses (European Commission, 2011a). In the case of dioxin contamination (Ireland, 2008), although less than 10% of pork products were potentially affected by the contaminated feed, 100% of products were recalled with an estimated cost of €200 million (Houses of the Oireachtas, 2009). [7]
2. Six of the seven biggest **risk factors for premature death** relate to nutrition and lifestyles.
3. **Obesity.** More than half (53%) of all adults in the EU are overweight or obese, which is associated with higher risks of chronic illnesses resulting in shorter lifespans and higher expenditures on health[8]. The prevalence of overweight and obesity among adults exceeds 50% in 17 Member States. Moreover, this is a rising trend: one in six adults on average across the EU was obese in 2012, up from one in eight in 2002. Obesity tends to be more common among disadvantaged groups. Consequently, targeting obesity has been a major objective of the 2007 Strategy for Europe on Nutrition, Overweight and Obesity-related Health Issues.

In terms of the sector's economic importance[9], the EU **food supply chain[10]** comprises all actors and activities from primary agricultural production, food processing, distribution and

[6] Beyond the legislative framework directly linked to food and feed (i.e. the GFL and other secondary legislation), the operation of the food and feed supply chain is also subject to requirements laid down in legislation pursuing other objectives in other policy areas. This includes the Common Agricultural Policy (CAP), and more specifically the Single Common Market Organisation, including marketing standards which can most notably impact the quality of agricultural products. Other relevant areas are internal market legislation, international obligations such as in agreements and standards, environmental protection and sustainability, industrial policy and SMEs, competition and its impact on choice and innovation, and the EU research and innovation agenda.

[7] The costs of safety incidents in other specific cases are explored further in the study on RASFF, which was conducted for the European Commission in parallel to this evaluation.

[8] Source: OECD (2014), Health at a Glance: Europe 2014, OECD Publishing.

[9] The GFL applies to both the food and feed sector. Due to data availability, different sources are used in this presentation of the food and feed sector's economic importance. For this reason, a distinction is made between the food and feed supply chain. In the Report findings, where a reference is made to the supply chain more generally, this refers to both the food and feed supply chains, unless otherwise indicated.

[10] The term **'food supply chain'** describes a wide concept comprising all actors and activities from primary production (agriculture and inputs), food processing (all four stages from e.g. animal slaughter to ready-to-eat products, including industrial and craft-based enterprises), distribution and retailing (supermarkets and farmers' markets), and finally consumption by citizens/consumers. This term is to be contrasted with the term **'food**

retailing and consumption. The EU agricultural, food and drink sector is crucial to the wider EU economy [11] employing over 24 million people, more than 11% of the total EU workforce[12]. The sector generates added value of around €650 billion per year, almost 6% of total EU gross value added (GVA), with a turnover exceeding €3.5 trillion. There are over 13 million holdings/ enterprises operating in the EU food supply chain.

The food and drinks processing sector contributes nearly a third to the total value added and turnover generated within the food supply chain, although it accounts for only 2.2% of the number of enterprises (286,000 companies). This is the largest sector in the EU manufacturing industry, representing 15% of turnover, 13% of value added and 16% of employment (4.2 million people) in manufacturing.

The sector is relatively fragmented and dominated in numbers by SMEs (including micro-businesses). SMEs represent 99% of food and beverage manufacturing enterprises, account for over half of total turnover (52%) and almost two-thirds of total employment (64%: 2.9 million people). Within the grouping of SMEs, the majority are micro-business (self-employed and up to 9 employees), which account for nearly 79% of all companies in the food and drink industry, 8% of turnover, 9% of value added, and 17% of employees. Further analysis by European Commission (2013) shows the importance of micro-businesses, which account for more than half of all food business operators in 16 of 23 MS for which there are data. In Austria, Belgium, Cyprus, Finland, Italy, Netherlands, Poland, Sweden and Slovenia micro-business account for at least two-thirds of the sector. Across the EU, in the food sector more generally[13], there is on average 15 employees per company.

Internal trade is important and amounts to around 20% of food and beverage production. The value of internal trade in this sector has increased by 72% over the past decade.

The EU is the leading food and drink producer worldwide; the sector's turnover is double that of the US or China. It is also the largest global trader and a net exporter of food and drinks, with total annual exports of €86 billion and imports of €63 billion (2012) [14]. Nonetheless, the EU share of trade in food and drinks in world markets has shrunk over the last decade, from 20.5% of global exports and 18.1% of global imports in 2002, to 16.1% and 14.0% respectively in 2012[15]. A similar loss in market share is observed for other traditional world exporters such as the US, Canada and Australia, while emerging trading partners such as Brazil, Thailand and Indonesia have continuously increased their world market share in recent years. As a generalisation, the EU tends to import raw materials and export further processed products. The main imported products are oils and fats, fruit and vegetables, wine, sugar, animal feed, and exotic products. The main exported products are animal products (meat and dairy), spirits and wine. The main trading partners for EU exports are the USA, Russia, China, Japan, Switzerland, Norway, Canada and Australia, with imports drawn mainly from Brazil, Argentina, the USA, Switzerland, China, Indonesia, Thailand and Turkey.

---

sector', which is more narrowly defined, focusing on the main economic actors from primary processing to the final point of sale: this mainly includes the food and drink industry, retailers, food crafts and wholesalers, as well as trade and distribution.

[11] Sources: Eurostat; Food Drinks Europe (FoodDrinkEurope: Data & Trends of the European Food and Drink Industry, 2013-14), unless otherwise indicated. All data are latest available (on a comprehensive basis): 2012, unless otherwise indicated.

[12] The sector creates an estimated 32 million jobs in the extensive food supply chain including food and drinks services and self-employed professionals.

[13] As indicated above, the term 'food sector' is more narrowly defined than the term 'food supply chain', in that it focusses on the main economic actors from primary processing to the final point of sale: this mainly includes the food and drink industry, retailers, food crafts and wholesalers, as well as trade and distribution.

[14] Source: Eurostat (COMEXT).

[15] Source: UN COMTRADE.

Regarding the economic relevance in individual Member States (MS), the food and drinks sector ranks among the top three manufacturing industries in terms of turnover and employment in several MS; it actually ranks first in France, Spain, the UK, Denmark and Belgium. The industry is an essential part of national economies. The share of employment in this sector surpasses 15% of the total workforce in more than half of the MS. Six MS (Germany, France, Spain, the UK, Italy and Poland) are the largest EU food and drink producers, accounting for nearly two thirds of the total turnover and workforce in EU-27 food and beverage manufacturing.

Food and drink are important areas of consumer household expenditure accounting for 14.6% of the total in 2012, currently making this the second largest expenditure category after housing, water and energy[16]. It is noted that, a decade ago, household expenditure on food and drinks ranked first, with housing, water and energy coming second; the shift in importance between these two categories is due to a constant increase, over the past decade, in the relative share of housing, water and energy expenditure, while the share of food and drinks expenditure has remained stable. The share of household expenditure taken by food and drinks differs considerably between MS, from just over 10% in the UK to over 25% in Romania and the Baltic MS.

Investment in research and development (R&D) in food and drink manufacturing has traditionally been low compared to other industrial sectors, averaging around 2.2% of the total investment in the EU. However, unlike other sectors of industrial activity, the food and drinks sector has continued to withstand the economic crisis to a certain extent, *inter alia* sustaining levels of R&D investment. Over a quarter of the world's leading food and drink companies in terms of levels of R&D investment are based in the EU: 17 companies investing €2.3 billion or a quarter of the global R&D investment by the world's leading companies in this sector (2012)[17]. Furthermore, the EU is supporting R&D in the sector through Horizon 2020, most notably under the work programme for Food Security, Sustainable Agriculture and Forestry, Marine, Maritime and Inland Water Research and the Bioeconomy, which has an overall budget of over 1bn for the 2014-17 period[18].

The EU **feed supply chain** extends beyond the food supply chain and includes the interface with animals, as well as procurement of raw materials from outside the agricultural sector (e.g. mining). Animal feed, including feed materials and compound feeds, feed additives and premixtures of feed additives, as well as medicated feed, are the main input into livestock production[19]. Compound feed are manufactured from a mixture of raw materials designed to achieve pre-determined performance objectives among animals. These raw materials are obtained from a wide variety of sources. Hence, the industry provides a major market for EU cereals, oilseeds and pulses. Some raw materials are obtained from the co-products of the food industry. Other important ingredients which cannot be grown in sufficient quantity in the EU are imported from third countries. These diverse sources of raw material supplies are an important factor in the industry's ability to manufacture feeds of both high quality and at competitive prices for livestock farmers.

[16] Source: Eurostat (National Accounts).
[17] Source: EU industrial R&D investment scoreboard, JRC and DG RTD, 2013
[18] In terms of the period covered by the GFL evaluation, the 7th Research Framework in the areas of consumers, nutrition, food safety, food processing and the environmental impact of the food chain, provided a total budget of approximately €500 million over the 2007-13 period, with SMEs being specifically targeted.
[19] No overview data at EU level of the sector covering feed additives (including premixtures of feed additives could be obtained in the course of the study. It is noted that feed additives and medicated feed are different types of feed (medicated feed is not a type of feed additive).

Within the EU-28, about 477 million tonnes of feed are used in livestock farming each year (source: FEFAC 2013 Yearbook, last update Feb 2015). Out of this quantity, 233 million tonnes mostly are roughages grown and used on the farm of origin. The balance, i.e. 244 million tonnes of feed, includes cereals grown and used on the farm of origin (51 million tonnes) and feed purchased by livestock producers to supplement their own feed resources (either feed materials or compound feed). In 2013, 154 million tonnes of compound feed were produced by EU compounders, accounting for 80% of all purchased feed. The value of all feed used by EU livestock producers, including forages produced on the farm, is estimated at €94.5 billion in 2013. This accounts for 38% of all inputs and 56% of the turnover in livestock production. Purchases of compound feed amounted, in 2012, to €55 billion.

In view of the important economic dimension of the food/feed supply chain, its **contribution** is most significant to three of the **flagship initiatives of Europe 2020**:

- The EU vision for industrial policy in the globalisation era (European Commission, 2010d), which sets out the objective of reindustrialising Europe: the target set by 2020 is for the share of industry in the EU economy to increase from 16% to 20 %. As the first EU manufacturing sector in terms of employment and added value, the food sector has a key role to play to reach this target.
- The EU flagship initiative 'A resource-efficient Europe' (European Commission, 2011e), which calls for incentives for healthier and more sustainable production and consumption of food, including the aim of halving the amount of edible food waste disposed of in the EU by 2020.
- EU initiatives aimed at fostering innovation, including the EU flagship initiative 'Innovation Union' which is closely linked to the Horizon 2020 integrated research programme, and through European Innovation Partnerships (EIPs), notably on 'agricultural productivity and sustainability' (European Commission, 2012g).

I.1.2 The General Food Law (GFL): aim, objectives and scope

Centrepiece and the foundation of the EU regulatory framework on food is the **General Food Law (Regulation (EC) No 178/2002)**. The GFL consists of several chapters which together establish common definitions and lay down overarching guiding principles and legitimate objectives for food law in order to ensure a high level of health protection and the effective functioning of the internal market. The GFL can be seen as the foundation on which EU food law has been reconstructed during the past decade, as reflected in the German term for it: "*Basisverordnung*" (van der Meulen, 2013). The GFL aims to harmonise at the Union level general food law principles and requirements already in existence at the Member State (MS) level, place these in the EU context and provide the basic framework of definitions, principles and requirements for EU food law. Finally, the GFL also establishes the European Food Safety Authority (EFSA) and procedures and tools on the management of emergencies and crises.

The GFL defines food law as "laws, regulations and administrative provisions governing food in general, and food safety in particular, at Union or national level". The scope is therefore broad and covers a wide range of specific fields that need to be regulated to ensure the production, trade and handling of safe food and feed. This means that everything to do with food and feed, whether at the Union or national level, directly or indirectly, falls under the auspices of food law. The GFL covers all stages of the production, processing and distribution of food and feed[20].

[20] While the general scope of the GFL Regulation includes all feed in general (Art. 1), the scope of the Chapter II excludes feed for non food producing animals (Art. 4). Certain provisions of that chapter apply to this category of feed via sectoral legislation with specific provisions on feed for non food producing animals.

In particular, the GFL pursues four main objectives:

1. To ensure a high level of protection of consumers, in particular of their health

This is a fundamental objective, although its pursuit should also take account of animal health and welfare, plant health and the environment. The GFL establishes strong guarantees on safety including:

- the separation of risk assessment and risk management, i.e. allowing for the independent assessment of risk;
- the creation of a general safety obligation and of a general requirement of verification (applying to all actors in the food/feed chain);
- specific requirements providing for the withdrawal and recall of unsafe food/feed and restricting the export of unsafe food/feed.

The protection of consumers against misleading information and fraud is also established as an objective to be pursued by food law.

2. To ensure a comprehensive and integrated approach of the food/feed chain as well as a common field for the free movement of foods by creating a harmonised framework for the development of all food law (EU and national)

In order to operate a level playing field within the internal market it is important that there is a harmonised scope for food law including definitions, principles and procedures. In order to pursue the objectives of a high level of protection of health and the protection of consumers' interests it is necessary to apply a risk analysis approach covering risk assessment, management and communication. Under the GFL, risk management is based on the results of risk assessment taking into account other legitimate factors[21]. A uniform basis for this approach is required to eliminate barriers to the free movement of food and feed within the internal market which might arise if the precautionary principle is applied in different ways. It is also imperative that public authorities take decisions in a transparent way and that the public receives consistent messages on risks to health. The GFL also recognises the EU's commitment to international obligations and EU food law is developed taking international standards into consideration, although the high level of consumer protection pursued by the EU remains paramount.

3. To ensure that food law is supported by high quality, independent and efficient scientific and technical support and to secure a science-based approach to risk

There is a need for food law to be science-based and the GFL establishes the European Food Safety Authority (EFSA) as an independent agency with sufficient scientific capacity to be responsible for providing scientific opinions (risk assessment) as a basis for legislative actions (risk management) taken by the EU institutions.

4. To ensure the prevention of crises (adequate prevention and management of emergencies in order to prevent them developing into crises)

The prevention and better management of crises involved the creation of new tools, in particular the obligation to ensure traceability along the food chain, the requirement for food/feed business operators to withdraw or recall food/feed at risk and notify public authorities, an improved and broader Rapid Alert System for Food and Feed (RASFF) allowing for adequate management of emergencies (to prevent small incidents becoming crises) and the establishment of procedures for emergencies/crises.

[21] According to recital (19) of Regulation (EC) No 178/2002, these include societal, economic, traditional, ethical and environmental factors, as well as the feasibility of controls.

The GFL was adopted in 2002 and entered fully into force in 2005, while existing national and EU food law principles and procedures were to be adapted to conform with the general principles in Articles 5 to 10 of the GFL by January 2007. The fundamental principles enshrined in the GFL and to be followed by public authorities are reflected in other horizontal and/or sectoral legislation (hereafter referred to as '**other secondary legislation'**) that has been adopted or revised following the adoption of the GFL.

These objectives are addressed through the intervention logic set out in the **ToR (Annex 1)**, which provides the theoretical framework against which this evaluation has taken place.

The legislative framework and state of play with respect to the GFL and other relevant secondary legislation is summarised in **Table 1**.

Table 1: Legislative framework and state of play: the GFL and other key secondary legislation *(a)*

Policy area/ legal act	Description of legislative framework / revisions	State of play
General food law	Regulation (EC) 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority (EFSA) and laying down procedures in matters of food safety entered into force on 21 February. It aims to ensure a high level of protection of human life and health, taking into account the protection of animal health and welfare, plant health and the environment, and applying this in a non-discriminatory manner.	Full application (Framework regulation applicable since 2005)
OTHER KEY SECONDARY LEGISLATION: FOOD		
Hygiene package	The food hygiene package comprises three basic Acts: Regulations (EU) 852/2004 and 853/2004, addressed to food business operators; and, Regulation (EU) 854/2004, which is addressed to competent authorities (along with Regulation (EU) 882/2004 on official controls (see below)). A series of implementing measures, adopted since 2005, complement the package. The objective of this package was to simplify the existing legal corpus on food hygiene, make it more coherent by separating the different disciplines (public health, animal health and official controls) and concentrate on objectives to be reached by food business operators rather than maintaining very detailed requirements. The experience gained from the application of the hygiene package was reviewed in a Report from the Commission to the European Parliament and the Council (European Commission, 2009a), and no fundamental overhaul was considered to be needed, although a number of suggestions for improvements have been made. A series of guidance documents on the implementation of the various provisions has been provided by the Commission.	Basic Acts applicable since 2006
Official controls along food chain	Regulation (EU) 882/2004 on official controls provides a general framework for official controls performed by MS CAs to verify compliance with feed and food law, animal health and animal welfare. It includes among others rules on the financing of official controls, administrative assistance and cooperation, enforcement and rules on controls on imported products. This legislation is currently under revision. The aim of the Commission proposal (COM(2013)265) is to simplify and clarify the legal framework, and consolidate the integrated approach to official controls in all areas related to the feed and food chain. Thus, the proposal foresees, *inter alia*, to: extend the scope of official controls to plant health, plant reproductive material and animal by-products in order to cover the whole agri-food chain; allow for the adoption of official control requirements adjusted to the needs of specific sectors (e.g. meat inspections, controls on organic products, animal welfare controls); increase the transparency of official controls activities carried out by national authorities, including – under certain conditions – publication of information on the results of controls on individual operators and to establish "rating schemes"; and, extend mandatory fees to most official controls to ensure that MS control authorities have appropriate resources to carry out their controls.	Commission adopted proposal in a 'package' on 6 May 2013

Policy area/ legal act	Description of legislative framework / revisions	State of play
Food information to consumers (FIC)	The EU 'FIC' Regulation (Regulation (EU) 1169/2011 on the provision of food information to consumers) considerably changed previous legislation on food labelling including nutrition information on processed foods, origin labelling of fresh meat from pigs, sheep, goats and poultry, highlighting allergens e.g. peanuts or milk in the list of ingredients etc. The new law builds upon the previous legislative framework, i.e. Directive 2000/13/EC (labelling, presentation and advertising of foodstuffs) and Directive 90/496/EEC (nutrition labelling for foodstuffs)	The new rules apply from 13 December 2014 with the exception of the rules on nutritional labelling which will apply as of 13 December 2016
Novel food	Foods and food ingredients that have not been used for human consumption to a significant degree in the EU before 15 May 1997 are considered as novel foods and novel food ingredients. The current rules (Regulation (EC) 258/97) date back almost 20 years. Since then, technological developments and scientific advice have evolved considerably. Between 1997 and 2014, there have been around 170 applications for authorisation across the EU (7-10 applications/year), of which so far around 90 novel foods have been authorised for use. To reduce the current length (3 and a half years on average) for the authorisation procedure, EU rules needed updating. Political agreement on the revised proposal for a new novel foods Regulation (COM(2013)894) was reached recently. The aim of the new Regulation is to make the authorisation procedure for novel food simpler, faster and more efficient, so that innovative food which is safe to consume can be put on the market faster. One of the main changes introduced is a centralised authorisation system, which will allow greater certainty for applicants seeking an authorisation for novel food and will simplify and speed up the authorisation process. Furthermore, to facilitate trade of traditional food from non-EU countries, which are considered novel foods in the EU, the new Regulation also introduces a more appropriate assessment procedure for food new to the EU. The new rules will apply two years from the entry into force of the new Regulation (around end 2017).	Commission adopted proposal on 18 December 2013 (COM(2013)894). The EP adopted the 1st Reading Agreement on 28 October 2015 and the Council on 16 November 2016.
Biotechnology / GMO	The legal framework regulating genetically modified food and feed in the EU framework aims to ensure a high level of protection of human health and environmental interests, while balancing these aspects with the effective functioning of the internal market. Key pieces of legislation are Regulation (EC) 1829/2003 (genetically modified food and feed), Regulation (EC) 1830/2003 (traceability and labelling), Regulation (EC) 65/2004 (unique identifiers), Regulation (EC) 641/2004 and Directive 2001/18/EC (release into the environment).	Assessment ongoing
Food contact materials	Food contact materials and articles are regulated by Framework Regulation (EC) 1935/2004, which provides harmonised general safety requirements for all food contact materials, as well as a general obligation on good manufacturing practices (GMPs) (the rules for which are laid down in Regulation (EC) 2023/2006). This framework is complemented by legislation on specific materials and on individual substances. In particular, certain FCMs — ceramic materials, regenerated cellulose film, plastics (including recycled plastic), as well as active and intelligent materials — are covered by specific harmonised EU measures; there are also specific rules on some starting substances used to produce FCMs. The most comprehensive FCM sector for which specific EU measures have been established is Regulation (EU) 10/2011 on plastic materials and articles, for which EU guidance has also been provided by the Commission. This Regulation sets out rules on the composition of plastic FCMs, establishes a Union List of substances that are permitted for use in the manufacture of plastic FCMs, specifies restrictions on the use of these substances and sets out rules to determine the compliance of plastic materials and articles. An important mechanism to ensure the safety of plastic materials is the use of specific migration limits (SML).	Framework regulation (FCM) applicable since 2004
Food improvement agents	EU rules on food additives, enzymes and flavourings, also known as "Food improvement agents", provide a common EU authorisation procedure for these agents. This is laid down in a legislative package which includes four regulations: Regulation (EC) 1331/2008 establishing a common authorisation procedure; Regulation (EC) 1332/2008 on food enzymes; Regulation (EC) 1333/2008 on food additives; and Regulation (EC) 1334/2008 on flavourings. A practical guidance for applicants on the submission of applications on these agents has been provided by the	Applicable since January 2011 *(b)*

Policy area/ legal act	Description of legislative framework / revisions	State of play
	Commission (latest update 26 January 2015).	
Food supplements (vitamins and minerals)	The objective of the EU harmonised rules on those products (which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, intended as an addition to a normal diet) is to protect consumers against potential health risks from those products, and to ensure that consumers are not provided with misleading information. The main EU legislation is Directive 2002/46/EC related to food supplements containing vitamins and minerals. The Directive lays down a harmonised list of vitamins and minerals that may be added for nutritional purposes in food supplements (Annex I), and a list of permitted sources from which those vitamins and minerals may be manufactured (Annex II); these lists were subsequently amended to include additional substances. Two related guidance documents for authorities (related to submissions for safety evaluation of substances, and to control of compliance with the legislation) have been provided by the Commission. The Commission has also issued since 2006 a Discussion Paper on the setting of maximum and minimum amounts for vitamins and minerals in foodstuffs; although having consulted extensively with MS and interested stakeholders on the issue, no proposal has been presented yet on this issue due to its complex nature and the divergent views that were expressed. A report has also been prepared by the Commission (COM(2008) 824) on the use of substances other than vitamins and minerals in food supplements.	Applicable since June 2002 *(c)*
Food contaminants (basic principles and maximum levels)	The basic principles of EU legislation on contaminants in food are provided in Regulation (EEC) 315/93. The setting of maximum levels for contaminants in the framework of this Regulation had started already in 1997 (Regulation (EC) 194/97). Maximum levels for certain contaminants in food are currently set in Regulation (EU) 1881/2006; while this is the current legislation establishing maximum levels for contaminants in food, it has subsequently been amended 26 times (currently in recast). In this legislation, maximum levels in certain foods are set for the following contaminants: nitrate, mycotoxins (e.g. aflatoxins, ochratoxin A, patulin), metals (lead, cadmium, mercury, inorganic tin), 3-MCPD, dioxins and dioxin-like PCBs and polycyclic aromatic hydrocarbons (benzo(a)pyrene).	Applicable step-by-step since March 2007 (maximum levels of certain contaminants first set in 1997)
Foods for specific groups (Dietetic foods)	Regulation (EU) 609/2013 (new Regulation on Food for Specific Groups) replaced previous Directives on foodstuffs intended for particular nutritional uses (including Directive 2009/39/EC on Dietetic foods). The new Regulation aims to protect specific vulnerable groups of consumers, by regulating the content and marketing of products intended for them (food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control), as well as to increase legal clarity for business and to facilitate correct application of the rules. The new rules will apply from 20 July 2016. Additional provisions for certain categories (milk-based drinks/similar products for young children, and food for sportspeople) are still under consideration by legislators.	New Regulation to apply from July 2016
Nutrition and health claims	EU rules on nutrition and health claims have been established by Regulation (EC) 1924/2006. This provides a legal framework to be used by food business operators when they want to highlight the particular beneficial effects of their products on the product label or in its advertising. The rules apply to nutrition claims (such as "low fat", "high fibre") and to health claims (such as "Vitamin D is needed for the normal growth and development of bone in children"). The objective is to ensure that any claim made on a food's labelling, presentation or advertising in the EU is clear, accurate and based on scientific evidence. The Commission has provided guidance on the implementation of the Regulation. The Commission has recently published a Roadmap as a first step towards the evaluation of the current EU legislation on nutrition and health claims.	Applicable since July 2007
OTHER KEY SECONDARY LEGISLATION: FEED		
Feed materials and compound feed	Rules on the marketing of feed materials and compound feed are laid down by Regulation (EC) No 767/2009 on the placing on the market and use of feed. The Commission has adopted several acts to implement this Regulation, such as the Catalogue of feed materials.	Applicable since September 2010
Feed additives and pre-mixtures	Regulation (EC) No 1831/2003 sets out the rules for the authorisation, supervision, and labelling of feed additives and pre-mixtures used in feed. The Regulation also foresees the establishment of an European Union	Applicable since October 2004

Policy area/ legal act	Description of legislative framework / revisions	State of play
	Register of feed additives.	
Medicated feed	Directive 90/167/EEC sets out the rules for mixing veterinary medicine into feed, its marketing and use across the EU. A proposal for a Regulation of the EP and Council (COM(2014)556 final) replacing the latter Directive is currently under the ordinary legislative procedure (former co-decision).	Fully applicable since January 1993
Undesirable substances in feed	Directive 2002/32/EC prohibits the dilution of contaminated feed material and sets maximum limits for substances in animal feed, which presents a potential danger to human health, animal health or the environment.	Applicable since August 2003
Feed hygiene	Regulation (EC) No 183/2005 lays down the requirements for feed hygiene. It enforces the compulsory registration and approval of all feed business operators by the competent authority, ensures that they operate in accordance with harmonised hygiene requirements, and implement good practice at all relevant levels.	Applicable since January 2006
OTHER LEGISLATIVE AREAS OF RELEVANCE		
Pesticides package, including MRL and SUD	Following the White Paper and the development of a Thematic Strategy on the sustainable use of pesticides in 2006, Regulation (EC) 1107/2009 replaced the earlier directive (Directive 91/414/EEC) and introduced important modifications such as the introduction of hazard based cut-off criteria, the establishment of candidates for substitution, and mutual recognition for plant protection products (PPPs). This was complemented *inter alia* by Framework Directive 2008/128/EC on the sustainable use of pesticides. Regulation (EC) 396/2005 sets maximum levels for pesticide residues (MRLs) for the various categories of food and animal feed products. The overall package aims to minimise risks to human health and the environment from pesticide use while encouraging low-input use.	Applicable since June 2011
Animal by-Products	EU rules on animal by-products (ABPs) regulate the movement, processing and disposal of animal by-products, which otherwise can spread diseases like BSE or allow chemical contaminants such as dioxins to reach the consumer. Animal by-products include animal feed, organic fertilisers (e.g. manure), and technical products like pet food. The consolidated Regulation (EU) 142/2011 adds clear requirements, less red tape, and better traceability from food production.	Applicable since March 2011
Animal welfare	There are several regulations and initiatives dealing with animal welfare, including the 2nd Animal welfare Strategy (2012-2015) that aims to further improve the welfare of animals in the European Union. The Strategy provides for a two-pronged approach: a proposal for a comprehensive animal welfare law and a reinforcement of current actions.	Communication end 2011
Animal health	The aim of the new Animal health Law aim is to set up the legal framework for the effective enforcement of the principles and objectives of the Animal Health Strategy for the EU (2007 – 2013) and at the same time to bring animal health legislation in line with the principles of Better Regulation.	Commission adopted proposal in a 'package' on 6 May 2013
Plant health	The EU plant health regime objectives are to support sustainable production through prevention of introduction and spread of new pests and diseases so as to avoid expensive campaigns to eradicate or control in a later stage; to ensure food security; to protect forests, the landscape and public and private green; and to ensure agricultural competitiveness.	Commission adopted proposal in a 'package' on 6 May 2013
Plant reproductive material	The EU legislation on the marketing of plant reproductive material combines securing food supply through high quality plant reproductive material with the protection of the genetic diversity of cultivated plants. Following a comprehensive evaluation, the Commission is currently concluding the review of the EU plant reproductive material marketing legislation, comprising the legislation on conservation and amateur vegetable varieties.	Commission adopted proposal in a 'package' on 6 May 2013

(a) This table includes other relevant secondary legislation covered by this Report and does not intend to provide an exhaustive list of EU food and feed law. The level of detail provided here includes relevant information to enable a better understanding of the issues that are raised by this Report for each piece of legislation, and does not aim to provide a consistent full description of the aims and requirements of the existing legislation.

(b) Regulation (EC) 1331/2008 entered into force in 2009; sectoral legislation (Regulations (EC) 1332/2008, 1333/2008 and 1334/2008) entered into force January 2011 latest, with precise dates of entry into force varying between the regulations.

(c) Directive 2002/46/EC: MS implementation by 31 July 2003; trade in products complying with this Directive permitted from 1 August 2003; trade in non-complying products prohibited, from 1 August 2005.

Source: Agra CEAS Consulting

I.1.3 The situation prior to the GFL (baseline)

Food law has always been of major importance to the EU economy and EU consumers. As a result, in the 1990s most of the (then EU-15) MS already had coherent and harmonised national food laws, ensuring public health and consumer protection, based also on international standards (Codex Alimentarius). Furthermore, at EU level, the Commission played an important role in protecting consumers' interests through the different internal market measures and supporting national food safety policies.

Until the BSE crisis of the mid-1990s, EU food law was mainly concerned with the creation of an internal market for food products in the EU. The first stage of this process was concerned with the harmonisation of specific national product standards using vertical directives; this facilitated the free movement of food products in the internal market. The second stage of the process was concerned with harmonisation through horizontal directives addressing common aspects applying to broader ranges of products. The BSE crisis and other food scares in the 1990s revealed the need for improvements to be made in European food law and the EU Commission proposed "a radical new approach" in its White Paper on Food Safety (CEC, 1999) driven by the need to guarantee a high level of food safety. The adoption of the GFL Regulation in 2002 was the ultimate result of this process; this third phase of development of EU food law prioritised consumer health protection.

The Green Paper and Whiter Paper on Food Safety describe the situation before the introduction of the GFL. There was no impact assessment as such carried out at the time of the introduction of the GFL. There is, however, some literature that describes the more historical background and evolution of the European approaches to food legislation leading to the global 'farm to fork' approach of the GFL (Alemanno, 2007).

During the 1990s, feed/food law at EU level faced some serious shortcomings. First of all, there was no central unifying text that would set common principles governing EU feed/food law and establish clear obligations for concerned parties. EU feed/food law also drew criticism for its lack of coherence and fragmentation of the various provisions. In the areas covered by the case studies of this evaluation (traceability; allocation of responsibilities; risk analysis; and, transparency), the analysis of the findings in section III indicates that, although processes and procedures were in place in some cases to perform these functions, these were not systematically or consistently applied and generally lacked reference to a common legal base.

The BSE and dioxin contamination crisis of the late 1990s demonstrated that the EU legislation in place in the field of food safety was not capable to respond effectively to the challenges. The increasing consumers' mistrust was a clear sign that the EU needed to develop a new coherent legislative framework that would strengthen EU food safety requirements, ensure that products put on the market are safe for consumers' health, and lay a firm and reliable foundation for the further development of the EU agri-food sector.

In the light of these considerations, the Commission released the Green Paper in 1997 followed by the White Paper in 2000. The Green Paper foresaw the review and amendments of the existing food safety legislation with a view to bringing a greater level of protection for consumers, making the implementation of market rules more effective and strengthening of scientific foundations for the food safety policy making. Subsequently, the White Paper proposed concrete measures, including the establishment of the European Food Safety Authority (EFSA) and strengthening food safety controls, aimed to make the EU food policy more integrated and responsive to the demands of producers, operators and consumers. The measures transforming EU food policy and setting up the common principles and rules governing the EU food sector were consolidated in the GFL.

It is noted that in the EU-12 MS that acceded to the Union starting from 2004, pre-accession preparations had already started in the late 1990s to align their national legislation to the EU *acquis*, including EU feed and food law. Although national law and administrative cultures, more generally, were historically considerably different in the EU-12 than those in the EU-15, in the area of feed/food law these countries were members of Codex Alimentarius thus ensuring a certain convergence and implementation of international standards.

I.2 Aim and objectives of the evaluation

This evaluation aims to feed into the Commission's **Fitness Check of the General Food Law (GFL)**. The Fitness Check of the GFL aims to assess the effectiveness and efficiency of the GFL, its relevance in delivering EU-added value, its coherence with wider EU policy priorities (synergies and trade-offs) as well as to focus on simplification and the reduction of regulatory costs and burden. The findings of the Fitness Check will feed into the Regulatory Fitness and Performance Programme (REFIT) exercise undertaken by the Commission. REFIT brings the policy cycle full circle by ensuring that feedback from policy analysis and evaluation is fed back into policy design. According to the European Commission's REFIT Programme, the purpose of the exercise is to identify excessive burdens, overlaps, gaps, inconsistencies and/or obsolete measures which may have appeared over time. REFIT is applied to policy areas encompassing a number of legal acts.

The present study is part of the Fitness Check of the GFL and it covers the general part of the GFL (Articles 1-21). According to the Terms of Reference (ToR) for the evaluation of the GFL (**Annex 1**), the main objective of this evaluation is to assess the extent to which:

- The fundamental principles and definitions to be applied by all public authorities under the GFL have been effectively implemented;
- The new responsibilities/requirements for operators are fit for purpose.

In making this assessment, the rules and standards established by subsequent legislation (other secondary legislation: **Table 1**) and their implementation are taken into account, in particular the cumulative effects and potential overlaps that may have been created by the general framework enacted by the GFL.

Specifically, the following **evaluation criteria** are addressed using a set of 34 evaluation questions (EQs):

- **Relevance**. The extent to which the original objectives of the GFL correspond to current needs. In making this assessment we keep in mind that needs can evolve and so it is possible that recent events, such as the horsemeat scandal, have resulted in a different set of needs to those apparent at the time the GFL was drafted.
- **European added value**. This term refers to the benefits accruing from establishing the GFL at the EU level rather than having Member States operating national or regional policies. The relationship to international obligations (Codex, OIE) is also important here.
- **Effectiveness**. The extent to which the intervention resulting from the application of the GFL (including the application of its fundamental definitions, principles and requirements in related specific pieces of food law) caused changes in the EU food safety area. This aspect of the evaluation also examines the extent to which the objectives have been achieved, identify areas where expectations have not been met, identify factors which have hindered their achievement and the role, if any, of policy measures outside the framework of food law as set out in the GFL, in the achievement of observed changes.

- **Efficiency**. The extent to which the costs involved (including the costs generated by the application of its fundamental definitions, principles and requirements in related specific pieces of food law) have been justified given the effects achieved. Actions to reduce regulatory burden, potential alternative policy instruments or mechanisms that could improve cost-effectiveness are assessed here.
- **Internal coherence**. The extent to which the GFL has contributed to the internal coherence of EU food law.
- **External coherence**. The extent to which the EU regulatory framework established by the GFL and its implementation works together with other Member State interventions which have similar objectives.
- **Complementarity**. The extent to which the EU regulatory framework established by the GFL proved complementary to other EU interventions/initiatives in the field of food policy such as the Common Agricultural Policy.

This Final Report, the final deliverable of the evaluation on the general part of the GFL (Articles 1-21), presents the analysis and synthesis of the findings of the study, including the overall conclusions and recommendations, which are based on the critical review and triangulation of data and evidence from the various data collection tools set up for the purpose of the study.

II. METHODOLOGY

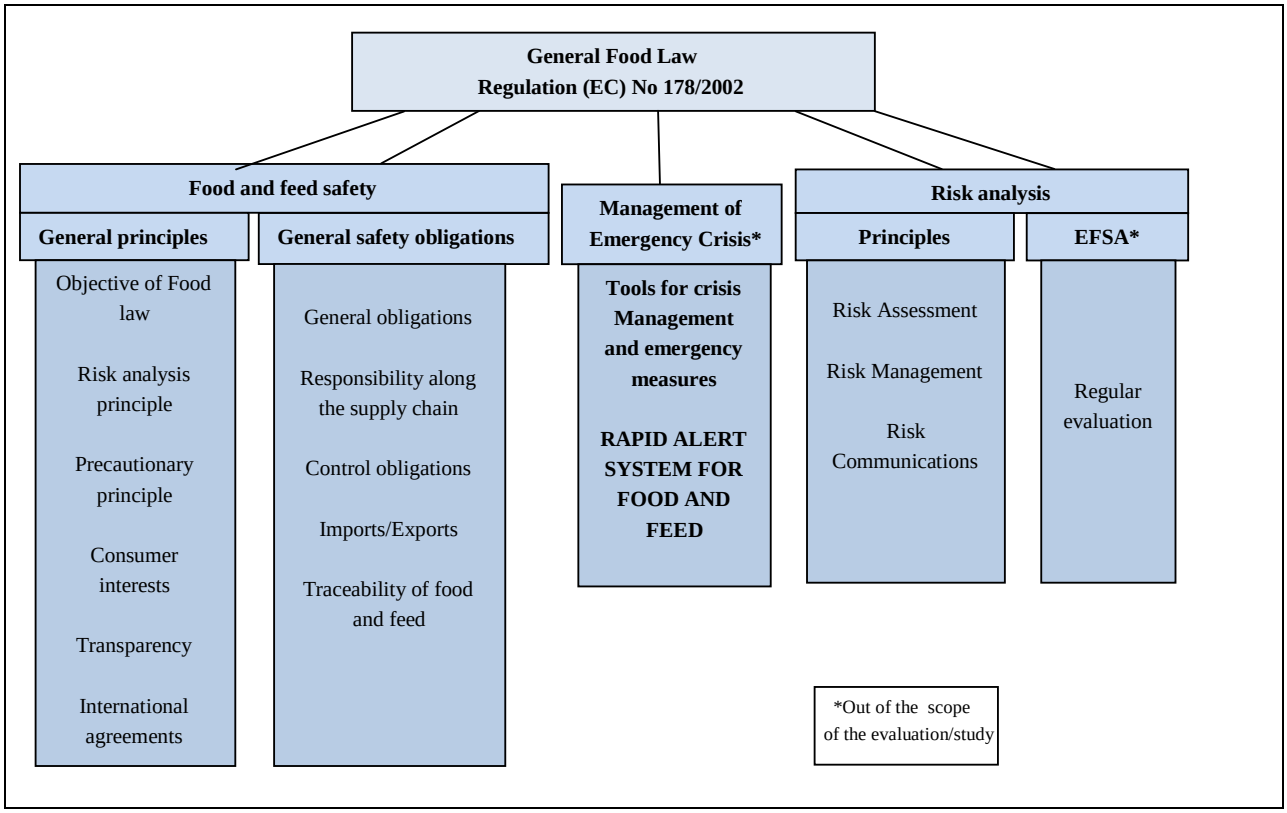
II.1 Scope

Geographical coverage. The evaluation covers the EU-28. The case studies focus on a number of representative Member States within the context of our thematic approach.

Period. The study focuses on the period since the adoption of the GFL, i.e. 2002-2013. Nonetheless, the evaluation also compares to the baseline (situation before the introduction of the GFL), as well as considering future trends and developments and providing recommendations for the future.

Legal reference: The scope of the evaluation is the GFL and its operational implementation, as presented in **Figure 1**. This evaluation covers in particular the key provisions stipulated in Chapters I and II of the GFL as follows: definitions and scope; general principles of food law; principles of transparency; general obligations of food trade; and, general requirements of food law.

Figure 1: Structure of the General Food Law



Source: ToR

Two issues are highlighted in terms of the scope of the GFL evaluation:

a. Data from other studies (RASFF; EFSA)

Two other separate reviews are also of relevance to the GFL evaluation, one of which was carried out within the same timeframe:

- Chapter III establishing the European Food Safety Authority (EFSA): this is not in the scope of the present GFL evaluation, as this is subject to a regular evaluation every six years. The most recent evaluation was carried out in 2012.
- Chapter IV establishing the Rapid Alert System for Food and Feed (RASFF) and laying down procedures and tools on the management of emergencies and crises is the subject of a dedicated evaluation, also being carried out by the FCEC.

Both Chapters III and IV are integral to the GFL and therefore, to the extent available, results were taken into consideration for the final assessment of the GFL.

b. GFL implementation through 'other secondary legislation'

Although this is an evaluation of the GFL and not of other secondary legislation which is based on/linked with the GFL, analysing the relationship between the GFL and other, secondary legislation is essential for assessing the relevance, efficiency, effectiveness, coherence and EU added value of the GFL. This has been investigated in some of the case studies. Certain pieces of legislation have been recently evaluated and it is not an effective use of resources to duplicate/overlap this work; in these cases we draw on existing evidence from completed evaluations.

II.2 Data collection strategy

II.2.1 Overview

This evaluation has certain characteristics of an ongoing or interim evaluation, in that a key objective is to not only focus on the extent to which the GFL has delivered to date, but also on a forward looking dimension in terms of providing recommendations on the need for adaptations. It also has some characteristics of a meta-evaluation in that it must pull together evidence from more narrowly-focused evaluations to provide an evidence base. The methodology that the evaluation team has followed for this evaluation aimed to address these overriding issues and challenges.

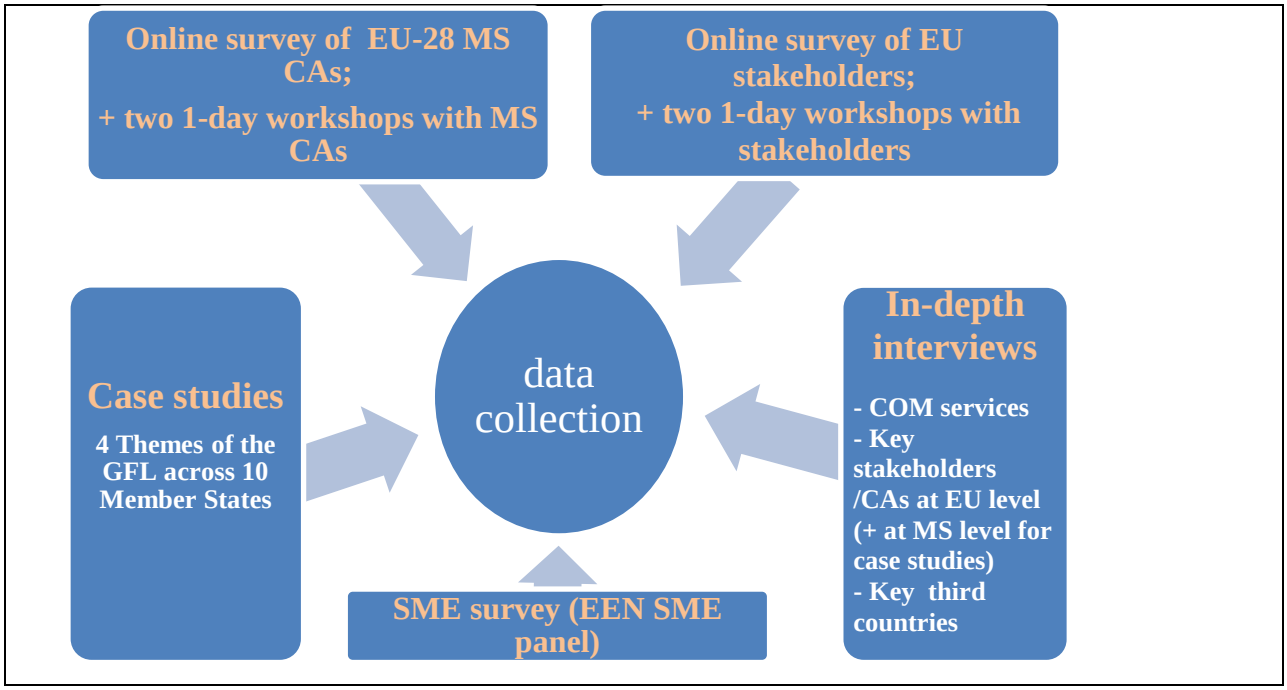
The data collection strategy was based on the use of a suite of complementary tools, which were continuously refined in the light of the experience gained during project course. **Central pillar of the data collection has been an extensive consultation, triangulation and validation process, involving consumers, supply chain stakeholders [22], Commission services, food law experts/academics, NGOs in various fields and other actors of relevance**. This has ensured both the collection of relevant material and that all relevant parties were consulted.

An overview of the data collection strategy is presented in **Figure 2**. It is noted that each of the data collection tools has played a distinct role. For example, the survey of stakeholders was addressed only to associations representing the agri-food chain, consumers and NGOs, while individual companies were targeted by the SME Panel; the case studies aimed to provide more in-depth investigation into focus areas of the GFL. The aim has been to collect a broad evidence base which we could triangulate to reduce bias and increase robustness. This has been a key element of our strategy to mitigate the challenges and limitations of this evaluation, as highlighted further below[23].

[22] As used in this study, the term **'supply chain stakeholders'** refers to Food Business Operators active along the feed and food supply chain (as defined in Article 3 of the GFL). The more general term '**stakeholders'** is used to group together all organisations representing consumers , NGOs and industry that were consulted during the study.
[23] In the presentation of the findings the source of the data/information are systematically identified.

The data collection tools (questionnaires; working documents; interview guides) are provided in **Annex 5**. The consolidated results of the on-line surveys survey are presented in **Annex 3**. The results of the SME Panel are presented in **Annex 4**. Overall, the response received to all surveys and the case studies was extensive, and provided consistent results.

Figure 2: Data collection strategy (GFL evaluation)



Source: Agra CEAS Consulting (FCEC)

II.2.2 Case studies

To allow a more in-depth collection of data and evidence, we carried out **four thematic case studies**, on four specific themes of the GFL, involving a total of ten Member States, in order to understand the issues that arise and differences/similarities in implementation. This has helped us to identify where the national implementation of the GFL is important in determining the observed impacts. This is fundamental because one of the key findings of the Commission's fitness check of all legislation with relevance to the food chain[24], as also confirmed by the findings of this consultation, has been that many problems in the wider body of food legislation stem from interpretation and implementation. The case studies were used to address specific evaluation questions where the focus is on implementation of key requirements of the GFL. The MS coverage as well as the selected themes were approved by the Steering Group at the end of the inception phase[25]. The case studies are as follows:

[24] European Commission. Commission Staff Working Document: A fitness check of the food chain: State of play and next steps - SWD(2013) 516 final (2013).

[25] Ten MS CAs were interviewed in the context of the case studies: Austria, Estonia, Finland, France, Germany, Hungary, Italy, Netherlands, Slovakia, and the UK. In selecting MS, we have endeavoured to strike an appropriate balance in geographical coverage as well as a mix of old/new MS, and larger/smaller MS. In addition, the selection has been determined by MS CA interest to participate actively and to provide data and information to these case studies, but has also taken into account the information collected from DG SANTE's previous consultations with the MS CAs in the course of the study.

- **Case study 1:** A key direct requirement introduced by the GFL is **traceability** (Article 18). It has therefore been important to examine how traceability has been enforced, the effectiveness and adequacy of the current provisions, and the costs and benefits of traceability. In terms of costs, the impact on SMEs is of particular relevance. In terms of benefits, these are expected to stem in particular from a more effective and efficient management of withdrawals and recalls.
- **Case study 2:** A key general requirement of the GFL concerns the allocation of **responsibilities.** Food and feed business operators at all stages of the supply chain are given primary responsibility to ensure that products placed on the market meet all requirements of food law (and not only those limited to food/feed safety) and to verify that such requirements are met (Article 17.1). MS have responsibility to control and enforce, including by laying down measures and penalties for infringements (Article 17.2). This requirement has been the backbone of the GFL and other related secondary legislation [26]. It has therefore been important to examine how the allocation of responsibilities has been implemented in the different MS, in particular in terms of its coverage and scope encompassing all actors along the supply chain. This issue is also of relevance in the context of implementing the provisions of Articles 19 and 20 on withdrawals and recalls.
- **Case study 3:** The GFL introduced general principles for **risk analysis** (Article 6) as applied in the authorisation procedures for regulated products. More generally, the consistent separation of risk assessment from risk management, at both EU and MS level, has been explored in this study. There are also questions raised on the consistency of application of the precautionary principle (Article 7) and the duration of the temporary measures adopted on this basis but also the extent to which other legitimate factors including economic impact are considered in the risk management decision-making process and the transparency and justifications of decisions made by risk managers. This case study focuses on four relevant sectors: food additives, feed additives, contaminants and food contact materials. These sectors are either not fully harmonised at EU level or considered to be subject to differential interpretation/ implementation of the risk analysis principles at MS level[27].
- **Case study 4:** Finally, the structuring phase has raised various issues in relation to the harmonised implementation of the **transparency provisions** under section 2 of the GFL: public consultation (Art 9) and public information (Art 10). The extent and scope of application of these rules in the Member States are being examined.

The case studies on all four themes have covered a similar range of issues (**Table 2**), including the extent to which similar provisions existed/were implemented prior to the GFL, the adaptations required to apply these provisions, the costs/benefits and impacts of the GFL provisions, their EU added value, the extent to which problems are identified in their implementation, and how these can be addressed. As such, the four case studies run through all the six themes of the evaluation: relevance, added value, efficiency, effectiveness, coherence, and complementarity. These issues have been developed further

[26] Article 17 introduces a general requirement imposed on food/feed business operators to ensure compliance with all food/feed law requirements (and not only those limited to food/feed safety), such as food information *etc*. Indeed, the definition of 'food law' covers food in general as well as feed produced for, or fed to food-producing animals, while food safety is only one of the aspects covered. This is also reflected in Article 8 that provides that food law should aim at preventing fraud or other misleading practices for the consumer, going beyond a strict 'food safety' approach.

[27] As indicated above, for the case study on risk analysis (case study 3), some specific policy areas ("sectors") have been chosen by DG SANTE, in agreement with the Steering Group. This case study focuses in particular on food additives, feed additives, contaminants and Food Contact Materials (FCM). In the interview process, as well as in the feedback received, both MS CAs and stakeholders also raised other areas, such as GMOs and nutrition and health claims. These supplementary areas will be taken into account where relevant in the final analysis. However, overall, the issue of authorisation procedures cannot be exhaustively covered for all cases as this would require a more detailed analysis of all other relevant secondary legislation.

into detailed questions in the Working Documents (**Annex 5**), which were presented to stakeholders and MS CAs ahead of the first round of workshops (conducted, respectively, on 19 December 2014 and 16 January 2015).

The impact of the GFL, as the basis for food law, on competitiveness and innovation in the food chain is an underlying issue which is being examined in all case studies. In particular, given the context of the evaluation taking place within the Commission's REFIT exercise, the opportunity for simplification and reduction in regulatory burden or more broadly '*red tape'* is a central objective of the case studies. The selected case studies allow us to go beyond the surveys, to collect more detailed data on the costs and burden of the GFL, and the potential for simplification. This is bearing in mind the challenges and caveats of the present analysis, as outlined in section II.3.

Table 2: Case study themes

Theme	Scope (GFL)	Focus sectors/issues [a]
Case study 1: **Traceability**	Art. 18	• Adequacy of '*one step forward – one step back'* approach (Art. 18), along the extended supply chain • Application in practice: is it enforced at the level required by Art. 18? Or, does it go beyond (e.g. due to contractual obligations)? Implementation of internal traceability? • EU added value • Impact on SMEs • How has it applied in food safety situations (in particular for withdrawals/recalls) and the outcomes positive/negative • Whether it is fit for purpose • Costs of traceability vs broader benefits
Case study 2: **FBO responsibilities**	*Art. 17.1;* Art. 19 to 21; Article 8	• Distribution of FBO responsibilities/liability along the chain, including retailers, brokers and where food/feed is manufactured outside the EU (importers) • Application in practice: implementation for withdrawals/recalls (Art. 19 to 21) • Own-controls – verification of food law requirements • Whether it is fit for purpose • Impact on SMEs • Costs vs benefits • EU added value • Sanctions applied in case of infringements of food law more generally (intended or unintended) (adequacy of Art. 8)
Case study 3: **Risk analysis and precautionary principle**	Art. 6 and 7; as implemented by Chapter III [b]	• Whether it is fit for purpose • Comparative assessment on how the risk analysis principle of GFL has been applied in other secondary legislation: Food additives; Feed additives; Contaminants; Food contact materials • Assessment whether the 3 components of risk analysis (risk assessment, risk management and risk communication) are clearly defined and have been consistently, efficiently and effectively applied. • Separation of risk assessment from risk management • EU added value of risk analysis • Science vs other legitimate factors in risk management • Application of precautionary principle
Case study 4: **Transparency**	Section 2 of the GFL (Articles 9 and 10)	• Public consultation during the preparation/evaluation/revision of food law at EU/national level (Art 9) • Public information (Art 10) – relation to Art 55.2 [c] • EU added value • How it is applied in practice • Whether it is fit for purpose

[a] *The full set of issues covered by the case studies is provided in the Working Documents (**Annex 5**).*
[b] *The evaluation of EFSA is not in the scope of the study, but the results of this evaluation were used where relevant in the analysis of the EQs pertaining to the base provisions of the GFL in Articles 6, 7 and Chapter III.*
[c] *This issue is also covered by the RASFF study; transparency tested in emergency situations.*

II.3 Fine-tuning of the methodology and tools

A detailed matrix of judgement criteria and indicators addressing the 34 evaluation questions (EQs), was developed and refined during the structuring phase. Data collection tools and data sources were further refined and adjusted where necessary to appropriately fulfil these criteria/indicators. In particular, the criteria were made operational by using relevant indicators which in turn have been used to develop the methodological tools, including the survey questionnaires, the working documents and interview guides on the case studies, the SME Panel questionnaire and the interview guide for third countries, as outlined further below in this section of the Report.

In fine tuning the judgement criteria and indicators challenges and limitations were highlighted, and the mitigating measures taken, as well as areas of the GFL which merit specific attention. This ensured that the evaluation, particularly of a wide ranging policy area such as that covered by the GFL framework, is proportionate in terms of relating resources to issues, in order to maximise the benefits of the evaluation for the Commission.

The challenges, limitations, and mitigating measures are described further below and have been discussed extensively with the Commission and the Steering Group, as well as during the consultation process with MS and relevant stakeholders (workshops). As an outcome of the output received from these discussions, the matrix of EQs, judgement criteria, indicators was further refined and finalised. The **final validated matrix of EQs, judgement criteria, indicators** and the corresponding detailed methodological tools for addressing each are presented in **Annex 2b**.

II.3.1 Challenges, limitations and mitigating measures

In the process of refining the judgement criteria and indicators, the evaluation team has come across a number of challenges, which were addressed with appropriate mitigating measures, as outlined below. Some of the challenges in carrying out this evaluation (e.g. data availability) commonly occur in policy evaluations, while others are specific to the more general policy framework of the GFL or relate to the complexity of the EQs as laid down in the ToR.

a) Cross-cutting linkages between EQs and themes

Challenge: As identified from the outset of this evaluation there are considerable cross-cutting linkages and overlap between many of the EQs, as presented in the ToR. These linkages were mapped out, to refine and streamline accordingly the judgement criteria and indicators so that the final analysis is both coherent and concise. It has been important to optimise the indicator framework because this is a means of answering the EQs and is not an end in itself.

Mitigating measure: This challenge has been addressed by focusing/redefining indicators in order to concentrate on those that are most appropriate for providing an answer to each EQ and those that allow systematic synthesis for concluding on the evaluation themes. In the same vein, where appropriate, over-arching or composite indicators have been identified as a means of addressing multiple EQs; similarly, some EQs are addressed by a combination of indicators derived from other EQs. The mapping of identified linkages between EQs is presented in **Annex 2a**, while the validated matrix of EQs/judgement criteria/indicators is presented in **Annex 2b**.

b) Comparing against absence of the GFL

Challenge: A key aspect of this evaluation, pertaining to many EQs (e.g. EQ2 on the EU added value of the GFL), has been the need to examine what would have happened if the GFL was not in place.

Mitigating measure: Although this limitation, by definition, suggests a more subjective approach, an objective indicator has been used, to the extent possible, to identify potential gaps/problems in the absence of the GFL as a framework: the situation prevailing in the period prior to the GFL (i.e. the baseline). It is noted that a further challenge is the absence of an impact assessment that could serve as the baseline, both for the GFL itself, and for some of the other secondary legislation. Nonetheless, the evidence that is available, e.g. from the Green Paper/White Paper that preceded the GFL and other relevant literature, have been used for this purpose.

Furthermore, when it comes to other secondary legislation on food/feed, the extent to which the GFL provides an added value by serving as a framework underpinning all areas of food/feed law, has been examined in a comparison between areas that are harmonised and areas where harmonisation of legislative provisions at EU level is incomplete. It is noted that such a comparison is possible in certain cases, e.g. it is made in the context of risk analysis between sectoral (vertical) legislation that is harmonised (e.g. food improvements agents) and areas where harmonisation is incomplete (e.g. food contact materials, food supplements).

c) GFL implementation through other secondary legislation

Challenge: Further difficulties and limitations in carrying out this evaluation relate to the nature and role of the GFL, i.e. the fact that it contains general principles rather than specific provisions, which are further implemented through other secondary, vertical or sector-specific legislation. Although this is an evaluation of the GFL, a review of the impact of other secondary legislation becomes inevitable. Some of this legislation has been previously reviewed, or has been revised through subsequent proposals, in which case evidence is readily available (although this may not necessarily cover or relate specifically to the EQs). In other cases, however, key other secondary legislation has not yet been reviewed. For the purposes of this evaluation, the consideration of other secondary legislation has been carried out only to the extent that provisions systematically raise issues of consistency/coherence with the GFL that are relevant for this evaluation.

Furthermore, it is noted that the potential differential implementation at MS level adds another layer of difficulty to the review of other secondary legislation.

In particular, the following methodological challenges are raised by the interaction of the GFL with other secondary legislation and by its implementation at MS level:

1) Where problems are identified at the level of other secondary legislation and/or its implementation, it becomes more difficult to establish the causal link of impacts identified back to the GFL. For example, it is difficult to assign causality to costs and burden on FBOs resulting from the GFL alone on the one hand and its interaction with other secondary legislation on the other.
2) In addition, there is a need to distinguish between problems/costs resulting from EU legislation and national level legislation and/or from private standards; it is accepted that in practice it is difficult for FBOs to make this distinction.
3) Similarly, because the GFL is a framework, and therefore by definition general, it is not possible to identify its impact at aggregate level with respect to issues such as trade. It is equally difficult to isolate the impacts the application of general principles have had on stakeholders.

Mitigating measure:
These challenges were partly addressed by carrying out a comprehensive consultation process, whereby evidence was sought from the full range of relevant stakeholders to identify and analyse further: i) those areas of the GFL where stakeholders do not experience problems and the GFL is meeting its objectives; and, ii) those areas that still pose problems. In the latter case, where stakeholders identified problems, on a systematic basis, the evidence put forward was triangulated and balanced with evidence available from other sources, to take into account, for example, the potential for a partial view or vested interest.

Thus, to address challenge c.1, any evidence collected of problems in other secondary legislation have been analysed and triangulated, including with the Commission services, to further establish causality between the GFL and other secondary legislation. In some cases the overall GFL objectives may have been achieved, despite problems caused for operators with other secondary legislation; in other cases overall objectives may have not been achieved or alternative provisions might achieve the objectives more effectively and efficiently.

In terms of the interface between legislation and private standards (challenge c.2), this issue has been further pursued in the interviews conducted with the FBOs, again triangulating the evidence with different groups of stakeholders along the supply chain (e.g. evidence from food manufacturers on standards imposed by retailers vs evidence from retailers).

Finally, to address challenge c.3, the consultation has aimed to identify specific product sectors in conjunction with specific vertical legislation, in order to use these, to the extent relevant, as tracers or exemplars of the impact of the GFL.

d) Limitations of using quantitative indicators/data availability

Challenge: As the GFL provides a general framework, it is difficult to identify relevant quantitative indicators to measure and quantify the impacts of the general principles laid down in the GFL, e.g. transparency principles, risk analysis principle, primary responsibility of FBOs. This is a common limitation in this policy area[28]. The lack of quantitative indicators applies to both costs and benefits. This results in a lack of available data and the Steering Group has recognised that it is difficult to monetise costs and benefits in this context.

Mitigating measures: In view of the challenges, it was agreed that it is important at least to identify the categories of costs or benefits involved and their relative importance. In view of these limitations, the approach finally adopted for the analysis of costs in this evaluation was to explore whether FBOs, and SMEs in particular, raise any specific concerns on costs, which cost categories are the most burdensome, and whether these stem from the GFL or other secondary and/or national legislation or other private standards to allow a quantification later on. See also points g) and h), section II.3.2.

Challenge: Quantitative indicators are further constrained by data availability, as they require that suitable data can be provided centrally at EU level or by individual MS (or – in the case of costs and burden – at FBO level).

[28] For example, in an overview report looking at official controls, which is a similar and even more applied policy field (i.e. laying down specific requirements), the FVO concluded that there is a general lack of accepted standard or performance indicators to measure the effectiveness and efficiency of official controls. This conclusion fully applies to the areas covered by the more general principles and requirements of the GFL.

Mitigating measure: Where suitable data could not be provided, qualitative analysis was used, drawing on discussions with the Commission, MS CAs and stakeholders. Data availability and the use of qualitative data have been further cross checked and detailed during the main phase interviews. The intention in establishing indicators has been to use the most robust data/evidence possible; where this has not been possible, the limits of the analysis are indicated in this Report.

The lack and/or caveats of quantitative indicators and approach for addressing this limitation are outlined further in section II.3.2.

e) Time constraints

Challenge: The progress of this study has faced a number of external time constraints, beyond the evaluation team's responsibility and control. These were, again, in part due to the challenges posed by the wide-ranging subject of this evaluation, and in part due to the need to ensure a wide-ranging consultation and transparency of the process in line with the Commission's ToR and REFIT methodology. In particular, the extensive consultation with various Commission services, especially in the structuring phase, and the request by stakeholders to extend the deadline in the observing phase have led to inevitable delays at this stage of the evaluation.

The various time constraints encountered by the evaluation team to date are as follows:

- Extensive cooperation with COM services. Given the high profile of this study sufficient time was needed for comments and steer from the various COM services. All survey questionnaires have been developed in close coordination with a number of COM services, notably DG SANTE and the Secretariat-General, for which our team has attended a number of informal meetings for the development of the methodological tools (questionnaires). This has inevitably led to some delays in the development of the methodological tools compared to the initial schedule of the structuring phase.
- Extended consultation deadline for stakeholders and MS CAs. Both groups repeatedly insisted that the initially foreseen deadlines for their contribution to the various consultation tools be extended, notably at the two workshops introducing the case studies. In response to these requests, the deadline for the written feedbacks to the working documents was extended to 27 March 2015. This was considered necessary to allow all respondents sufficient time to perform internal consultations and to contribute with quality, verified inputs. In the case of the on-line survey, the deadline was set at 27 March to allow 8 weeks of consultation.
- Launching of SME Panel. The SME Panel questionnaire has also been developed based on extensive cooperation and discussions with relevant COM services, in this case DG SANTE, DG GROW and the Secretariat General. The final questionnaire was tested by Europe Enterprise Network (EEN) national contact points in some MS, to provide feedback for improving the terminology and flow of the questions. Furthermore, the context of this specific EEN SME Panel process has been characterised by some re-organisation constraints that have led to some delays.

Mitigating measure: The impact of these delays on the overall timetable for this study were compensated by an anticipated delivery of the Draft Final Report, so that the final output of the evaluation has stayed in line with the original schedule.

II.3.2 Challenges and caveats of using certain quantitative indicators

The extent to which the food law system as a whole is effective - or not effective (systemic failure) - is ultimately manifested in terms of the GFL meeting its core objectives:

- With regard to **consumer protection**, i.e. protection of consumer health and interests (Art. 5; Art. 8; Art. 17.1): this could be established by the trend in food safety incidents/emergencies culminating, when untreated, in crisis situations; and, fraud issues.
- With regard to the **internal market**, failure of the system results in restriction of free movement. This has impacts in terms of: higher costs; competitiveness; and, innovation. Generally, the GFL costs in these terms are to be explored through specific indicators on key requirements directly or indirectly introduced by the GFL; the case studies are used in particular for this purpose. The benefits of the GFL are more difficult to determine in quantitative terms, as it is difficult, for example, to establish attribution of any positive indicators of growth and innovation to the GFL provisions. In fact the Steering Group has recognised that the constraints for monetising costs and benefits in the context of this evaluation; nonetheless, attention has been paid as to identifying the categories of costs or benefits involved and their relative importance.

The challenges and caveats of addressing these issues with the use of quantitative indicators are explained further below:

f) Analysis of indicators in relation to consumer protection

Challenge: For the identified indicators on the extent to which the GFL protects consumer health and interests, limitations/caveats are outlined below:

1. *Trend in food safety incidents*: RASFF notifications provide trend data up to 2014. However, data on the number of notifications do not provide information on the extent (level) of the risk involved; furthermore, each 'notification' may refer to one or more consignments. More fundamentally, even if data were available, a comparison would not allow drawing any conclusions on the reasons underlying any observed trends, as many other factors influence both the occurrence and the reporting of food safety incidents. Therefore, trend analysis or comparison between countries, or between products or between hazard categories does not provide conclusive evidence on the improvement in food safety levels.
2. *Trend in consumer complaints*: this was identified as a potential indicator of consumer concerns on food safely issues. To be a meaningful indicator, data would need to be available over a number of years to provide trends; furthermore, ideally, they would need to indicate whether complaints are raised on specific provisions of the GFL, or other secondary legislation provisions which are based on the GFL. During the interviews, it was established that consumer organisations (BEUC; national member organisations in the MS) do not systematically collect any such data on consumer complaints.
3. *Consumer trust*: data on consumer trust in food safety authorities and perceptions of food-related risks exist from Eurobarometer (for 2005 and 2010), but there are no further updates. Our enquiry about the availability of more detailed data at MS level with the MS CAs and national consumer organisations has not yielded results that can be systematically analysed. It is noted, however, that such data provide only a partial indicator of the effectiveness of the GFL in meeting a high level of consumer protection and pose certain limitations/caveats. The indicator measures perceptions rather than facts, while it is highly dependent on the methodology applied in the public/consumer opinions polls/surveys (including sampling, context, questions, etc.) as well as the timing of the surveys and new developments (e.g. results are influenced at the aftermath of a food scare event). This makes the use of this indicator difficult for comparing consumer perceptions across MS or through time, both of which are only possible when using the same survey data set.
4. *Benefits for consumers*: assessing/quantifying benefits for consumers/public health is a very complex exercise because it requires detailed analysis of a counterfactual scenario, the potential magnitude of which is largely unknown/speculative. For example,

establishing the benefits in terms of avoiding the costs of a potential food safety crisis, or the avoidance of longer-term public health impacts, when their potential magnitude is unknown[29]. Furthermore, this analysis depends on the legislative area, hence the benefits cannot be assessed in a standard manner, but require a case-by-case analysis (this is explained, for example, in the BEUC position on novel foods). Our consultation to date, including with the consumers' organisation (BEUC; national member organisations), and the meetings with the Steering Group confirmed that it is not possible to quantify consumer or other benefits of the GFL more globally in economic terms. This has been previously pointed out, for example, in a stakeholder consultation document prepared by BEUC on a COM public consultation on Impact Assessment Guidelines[30].

Mitigating measures: The various questionnaires (surveys, SME Panel) were developed taking into account the above constraints and limitations. In the absence of quantitative indicators to measure consumer protection, most EQs relating to these themes were addressed using a semi-quantitative approach, to the extent this was possible and relevant for the specific EQ. The survey questions for example focus on the overall impact of some provisions of the GFL, in meeting the objectives of food safety, consumer health and consumer protection. Detailed interviews with consumer organisations have aimed to identify particular cases causing concerns. Reference to the above quantitative indicators in the final analysis is made only to the extent suitable and indicating the limitations/caveats. It is, however, important to note, that overall, our consultations with consumer organisations have highlighted the positive contribution of the GFL in terms of ensuring a high level of food safety and consumer protection in the EU.

g) Analysis of effectiveness and efficiency

Challenge: As already indicated, there is a lack of suitable indicators for measuring the effectiveness and efficiency of general provisions such as those embedded in the GFL[31]. In particular, a number of indicators on the effectiveness of implementation and more generally the performance of the GFL provisions were identified; limitations in their use are outlined as follows:

1. *Trend on non-compliance with the GFL/food and feed law*: the analysis of non-compliance trends would be an indicator that addresses many of the questions raised by this evaluation. It points to the effectiveness of the GFL provisions, and to areas where problems can be identified and the potential reasons for these. However, our interviews with the relevant Commission services have indicated that a quantitative analysis is not possible and could be misleading. Although data exist for most MS, these are not uniformly collected across the EU. Furthermore, according to the trend analysis performed by the Commission[32] on the basis of Annual Reports submitted by MS, non-compliance data are not directly comparable between MS or through time. This is due both to the lack of uniformity in the data collection, and the evolution of the approach in many MS towards more risk-based control systems, as foreseen in Regulation (EC) 882/2004 on official controls. The latter means that caution is required in interpreting the results: an increase in non-compliance is generally observed in more risk-based

[29] Reference can be made to the extent relevant to the analysis, to any available evidence e.g. on the actual costs of a food safety crisis (see section I.1.1).
[30] Commission public consultations on Impact Assessment Guidelines and Stakeholder Consultation. BEUC response, 29 September 2014.
[31] This is a common limitation highlighted in previous policy analysis exercises in this field. For example, the FVO overview report on the effectiveness and efficiency of official controls, under Art 8(3) of Regulation 882/2004 , concludes that "*a number of CAs considered that defining and measuring effectiveness of official controls posed a significant challenge*". The FVO auditors also acknowledge "*the lack of a prescribed or generally accepted standard or performance indicators for measuring effectiveness of official controls*".
[32] European Commission Food and Veterinary Office 2013b.

controls, as the focus of these controls is on private operators with weaker compliance records. Thus, an increase in non-compliance may actually reflect more effective (as well as more efficient i.e. more risk-based) controls.

2. *Trend in complaints and infringements* (based on information provided by DG SANTE): infringement procedures (Article 258 TFEU) stem from complaints which may be lodged by citizens/NGOs/companies, or on the basis of FVO inspections or on COM's own initiative (more rarely). The number of complaints is not necessarily an appropriate indicator of the functioning of the GFL or of other secondary legislation; in fact the number of complaints on a topic depends on the level of citizen awareness, on the political/media trend, on whether there are active associations in a given field, etc. In particular:
    - With respect to GFL-related complaints, there have been only 11 complaints since the GFL was introduced in 2002: eight complaints were issued before 2011, and three complaints between 2011 and 2013; there has been only one letter of formal notice issued on a GFL-related topic. The available data do not provide the basis for identifying any meaningful trends. According to SANTE, the small number of complaints relating to the GFL may be explained by the fact that the GFL is a framework.
    - The available data indicate that more cases (some 75 complaints per year) are linked to 'sectoral' legislation.
    - Furthermore, in many MS, complaints (e.g. when lodged by companies) are addressed to the national authorities/court rather than directly to the Commission. It has not been possible in the context of this evaluation and in view of the scope of its coverage - GFL and other secondary legislation - to collect more data on such complaints/court cases at national level, due to the extent of the work required.
3. *Trend on withdrawals and recalls*: there are no data systematically collected on withdrawals and recalls. Some cases are reported in RASFF notifications, however, these are only cases with implications for other MS (this also depends on the seriousness of the risk).

Mitigating measure: the various questionnaires (surveys, SME panel) were developed taking into account the above constraints and limitations. In the absence of quantitative indicators to measure effectiveness and efficiency, most EQs relating to these themes were addressed using a semi-quantitative approach, to the extent this was possible and relevant for the specific EQ. The survey questions for example focus on the overall impact of some provisions of the GFL, such as how benefits compare to costs, etc. This aims to address in a more qualitative manner the evaluation criteria. This approach has limitations, in that it does not provide an objective and quantified/ monetised measure of effectiveness/efficiency. Nonetheless, it allows a first level of analysis (e.g. to identify whether there are effectiveness/efficiency issues or not, and a broad description/examples); it can also allow some comparison e.g. between different sizes and types of business.

h) Analysis of regulatory burden

Challenge: A full analysis of administrative costs and burden (in the context of EQs 29-31) is impaired by the scope of the study and the general framework of the GFL. The challenge of the calculation of specific regulatory costs in the GFL study context is the fact that it requires: a) sectoral focus, and b) company focus.

The calculation of costs for the GFL evaluation involves the analysis of the following complex matrix of the following three parameters (supply chain * product sectors * other secondary legislation):

i. The supply chain covered by the scope of the GFL (see section I.1.1) extends from raw materials (some of which are sourced from beyond the agricultural sector), to feed/food

manufacturing, to distribution/ storage/logistics and retailers. This encompasses a diverse range of business sectors.

ii. The food processing sector alone encompasses a wide range of product sub-sectors; due to the diverse supply chain characteristics of these product sectors (in terms of product characteristics, supply chain structures etc.), they can be considered to a significant extent different business sectors. This makes it difficult to select for instance one or two representative examples of sub-sectors on which to focus the analysis. Furthermore, there are very considerable differences in industry (and supply chain) structures between Member States.

iii. The GFL as such imposes little direct costs and burden on business, beyond the basic rules on traceability (Art. 18), withdrawal and recalls (Art. 19 and 20), and the primary responsibility of FBOs (Art. 17.1). The actual application of the GFL principles and requirements is taking place via other secondary legislation. Therefore, it is other secondary legislation and its implementation, in many cases via implementing and delegated acts, that entails such burden. Regulatory burden generated through implementation of GFL principles via other secondary legislation (i.e. to the extent relevant by the scope of the evaluation) has also been covered by the analysis.

Mitigating measures: The above complexities impose serious limitations on undertaking a systematic, formal calculation of regulatory costs and burden within the current boundaries of this study. Therefore, a lighter approach has been followed, on the basis of the Standard Cost Model (SCM) method, with a view to identifying the overall extent of the burden in terms of costs and the specific Information Obligations (IOs) that are the most burdensome.

This overview analysis of regulatory costs and burden has required the incorporation of specific questions addressed to the supply chain organisations, in the survey questionnaire and thematic case studies (traceability, distribution of FBO responsibility and risk analysis). This approach was agreed with the Steering Group, and data collection tools (survey questionnaires and case study Working Documents) were finalised on this basis, in close coordination with relevant services in DG SANTE and the Secretariat-General. The purpose of the analysis has been to provide evidence for the Commission to consider whether further detailed investigation is required of regulatory costs and burden and the potential for their reduction, in the event that this is identified to be a substantial issue.

II.3.3 Judgement criteria and indicators

In view of the challenges encountered for carrying out this evaluation, extensive work was conducted throughout the structuring phase of the evaluation to develop the approach for answering the evaluation questions (EQs) and to adjust and link the judgement criteria and indicators to the finalised methodological tools (i.e. the survey questionnaires, SME Panel questionnaire, working documents and interview guides for the case studies). The output of this work is the **final matrix of EQs, judgement criteria and indicators**, which is presented in **Annex 2b**.

In particular, the focus has been to refine the matrix, as summarised below:

- The evaluation team streamlined the approach in terms of the indicators and the evidence base required: given the complexity of the links between EQs and that some EQs are actually judgement criteria for other EQs, responses to e.g. a survey question feed into more than one EQ.
- The identified challenges have meant that the development of suitable quantitative indicators to measure the performance of the GFL has only been possible to a limited extent: the refinement and finalisation of the indicators has therefore sought to develop a balanced mix of indicators, to allow a more comprehensive and robust evidence base. Thus, EQs are addressed on the basis of input from the surveys, case studies, SME Panel, interviews (CAs, Commission Services, stakeholders) and literature review.

These five major sources of data/information therefore form the backbone of our evidence base.

Overall, the identified indicators (**Annex 2b**) can be classified into three broad groups:

- **Quantitative** indicators, e.g. costs, trend in number of food safety incidents (RASFF notifications), trend in number of food safety crises, etc. Some of these indicators can be estimates if actual data are not available (e.g. costs).
- **Qualitative** indicators, e.g. analysis of areas/cases where the GFL has systematically failed and reasons for failure.
- **Semi-quantitative** indicators, e.g. scoring questions soliciting MS CAs and stakeholders to provide a reasoned ranking on a certain aspect of the GFL based on their experience to date, for example, trend over time in consumer perceptions of food safety, trust in the food chain, cost rankings, etc.

In addition, any of the above indicators can be:

- **Overarching**, i.e. typically pertaining to the higher order objectives, principles and requirements of the GFL or of a specific EQ, and therefore potentially applicable to multiple EQs. For example, a qualitative overarching indicator can be framed around a null hypothesis that the GFL has not failed. This can be tested by trying to identify areas/cases where the GFL has failed and by identifying the reasons for failures. A quantitative overarching indicator is, for example, the trend in the number of food safety incidents. These types of indicators are particularly relevant for overarching EQs, such as EQs 1 to 5.
- **Specific**, relevant to a specific area of the GFL/other secondary legislation and/or a specific EQ.

II.4 Analysis and synthesis of results, including quality checks and data validation

The validation of data collected through the different data collection tools (**Figure 2**) has been of key importance to ensure the integrity of the analysis and results and judgement (overall assessment). The evaluation team has checked the consistency of the data collected and followed up inconsistencies with the relevant stakeholders[33]. Another key component of the validation exercise has been that, continuously during the data collection process, evidence was triangulated between the different sources and groups of stakeholders with potentially different interests, e.g. between MS CAs, operators, and consumers/NGOs; between different actors along the supply chain; between different sectors and between the different MS. Quality checks/validation were applied on:

- relevant information extracted from literature and other supporting documents (e.g. position papers of the consulted stakeholders);
- data and comments from the two online surveys (MS CAs; stakeholders);
- data and comments from the SME Panel;
- information from workshops and feedback to the working documents; and,
- interview notes and data provided during the consultation.

[33] As also explained in section II.2.1, the general term 'stakeholders' is used in this study to group together all organisations representing consumers, NGOs and industry that were consulted in this study. The term 'supply chain stakeholders' refers to Food Business Operators active along the feed and food supply chain (as defined in Article 3 of the GFL). Where differences are observed in the feedback received from these different interest groups, the source of the feedback is separately/individually identified (e.g. 'NGOs'; 'consumers'; 'supply chain stakeholders'; or, more precise sector of activity). Where consensus is observed, the more general term 'stakeholders' is used.

For each item, the information collected was verified and compared with other relevant sources/documents, e.g. the legal base, existing reports, etc. This safeguarded the integrity of data and maintained a sound evidence base for further analysis.

The analysis and synthesis of results which are presented in this Final Report has focused on bringing together the different sets of collected data/information and producing a reasoned, evidence-based analysis allowing the overall assessment and conclusions to be drawn on the weight of the available evidence, and pointing out any caveats and limitations. This has been a step-wise process that involved a number of sub-tasks detailed in order of sequence as follows:

- Extraction, compilation and analysis of data and evidence from the main consultation tools, i.e. surveys (aggregate data such as those presented in Part B, as well as comments provided by individual respondents), working documents (case studies), interviews, and SME panel results, as well as from the review of relevant literature;
- Cross-referencing data and evidence provided by the various sources, to establish consistency, identify common/divergent issues between groups of respondents and investigate reasons for potential differences in views/impacts (including potential bias);
- Critical review and final triangulation of the data/evidence available from the various sources (completion of the triangulation/validation process performed in the data collection process);
- Identification and filling of any remaining gaps (including analysis of constraints and caveats, and justification where gaps have not/cannot be addressed);
- Cross-referencing data/evidence to the judgement criteria and indicators (**Annex 2b**);
- Drafting of each EQ, following the judgement criteria and indicators, on the basis of the analysis of the final validated set of data/evidence, with indications of the source;
- Discussion of key findings per EQ, focusing in particular on:
  - Areas/issues where consensus is identified and reasons why;
  - Areas/issues where there are different views and approaches and reasons why;
  - Areas/issues where evidence is inconclusive and reasons why;
- Analysis of key findings, on the basis of which a synthesis is provided for each evaluation theme (relevance; effectiveness; efficiency; coherence; EU added value).
- Synthesis of overall conclusions and recommendations.

The output of this process (analysis and synthesis by EQ and Theme) has fed directly into the preparation of the Final Report as presented in this document.

The following points have been taken into consideration for the analysis and overall assessment, as incorporated in this Final Report:

- Differences between the food and the feed sector, where such differences exist and available data/evidence allow such an assessment, are highlighted;
- Product sectors and type of operators (positions in the supply chain) particularly affected/impacted by some issues are identified, and supporting evidence/data provided (to the extent available);
- Specific impacts on SMEs, where identified on the basis of the results of the SME Panel and the evidence collected from the online surveys, case studies and interviews, are highlighted.

Finally, as outlined in the fine-tuning of the methodology tools, the analysis and reporting has **focussed on areas where systemic failures are identified in the implementation** of the GFL and of other relevant secondary legislation. Such an approach has been essential for a study of this amplitude and breadth of scope, in order to highlight the key overall impacts and the main areas where substantial gaps and/or problems were consistently identified.

III. MAIN FINDINGS: ANALYSIS OF IMPLEMENTATION STATE OF PLAY AND IMPACTS (ANSWERS TO EQs)

This section presents the analysis of the main findings on the implementation state of play and impacts of the core principles and requirements of the GFL (Articles 1-21), in response to the evaluation questions (EQs). The findings are presented for each EQ with reference to the key criteria of relevance, effectiveness, efficiency, coherence, and EU added value, as pertinent to each EQ.

III.1 Interpretation and enforcement of the GFL (EQ24)

EQ24. With reference to questions on Articles 6, 7, 8, 9, 10, 11, 12, 14, 15, 17, 18, 19, 20 to what extent have the provisions of the GFL been interpreted and enforced in a consistent and harmonised way? To what extent does this influence achieving of the objectives? To what extent do insufficiencies in interpretation and enforcement cause distortions in public health protection and the market?

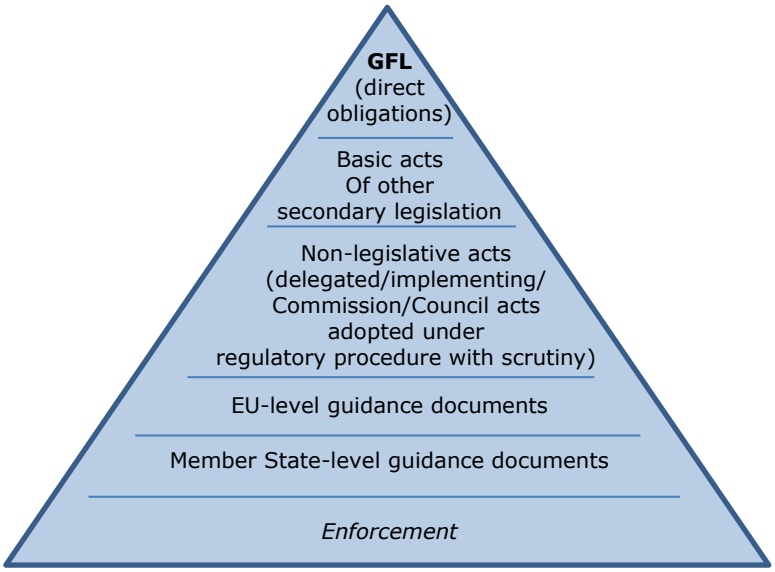
Key findings (EQ24):

The evaluation has found that differences in the implementation/enforcement by MS of the GFL provisions (Articles 6, 7, 8, 9, 10, 11, 12, 14, 15, 17, 18, 19, 20) were raised extensively and by all parties, as has been the case in earlier findings (Commission Staff Working Document Fitness Check of the Food Chain: state of play). However, for the most part, the differences identified do not occur systematically. Furthermore, the analysis has highlighted that such issues are not due to the GFL provisions as such, but often relate to different interpretation, either directly of the GFL provisions, or of further provisions laid down in other secondary legislation. This is partly attributed to the complexity of the field: for example, there is considerable potential for differences in implementation/ enforcement in the area of risk analysis and the precautionary principle (Articles 6 and 7), which is by its nature complex and involves highly technical matters. Despite the identified differences, these do not for the most part hinder the achievement of the GFL's core objectives, i.e. public health protection and the effective functioning of the internal market. Nonetheless, a level playing field has not been fully achieved due to differences in implementation and/or incomplete harmonisation in some fields of secondary legislation. In the context of national measures adopted by MS in areas that are not harmonised, it was also indicated that the TRIS system for MS notifications of national measures is not currently used to its full benefit to prevent or follow up on potential trade barriers.

In analysing the evidence in relation to the interpretation and enforcement of the GFL, it is important to outline how the framework established by the GFL and its provisions have been put into effect. In this context, two important general observations need to be taken into account:

1. The GFL provides a general framework of principles and general requirements. In practice, this is put into place, through **successive layers of implementation**, as follows: other secondary legislation; non legislative acts (comitology-related measures, delegated/ implementing acts); guidelines (Commission/national authorities/private); and, final enforcement (**Figure 3**). This has implications and poses challenges (as discussed in section II.3.2) in terms of assessing the effectiveness and efficiency of the implementation of the GFL, as the overall objective of the GFL evaluation is to identify opportunities for simplification.

Figure 3: Layers of implementation of the General Food Law (GFL)



Source: Agra CEAS Consulting (FCEC)

2. Another general observation, linked to the above point, is the **staggered implementation of the GFL** during the period under review. Although the GFL was adopted in January 2002, with some provisions coming into force in January 2005, the deadline for its full enforcement in terms of adaptation of legislation at MS level was January 2007. When it comes to implementation via other secondary legislation, several pieces of legislation pre-date the GFL and have not been updated, while others were introduced more recently or are in the process of being introduced (e.g. implementing provisions under the Regulation (EC) 1169/2013 on food information to consumers) or being updated (e.g., Regulation (EC) 882/2004 on official controls; Directive 90/167/EEC on medicated feed; delegated acts under Regulation (EC) 609/2013 on Food for Specific Groups). The timeline of introduction of other secondary legislation vis-à-vis the GFL is illustrated in **Annex 6.A**.

The implementation of Articles 1-21 of the GFL has not hitherto been described or analysed. However, in some cases the implementation of other secondary legislation has been analysed in depth in several studies and implementation reports prepared for or by the Commission.

Furthermore, the operation of EFSA and of the GFL provisions relating to EFSA (Chapter III, Articles 22-49) has been analysed in depth in regular reviews, the latest of which was published in 2012 (covering the period from 2006 to 2010).

At present, an evaluation of the RASFF, emergency and crisis management provisions (Chapter IV, Articles 50-57) of GFL is ongoing by a separate study conducted for the Commission by the FCEC.

There has been little comprehensive research, especially from primary sources, on the practical operation and effects of the GFL since its entry into force. Prior to carrying out this fitness check, there was little relevant comprehensive information on the views and policies of stakeholders, in particular the MS and national social partners, regarding the impact of the GFL.

The impact of the GFL for the EU as a whole depends on the situation prevailing before implementation (baseline, section I.1.3). Although there is no comprehensive source for this information, as no impact assessment was carried out at the time of the adoption of the GFL, the Green Paper/Whiter Paper on Food Safety describe the pre-GFL situation. Also, some literature exists from the time of the entry into force of the GFL, including feedback from consultation with industry and experts albeit before full implementation of the GFL had taken place, which highlighted the expected benefits of the GFL. For example, Wijnands, *et al* (2006), in the context of their assessment of the competitiveness of the European food industry, highlighted the expected benefits in terms of the GFL paving the way for improved harmonisation. Similar conclusions can also be drawn from Alemanno (2007), in particular in terms of the GFL improving the scientific basis and independence of risk analysis with the establishment of EFSA, and more generally introducing a 'global approach' to food safety that encompasses the entire 'farm to fork' chain.

The impact of the GFL at MS level, for some provisions in particular, was not the same across the EU. The baseline situation in individual MS is highlighted in the context of the case studies. Some MS already had similar or equivalent legislation or systems and procedures in place (sometimes going beyond the GFL requirements); others had to introduce major changes, particularly the new MS. A case in point where this is described in detail is the implementation of Article 6 on risk analysis (section III.4). Several MS already had mature, developed mechanisms of e.g. registering information and performing risk analysis or consultation so that there was no need to change their systems, except for minor adjustments if any. However, the GFL led to major changes in other MS, particularly the new MS.

A key issue highlighted by the Commission's 2013 state of play regarding the Fitness Check on the food chain (Commission Staff Working Document, SWD(2013) 516 final) was that many problems in the wider body of food legislation stem from interpretation and implementation (**Annex 6.A**). The analysis of the findings collected during this evaluation, the results of which are presented in this Report, has elaborated further on some of these issues/problems identified in earlier work.

During the consultation the issue of **differences in the implementation/application of the relevant Articles of the GFL by MS** (*indicator 24.1a*) was **raised extensively on several aspects** covered by the evaluation, and **by all parties** (including particularly supply chain stakeholders[34] and consumers, but also MS CAs and experts). The online survey provides an indication of the extent to which there have been such differences for the range of GFL provisions covered by this evaluation. According to survey results (Q53), while there are a large number of 'don't know' responses to this question (from 36% to 69% of all respondents), a majority of respondents (both stakeholders and MS CAs) indicate that differences occur to some extent/in some cases in the implementation of most of the examined GFL provisions. Nonetheless, the **differences identified are for the most part not systematic**, i.e. do not occur systematically. The areas where differences are mostly identified (albeit to some extent/in some cases) are risk analysis (46% of 67 responding stakeholders; 11 of the 25 responding MS CAs) and the application of the precautionary principle (42% of stakeholders; 40% of MS CAs, i.e. 10 MS CAs). MS CAs also indicated that the imports of feed/food from third countries are an area where differences occur to some extent (44%, i.e. 10 MS CAs) although this area was identified less by stakeholders (19%). On the other hand, traceability stands out as an area where the least differences are identified (32% of MS CAs, i.e. 8 MS CAs, and 10% of stakeholders indicated there are no differences amongst MS while a further 12% of MS CAs, i.e. 3 MS CAs, and 22% of

[34] As explained in section II.4, the term 'supply chain stakeholders' refers to Food Business Operators active along the feed and food supply chain (as defined in Article 3 of the GFL).

stakeholders indicated there are differences only to a limited extent and 20% (5 MS CAs) and 21% respectively indicated there are differences to some extent/in some cases).

Further consultation during the case studies has confirmed there is considerable potential for differences in implementation, particularly in the area of risk analysis which is by its nature complex and involves highly technical matters (section III.4). The analysis has for the most part highlighted that **such issues are not due to the GFL provisions as such, but often relate to different interpretation, either directly of the GFL provisions, or of further provisions laid down in other secondary legislation**.

Despite the **identified differences in implementation/enforcement** of the listed GFL Articles outlined above, survey results (Q1) indicate that these **do not for the most part hinder the achievement of the GFL core objectives**, i.e. public health protection and the internal market, although the former objective is more achieved than the latter (*indicator 24.2a*). In particular, as discussed throughout this report, a level -playing field has not been fully achieved due to differences in implementation and/or incomplete harmonisation in some fields of other secondary legislation.

Throughout the consultation, stakeholders in particular, but also MS CAs for the most part, outlined the benefits of harmonisation, both in the design and in the implementation of EU legislation, and the need to address the **shortcomings stemming from lack of harmonisation**. This is the case with national measures adopted by MS in areas that are not harmonised, as discussed further under the risk analysis part of the Report (section III.4) (*indicator 24.2b)*. For example, for many food contact materials harmonised legislation is not available, except for a few materials such as plastics, recycled plastics, active and intelligent materials and ceramics. Consequently some MS are initiating national legislation in this field. Although the basis on which such measures are taken is harmonised, as defined in the GFL (Article 6), the findings indicate that there is some divergence in implementation and this results in divergent regulation. Supply chain stakeholders were particularly concerned about the potential of national measures taken by MS, by their nature and in view of the constraints involved in implementing the risk analysis process, to become a barrier to trade, hence making the case for more harmonisation. In this context, it was indicated that the TRIS system for MS notifications of national measures is not currently used to its full benefit to prevent or follow up on such trade barriers, and could be improved to prevent trade barriers resulting from national measures, e.g. by facilitating input and comments from business operators.

The **differences in implementation**/**enforcement** are further discussed throughout the analysis of the various GFL requirements in the Report. These issues are particularly highlighted in the context of the following core GFL requirements: withdrawals/recalls (section III.3.3.1); allocation of responsibilities (with reference to MS CA controls, allocation of liability, and the penalty/sanction system: section III.3.2); risk analysis and the precautionary principle (section III.4); transparency (section III.5); and, import/export controls and restrictions (section III.6.1).

It is important to **distinguish between the variable implementation of harmonised rules** (e.g. with regard to withdrawals/recalls) **and areas where harmonisation is incomplete** (e.g. contaminants, food contact materials, and microbiological safety criteria). This distinction and the impacts of the differences in implementation on the functioning of the internal market are also outlined in section III.8.2.

III.2 GFL definitions and scope (EQ19)

EQ19: To what extent have the provisions of the GFL ensured a comprehensive, integrated and effective approach to food chain management? Did the definitions laid down in Articles 2 and 3 contribute to an integrated approach to food law? Was the scope correctly defined (Article 4.1)?

Key findings (EQ19):

According to all consulted parties, the scope and general definitions of the GFL have been sufficiently broad to ensure an integrated approach to food/feed safety management, and relevant to address the core objectives of food law (EU/national), i.e. to ensure a high level of protection of human health and consumers' interest and the effective functioning of the internal market. In particular, the current GFL scope and definitions have been instrumental in achieving a comprehensive, integrated approach for the management of food safety from 'farm to fork', which is demonstrated in the evaluation of the core requirements of the GFL (e.g. traceability and allocation of responsibilities, sections III.3.1 and III.3.2). Despite the overall positive feedback, some shortcomings were identified; a closer investigation of issues systematically raised by consulted parties highlights the potential for a broader than intended interpretation of the definitions which can result in differences in practical approaches to enforcement. Although having in place sufficiently broad general definitions, in line with international definitions, is valued in that is ensures that the legal scope for control is wide enough, at the same time it creates the scope of such differences. This occurs even in cases where the scope and definitions are clarified in the Commission guidelines and/or in subsequent secondary legislation. Examples include the definitions of 'food' (Article 2), 'retail' (Article 3.7), 'food business' and 'food business operator' (Articles 3.2 and 3.3). Other issues raised with regards to practical enforcement include cases where it is difficult to distinguish 'food' from 'feed' (e.g. borderline products or materials of potential multiple use), definitions/elements considered to be missing/not explicitly included in Articles 2, 3 and 4.1 of the GFL (e.g. 'consumer interest'; 'local' or 'craft'; e-commerce/distance selling; certain elements of the supply chain, e.g. food contact materials, processing aids).

The extent to which the key provisions of the GFL more generally have ensured a comprehensive, integrated and effective approach to food safety management is assessed in the implementation of the various detailed provisions (in particular: traceability: section III.3.1; responsibilities: III.3.2). The analysis here focusses on **the role that the scope and general definitions of the GFL have played** to this end.

The White Paper has aimed to ensure a comprehensive and integrated approach to food law, in particular to feed/food safety management. The evaluation has therefore addressed the adequacy of the current definitions and scope in terms of allowing/ensuring an integrated approach to food safety management, including the identification of areas/aspects considered to be missing.

Overall, the consultation has found that the **scope and general definitions of the GFL**[35] have been **sufficiently broad** to ensure an integrated approach to food/feed safety management (*indicators 19.1a and 19.2a*), and **relevant to address the objectives of food law** (EU/national), i.e. to ensure a high level of protection of human health and consumers' interest and the effective functioning of the internal market (*indicators 19.1b*

[35] The definitions of food (Art. 2), of feed (Art. 3.4), of food BO (Art. 3.3), of feed BO (Art. 3.6), retail (Art. 3.7), placing on the market (Art. 3.8), risk (Art. 3.9) and scope (Art. 4.1).

and 19.2b) (survey results, Q3a and Q3b) [36]. The sufficiency and relevance of the scope and definition of the GFL were largely confirmed by all consulted parties, including MS CAs, supply chain stakeholders, consumers, and experts. Very few negative responses were provided, mainly in relation to the broadness of definition of retail (Art. 3.7)[37]. As outlined in the White Paper, and demonstrated in the evaluation of the core requirements of the GFL (e.g. traceability and allocation of responsibilities, sections III.3.1III.3.2), a **comprehensive, integrated approach for the management of food safety from 'farm to fork' is one of the key factors contributing to the effective implementation** of the various provisions with a view to ensuring that the GFL objectives are met.

Most of the definitions laid down in the GFL are in line with those used at international level (e.g. by Codex Alimentarius in the CAC Procedural Manual). This is considered by all consulted parties to enhance the international orientation and objectives of the GFL. Consumer organisations welcome the broader definition of risk management in the GFL which, when weighing policy options, in addition to risk assessment includes "*other legitimate factors*" (defined as "*societal, economic, traditional, ethical and environmental factors and the feasibility of controls*" in the GFL's recital 19). By contrast, the definition of risk management in Codex only refers to "other factors relevant for the protection of consumers' health and for the promotion of fair trade *practices*". As such, the Codex definition is more restrictive and does not allow for as high a level of protection of consumers' interests as the EU definition[38].

Despite the overall positive feedback, some shortcomings were identified with the enforcement in practice of certain definitions. A non-exhaustive list of issues systematically raised by stakeholders and/or MS CAs is provided in **Table 3**. A closer investigation of these issues with all consulted parties highlights the potential for a broader than intended interpretation of the definitions which can result in differences in practical approaches to implementation. It is noted that in several cases, the interpretation problems were considered (both by MS CAs and supply chain stakeholders) to stem from linguistic differences between the different language versions of the GFL (e.g. 'distribution': Articles 3.1, 3.2 and 3.5).

Although having in place sufficiently broad general definitions, moreover in line with international definitions, is valued in that is ensures that the legal scope for control is wide enough, at the same time it creates the scope of differences in practice in enforcement. This occurs even in cases where the scope and definitions are clarified in the Commission guidelines and/or in other subsequent secondary legislation. The definition of 'retail' is a case in point, with various problems identified. For example, some MS CAs consider the definition in Article 3.7 too broad in relation to practical enforcement of specific rules laid down in other secondary legislation (e.g. hygiene rules for animal products; the FIC Regulation). The GFL definition covers different stages of the supply chain that should be distinct - in particular wholesale and retail. Furthermore, authorities in some cases are uncertain whether to apply the generally broader definition of the GFL or the more specific definition (when this is laid down in other secondary legislation), or to enforce as relevant to

[36] Both stakeholders and MS CAs provided average ratings higher than 4 in most cases, on a scale from 1 to 5. In the case of the definitions of feed and feed business operator, the high number of 'don't know' responses is due to the fact that the largest number of respondents comes from the food sector. Similarly, for the definition of 'retail' there are several 'don't know' responses by stakeholders that did not have a view/are not involved in this sector. It is noted that more than 50% of stakeholders and 11 of 25 responding MS CAs could not rate the extent to which the other definitions of Article 3 have been sufficiently broad to ensure an integrated approach to food/feed safety management or relevant to address the objectives of food law.

[37] Negative responses: 2 out of 25 MS CAs scored '2' and 5 out of 67 stakeholders scored '1' or '2'.

[38] It is noted that, in practice, the Codex definition gives a margin to member countries to address the protection of consumers, which is an objective usually included within the goal of ensuring fair trade practices.

the specific rules contained in other secondary legislation (e.g. hygiene rules for animal products do not apply in the case of retail establishments).

Overall, the following key points emerge from the consultation[39]:

- A common theme raised during the consultation, particularly by MS CAs, is that **while all definitions are considered sufficiently broad, in some cases they can be 'too broad'**. In practice, the broadness of the definitions can cause different interpretations by authorities, particularly where definitions are further specified in other subsequent secondary legislation, in which cases there is some confusion amongst MS CAs on which definition applies. Stakeholders also expressed concerns over the different interpretations of some of these definitions by MS CAs. The potential for variable MS interpretation is particularly strong in cases where current definitions are not explicit on what is covered/not covered, or not sufficiently clear, or in borderline cases. For example:
  - The definition of 'food' (Article 2) is very broad, which has caused difficulties in the case of 'borderline' products. Practical difficulties were noted in this respect in defining whether a product is food, medicinal product or medical device.
  - The definition of 'feed' (Article 3.4) is very broad and it has been necessary to define it more specifically in sectoral legislation[40].
  - The definition 'retail' (Article 3.7) is not precise enough, in particular with reference to 'distribution' (which appears more generally in the definition of 'food business' in Article 3.2 and can also be interpreted more broadly or more narrowly in the different languages). It contains different types of establishments (e.g. distribution terminal, distribution centres, wholesale outlets, restaurants, canteens etc.) but further specification/explanation is considered necessary to ensure that specific rules laid down in other secondary legislation apply to the intended stages of the supply chain. For example, there are more specific provisions on retail and catering in the FIC Regulation; also, some MS CAs have highlighted that it is considered too broad in the context of implementation of the hygiene rules for animal products (from which retail establishments are exempted). Furthermore, the definition 'retail' does not explicitly cover feed (although the scope of the GFL covers both food and feed); however, the feed Regulation 183/2005 applies differently to retail or wholesale of pet food, therefore the definition of retail should apply also to feed and these two concepts (retail and wholesale) should be distinct.
  - The definition of 'food business' and 'food business operator' (Articles 3.2 and 3.3) is also not specific in terms of covering all stages of the supply chain (e.g. whether importers, agents/traders and e-commerce/distance selling are included in 'distribution'). Although the Commission guidelines e.g. regarding operator responsibilities (Article 17) and traceability (Article 18) specify further the different types of stakeholders covered by these requirements, in practice, according to supply chain stakeholders, different approaches are followed, including by national authorities.
- In the case of the **definition of food vs. feed**, several problems arise in practice: several supply chain stakeholders noted that it is difficult in some cases to distinguish a 'food' from a 'feed'. This has implications as feed and food are subject to different

[39] The consulted parties could not make a distinction between the indicators of adequacy (broadness) and relevance of the definitions and scope of the GFL. This is also indicated by the fact that average ratings and individual organisation scorings are the same/very similar for survey results Q3a and Q3b. Thus, the key points emerging from the consultation are referring to both indicators.

[40] The general GFL definition of feed is referred to in the sectoral legislation. The latter, in addition, provides more specific definitions concerning the different types of feed (e.g. feed materials, compound feed, feed additives *etc.*) and a specific definition of 'oral feeding' of animals (in Regulation (EC) 767/2009 the placing on the market and use of feed) which is also mentioned in the GFL Regulation (Article 3.4).

legislative requirements. In practice, the borderline between feed and food is not obvious for many products of potential multiple use (in particular unprocessed or partially processed material of vegetable origin, such as cereals and oilseeds) until the moment when the final destination (feed, food or other) is decided, which can be at the level of the supplier or at the level of the purchaser. Products meeting the food standards do not automatically meet the feed standards: on certain aspects the legal requirements may be more demanding for products destined to feed vs. food. Stakeholders noted that this leads to unnecessary complexity and burden to establish on a case by case basis. However, this appears to be a problem associated with the multiple use of certain products for both food and feed, rather than of the GFL definitions as such. Operators note that, in principle, the issue is not related to the GFL itself, which only provides a general frame; rather, the problem pertains to the practical problems that arise in enforcement and implementation due to potential multiple use. Moreover, consumer organisations highlight that it is precisely the risk potential of multiple use materials that requires a stricter approach until their final use is decided. Examples of such products were provided as follows:

  - Crude oil and grains are sometimes considered as food and sometimes as feed depending on their intended use and how this intended use is justified to the control authorities; depending on their characterisation, different rules apply e.g. in relation to the presence of chemical contaminants (such as lead, cadmium, mycotoxins, *etc.*), and microbiological contamination (e.g. microbiological criteria for salmonella in food, for which furthermore harmonised limits apply, versus salmonella in feed for which national legislation applies).
  - Skimmed milk powder (SMP) is subject to additional requirements (under the animal by-products (ABP) legislation) when destined to animal feed vs. when destined to food.

- Some elements were highlighted which were considered to be **missing/not explicitly included** in the current scope and definitions of the GFL, particularly as these in the GFL and/or in other subsequent secondary legislation. For example:
  - 'Consumer interest' is not defined, although the GFL provisions refer to the respect of requirements linked to information to consumers (explicitly, in Article 8; implicitly in reference to food law more generally, in Article 17.1 and definition of food law in Article 3), and other secondary legislation not only addresses food safety, but also holds requirements for providing information to the consumers.
  - The term 'local' or 'craft' are not defined in the GFL although they appear in other secondary legislation (e.g. FIC under which local and craft foods are exempted from nutritional labelling rules).
  - E-commerce/distance selling is an element of the supply chain that was systematically identified to be missing/not explicitly included in several of the definitions of Article 3.
  - Article 3 does not explicitly address the sector of food contact materials which, as some MS CAs have highlighted, can result in questioning whether these businesses are obliged to follow the core obligations/ requirements of the GFL. The position of processing aids is also considered unclear, as at EU level these are only partly addressed by other secondary legislation (e.g. Regulation Reg. 1333/2008 covers processing aids only when used as additives).
- More generally, the **GFL does not have all definitions subsequently developed and contained in other secondary legislation** and this poses problems in interpretation by MS CAs depending on which legal basis they consider to apply, but also for operators in understanding whether rules apply to them or not.
- Most of the **missing definitions as well as the cases where there is potential for variable interpretation/enforcement by MS authorities** were also provided as one of the justifications why the core **objectives** of the GFL are not fully achieved or other objectives/needs and current trends are not sufficiently addressed by the GFL at present (section III.8).

- The **most critical** stakeholders on the scope and definitions of the GFL are **NGOs in the environment and animal welfare field**, who consider the current aim and scope of the GFL not to be sufficiently specific when it comes to the concept of protecting the environment, animal welfare etc. NGOs, in particular, commented that the simple listing of these considerations as general objectives in Article 5(1) dilutes focus on the achievement of the individual objectives and can lead to different emphasis/ implementation between MS. These issues are further discussed under section III.8.3.

Table 3: Problems identified with definitions (GFL; other secondary legislation) *(a)*

GFL article	Cases where problems occur in interpretation/implementation/enforcement:
Food (Art. 2)	• Not clear distinction between medicinal products and other products such as medical devices, foodstuffs (including food supplements) and cosmetics; this leads to national approaches to the distinction between foods and medicines, thereby problems for FBOs to market products that are considered foods in one MS but medicines in another MS. *(MS CAs; food sector)* • Does not cover food for personal consumption, e.g. production of animal products (*NGOs*) (*Note: the exclusion of personal consumption from the GFL scope is stipulated in Article 1.3)*
Food business / operator (Art. 3.2 and 3.3)	• Although 'distribution' is included in the GFL broad definition of 'placing on the market' and 'food business' (Art. 3.8; Art. 3.2), it is not clear whether this includes importers and agents/traders, especially in relation to ingredients or chemicals intended for use in food e.g. food additives *(food sector)* • Does not explicitly address e-commerce *(MS CAS; food sector) (c)* • Not clear whether this includes cold stores; this has implications in approach taken in some MS on FBO obligations e.g. on approval for retail of FBOs which are not just processing foods but also cold stores (approval is required in the context of Hygiene Regulation provisions) *(food sector; cold storage)*
Feed (Art. 3.4)	• Borderline between food and feed not always clear (*primary producers; input suppliers; food and feed manufacturing sector*) • Could be improved by defining animal (i.e. animals for human consumption, pets, insects) (*food sector*) • Water is not part of the definition of feed, unlike the definition of food (recital 6, Regulation (EC) 767/2009). The use of water by feed business operators is covered by Regulation (EC) 183/2005 on feed hygiene (Annexes I and II). (*MS CAs; feed sector*). • Veterinary medicines should be explicitly excluded from the definition of 'feed', since they are also intentionally given to animals as oral feeding alone or included into feed but do not constitute 'feed'. (*feed sector*)
Feed business / operator (Art. 3.5 and 3.6)	• Although 'distribution' is included in the GFL broad definition of 'placing on the market' and 'feed business' (Art. 3.8; Art. 3.5), it is not clear whether this includes importers and agents/traders, especially in relation to ingredients or chemicals intended for use in feed (*feed sector*) • Does not explicitly address e-commerce (*feed sector*) *(c)*
Retail (Art. 3.7)	• Considered too broad, e.g. wholesale should be distinct from retail (*MS CAs; food sector*) • Does not explicitly address e-commerce *(MS CAs; food sector)* • Discrepancy with the FIC Regulation definition of 'local' retail establishments ; 'local' not defined in the GFL (SMEs) • Does not cover feed (*MS CAs; feed sector*)
Placing on the market (Art. 3.8)	• Not clear with regard to e-commerce *(MS CAs; food sector) (c)* • Not clear with regard to the wording *"for the purpose of sale"* which are subject to different interpretations *(food sector)* • Not clear that placing on the market means the EU market, and not the national market; this would be in line with the FIC Regulation and non-food product safety legislation (*retailers*) *[Note: this issue relates to liability/sanctions which remain national law/jurisdiction, as discussed in section III.3.2.2.]* • Not clear that placing on the market involves also production i.e. includes the holding of food, still under the control of the FBO who produced it. FBOs aren't necessarily aware of this (e.g. in the context of Article 14 (1) this requirement is relevant also to production phase) (*MS CAs)*
Risk (Art. 3.9)	• At the moment is only refers to 'adverse health effect', and does not include the environment and animal welfare (*NGOs*)
Hazard (Art. 3.14)	• Coherence between definition of hazard (Art. 3.14) and definition of unsafe food (Art. 14.2) as the latter includes food "*unfit for human consumption*" which does not necessarily imply an adverse health effect *(food sector; MS CAs*) • At the moment is only refers to 'adverse health effect', and does not include the environment and animal welfare (*NGOs*)

GFL article	Cases where problems occur in interpretation/implementation/enforcement:
Scope (Art. 1; Art. 4)	Art. 1: • Considering the very wide breadth of scope of certain terms, such as 'primary production' and 'stages of production', there is no distinction between 'methods of production', which may pose differing food safety and consumer interest concerns. This would ensure more clarity/relevance when distinguishing between different types of farming, for example, where different livestock farming methods pose varying risks. • Not clear whether "human health" includes the health of workers handling food and feed products; as such, the interface between food and feed hygiene, occupational safety legislation, chemical legislation and feed legislation is also unclear. *(food sector; feed sector; MS CAs)*
Missing definitions/ elements (GFL) *(b)*	• e-commerce (not explicitly included in several of the above definitions) *(c)* • 'local products' • 'traditional products' • 'handcrafted food' (as per Annex V point 19 of the FIC Regulation) • 'consumer interest' (in addition to Art.8) (e.g. FIC Regulation) – incl. definition of food fraud • 'withdrawal/recall' (general definition) • 'food unfit for human consumption' (in addition to Art. 14) • 'processing' (as per Regulation 852/2004 on the hygiene of foodstuffs) • food contact materials • processing aids used in food processing (as per) *(d)* *(food sector; feed sector; MS CAs)*

(a) The list in not exhaustive. It highlights problems that were more systematically identified, by stakeholders and/or MS CAs (source indicated).

(b) These definitions are considered to be missing from the GFL, although they may appear in other subsequent secondary legislation.

(c) E-commerce is included in the broad definition of 'placing on the market' (Article 3.8), so same rules apply as with other forms of distribution unless otherwise specifically provided in other secondary legislation. For instance, specific provisions in Regulation (EC) 767/2009 concerning labelling requirements on feed offered for sale by means of distance communication – Art. 11(3).

(d) Processing aids used in the processing of food and of feed are defined respectively in Regulation (EC) 1333/2008 on food additives and in Regulation (EC) 1831/2003 on additives for use in animal nutrition. However, the rules laid down in both Regulations do not apply to processing aids.

Source: Agra CEAS Consulting, based on the results of the consultation

III.3 Core requirements for feed/food operators

III.3.1 Traceability *(EQ14/EQ15)*

Article 18 of the GFL establishes rules on traceability for food/feed safety purposes. It requires business operators to:

- Be able to identify from whom and to whom a food/feed/food-producing animal/any other substance intended to be (or expected to be incorporated into a food/feed has been supplied ("one step back – one step forward" approach); and,
- Have systems and procedures in place that allow this information to be made available to the CAs upon request.

The traceability obligation of Article 18 is a key and one of the most detailed/prescriptive requirements of the GFL; hence this issue was the subject of a dedicated case study, which examined how one step back – one step forward traceability rules were put into place and what were the impacts.

EQ14: What is the role played by the traceability requirements (Article 18)? Has Article 18 been a sufficient tool for food and feed tracing?

EQ15: What is the current added value of the traceability requirement in terms of improved safety of food/feed?

Key findings (EQ14/15):

Although one step back – one step forward traceability was already applied to some extent on a voluntary basis prior to the GFL, its application across the feed/food supply chain tended to be fragmented/disjointed. Article 18 has played a key role in achieving the generalised application of the requirement to cover the full supply chain; its impact has been not only quantitative (from partial to complete implementation of 'one step back-one step forward' traceability by all operators), but also qualitative (from fragmented to full application along the chain), in line with the underlying "farm to fork" vision on food safety. The available evidence indicates that this has enabled the effective tracing of affected products throughout the chain, in the event of food safety (e.g. dioxin, e-coli) and non-safety related incidents (e.g. horse meat fraud). Thus, Article 18 (one step back – one step forward traceability) has proved to be a sufficient tool for food and feed tracing. Although in some cases a more extended traceability is in place, this is either justified by the specific objectives laid down in vertical legislation, or by business needs (with regards to internal traceability, voluntary certification schemes). It is therefore not considered appropriate or justified for the general objectives of the GFL to have an extension of the traceability requirement beyond one step back – one step forward, on a compulsory basis. The findings also confirm the added value of the current traceability obligations in terms of concrete benefits conferred by its application along the full chain, which have all contributed to ensure the improved safety of feed/food placed on the market, as confirmed by the broader range of consulted parties including consumers.

III.3.1.1 Implementation

For the most part, operators applied one step back – one step forward traceability, as outlined in Article 18, prior to the introduction of this requirement by the GFL; in particular, 44.2% of food and feed business operators indicated that they applied it always/in most cases and another 38.5% that they applied it but not systematically (survey results, Q11)[41] (*indicator 14.1a*). Business operators had traceability systems in place, acting in their own interests without a legal obligation but on a voluntary basis. It is indicative that FoodDrinkEurope (FDE) had developed guidelines for its members to apply one step back – one step forward traceability already in 2004, which were drafted based on the experience of individual members. Also, operators that were part of a certified food safety scheme tended to have some traceability system in place. Generally, these systems tended to be company specific, less formalised, driven by business needs and customer requirements and therefore traceability along the supply chain would have been more fragmented. However, it is not possible to provide a global estimate on the rate of application of traceability in the feed and food sector prior to the GFL, as this information has not been recorded anywhere. The processed aquaculture products industry estimates the rate of application of one step back – one step forward pre-GFL in their sector at 80-90%.

The consultation, both with stakeholders and with MS CAs, confirmed the improvement in the rate of application (*indicator 14.1b*). It is not possible to estimate the actual rate of

[41] Food and feed business operators widely commented that it is difficult to provide feedback on a situation dating from more than 15 years ago. Furthermore, 17 stakeholders did not answer this question ('don't know'), in most cases as this was not applicable in their area of activity (e.g. consumer organisations, NGOs).

improvement, given that the rate of application of 'one step back-one step forward' traceability prior to the introduction of the GFL is not available. Nonetheless, as this was not a compulsory obligation and operators applied it in their own interest on a voluntary basis, traceability was fragmented/disjointed along the supply chain. The **introduction of the compulsory traceability requirements of Article 18 is considered to have resulted in principle to full 100% application along the complete supply chain**. The **role/impact of Article 18 is** therefore **not only quantitative** (from partial to complete implementation of 'one step back-one step forward' traceability by all operators), **but also qualitative** (from fragmented to full application along the chain). This is in line with the underlying "farm to fork" vision on food safety, which requires traceability to cover the whole food supply chain.

As it stands today, where a competent control authority has undertaken an investigation on a specific food/feed, 'full' traceability has been achieved always/in most cases (as indicated by 13 of 25 MS CAs) or has been achieved but not systematically (11 of 25 MS CAs) (survey results, Q14). Both MS CAs and stakeholders commented that the understanding of "full traceability" may vary, as there is no legal requirement for this. Going beyond one-step up one-step down traceability is a business decision, taken on the basis of risks versus benefits, and therefore MS CA findings when undertaking an investigation vary depending on decisions taken by business operators. It was highlighted that the concept of "full traceability" would include internal traceability, which is clearly not mandatory according to Article 18, as explained in the Commission guidelines.

Adjustments made by FBOs to apply traceability in practice, including constraints and difficulties encountered were also investigated (*indicator 14.1c*). Traceability requires a recording medium, which can vary from paper copies (e.g. of supplier invoices) up to advanced, sophisticated data bases holding an extensive range/variety of data. Traceability is generally achieved through book-keeping or stock keeping systems, and is more generally often integrated in quality management processes or systems, which encompass an extensive range of parameters including regulatory requirements, product/process specifications, customer data, contractual obligations, quality management criteria etc.. The various stakeholders representing the EU food and drinks supply chain indicated that it is not possible to provide a consolidated answer on how the traceability requirements of Article 18 were integrated in existing structures, processes and/or systems. The actual method of integration would depend on a range of factors, including the size and type of the company, business model, sector of activity, product portfolio, range of suppliers and customers, sourcing patterns/practices, and complexity/length of the supply chain. Furthermore, the baseline would have been different for each operator, with some already having systems in place, for example certain operators that were already part of a certified food safety scheme before the GFL (*see indicator 14.1a*).

Bearing in mind the diversity of the EU feed and food supply chain, there is no single model of integration of the various GFL requirements, including traceability. Even when looking at one part of the chain, the EU food and drinks manufacturing sector, this is very diverse: it covers companies manufacturing products to be delivered to final consumers and ingredients to be used in the manufacturing of products; the size of the companies also varies considerably, with over 95% of all companies in this sector being SMEs.

In addition, there are many IT options and commercial choices available to businesses. In fact, since the adoption of the GFL in 2002, an extensive commercial services field has sprung up for developing IT systems to comply with various regulatory (and non regulatory) requirements, including the traceability provisions prescribed in Article 18. Companies had (and have) the choice to either use these commercial services, or to develop a particular system best suited to their specific business needs. Some larger companies have since

developed their own tailor made IT systems. New systems continue to be developed, in line with the continued technological innovations and, more generally, the search for more effective and efficient quality management solutions. Many businesses continuously invest in appropriate new technologies best suited to their business model. As such, it is difficult to differentiate the adjustments/costs linked to regular innovation and those adjustments/costs strictly linked to regulatory requirements of the GFL. For example, in the retail and distribution sectors, some companies have integrated the traceability requirements of Art. 18 in their stock keeping programs while others link it to track-and-trace operations for e-commerce, which is a growing trend; the drivers for choice (and costs) of either system cannot be separated.

Given the diversity of operational contexts and options/systems available, some companies had to implement new software solutions, others were able to fully integrate into existing systems, and others would have had to adjust their systems to varying extents. Generally, where systems already existed but were outdated, the introduction of the new rules has acted as an incentive for operators to update their systems and IT software solutions used, also aligning with technological/IT innovations, or to pass from paper-trail based to electronic systems. It is noted, however, that for a considerable (although not precisely known) part of the supply chain, the introduction of Article 18 should have had a neutral impact, given that they already applied this level of traceability prior to the GFL (see *indicator 14.1a*).

As also indicated by both stakeholders and MS CAs, the integration of traceability provisions in some MS was helped by the fact that national associations and individual operators liaised with the national food authorities and enforcement officers to ensure a smooth transition and the correct understanding of the new requirements.

The food and feed supply chain noted that **constraints in applying traceability systems did not generally stem from Article 18 provisions as such, but rather other secondary legislation and private standards imposing additional traceability requirements, and diversity in implementation/enforcement approach at MS level**. In this respect, setting up systems to cover traceability are often complicated and made more difficult by additional requirements stemming from other secondary legislation and private standards, in particular on the level of detail of the information required to be recorded, as also interpreted by enforcement authorities.

As noted above, the manner in which the traceability requirements of Article 18 were integrated in processes and systems, and the **constraints encountered, depend on a range of factors including the baseline situation at the level of each operator**. There is no linear correlation to the size of operator as such. According to supply chain representatives, as a general rule, **smaller operators with a large range of products and suppliers, using paper-trail based traceability would have been the most impacted**. At the other end of the spectrum, local operators with a limited range of products and suppliers, or operators of any size with well established systems therefore requiring minimal adjustments, certainly would have had an advantage compared to other operators.

According to SME panel results (**Annex 4**), although the majority of respondents rarely/never find it hard to meet the traceability requirement, 42% of respondents face some difficulties, either often (17%) or sometimes (25%) (Q2). For nearly half of the respondents, the one step back-one step forward traceability requirement goes beyond a normal book-keeping exercise (Q5); it is noted that over a quarter of respondents do not know whether this is the case, while three quarters of respondents have set up internal

traceability systems, mostly at their own initiative (Q7/8). During interviews, some representatives of the SME sector[42] noted that, in very small food outlets such as market stalls or mobile caterers, the information is usually so simple and unique that the owners know without detailed records needing to be kept. In this respect, the rules/systems demanded are only applicable to large throughput traders, as some electronic systems are not always practical for micro-enterprises, which may therefore be disadvantaged.

The **EU guidelines on the traceability requirements of Article 18 have been largely useful** in assisting feed/food operators and MS CAs to comply with their respective obligations (*indicator 14.1d*). In fact, in assessing the usefulness of all guidelines relating to GFL provisions (survey results, Q52), stakeholders provided the highest ratings, on average, to the guidelines on traceability requirements (4.24). MS CAs also highlighted the usefulness of EU guidelines in assisting them to comply with their obligations, with those on traceability requirements (4.16) receiving some of the highest average ratings. There was no further information on whether national authorities issued further guidelines and how useful these might have been, although stakeholders commented more generally that they encourage the drafting of guidelines at EU level to ensure consistency across the EU and to avoid potential misinterpretation of the legal provisions or even 'gold plating' by national authorities. Although EU guidelines are generally considered useful as a more descriptive reference tool for both operators and control authorities, operators note that ideally the legislative text should be clear enough so that no interpretation guidelines are needed, which is not always the case. Furthermore, some business operators are sceptical about the value of EU guidelines more generally, when no legal responsibility is taken for the explanations contained therein and no formal recognition of these guidelines. Several MS CAs pointed out that the guidelines on traceability requirements should be updated to make reference to Regulation 931/2011 on traceability requirements for foods of animal origin and Regulation 208/2013 on sprouted seeds and seeds for sprouting, while some MS CAs noted that the current guidelines need to be more clearly set out and more clarifications are required in order to enable operators to comply with the traceability provisions.

No systematic cases of failures in the current implementation of traceability, as laid down in Article 18, were identified (*indicator 14.3c; see also EQ15, indicator 1c*). One MS CA noted that in some cases one step back is not enough to ensure traceability because sales of food/feed, especially raw materials, can be very complex. Some MS CAs noted that failures in feed traceability in particular may occur from the fact that some operators (e.g. food operators producing products used both in food and feed, e.g. SMP, with roughly 50% destined to food and 50% to feed; or raw materials destined to feed and other, non-feed and non-food uses) do not register their activities in feed circulation, as also confirmed by feed sector stakeholders, although no specific incidents of safety failures were identified in this context. One EU supply chain stakeholder (processed fish products sector) indicated that they are not on a level playing field vis a vis EU imports, for which the traceability requirement is less extended, but which constitute an important source of supply of the EU market in this product sector.

Generally, amongst all key provisions of the GFL, traceability stands out as the area where the least differences in the interpretation and enforcement by national authorities are identified, and, overall, the identified differences are for the most part not systematic (survey results, Q53)[43] (*indicator 14.3b*). Nonetheless, **MS CA approaches to internal traceability can differ** according both to supply chain stakeholders and MS CAs, with

[42] UEAPME

[43] While there are a large number of 'don't know' responses (43% of 67 stakeholders, and 9 of 25 MS CAs), differences are identified 'systematically' by 3% of stakeholders and no MS CAs; 8 MS CAs and 10% of stakeholders indicated there are no differences, while for a further 3 MS CAs and 22% of stakeholders differences exist only to a limited extent and for 5MS CAs and 21% of stakeholders to some extent/in some cases.

some MS having far more complex data and information requirements than others; these differences also create potential inequalities for operators across the EU.

All of the interviewed MS CAs (in the 10 case study MS) acknowledged that internal traceability in food is not covered by Article 18 provisions and therefore does not constitute a compulsory requirement, as also specified in the EU guidelines. Although having in place some form of internal traceability tends to be a recommendation to operators to minimise potential losses in the event that withdrawals/recalls are necessary, it is also generally acknowledged by MS CAs that this ultimately remains a business decision.

Nonetheless, several stakeholders from the food supply chain noted that the experience of operators when national control authorities visit their premises can vary between MS, as well as within MS, and that in some cases operators are requested by CAs to provide records proving internal traceability provisions. According to stakeholders, MS approaches on this can vary from providing a recommendation to operators and assessing the situation on a case-by-case basis in the event of withdrawals/recalls, to stricter application. It was noted that in practice internal traceability has become a mandatory requirement in some cases, with authorities requiring evidence of the linkages between incoming ingredients and final products and/or between premises belonging to the same operator[44], otherwise the products/the operator are considered 'non compliant'. When enquiring further with both stakeholders and MS CAs the implications for operators not having in place internal traceability, it was confirmed that in case of an incident, all production that cannot be traced down to batch/lot level has to be withdrawn.

By contrast, it is noted that in secondary feed legislation (Regulation (EC) No 183/2005 on feed hygiene) internal traceability is required for feed producing companies.

The **need for a more extended traceability system** (i.e. extending further than the provisions of Article 18) was also investigated, both with regards to specific product sectors and horizontally across all sectors of the feed/food supply chain (*indicator 14.3d*):

- **Traceability requirements in specific sectors (other secondary legislation):**

Both stakeholders and MS CAS have highlighted the **distinction in objectives between the requirements of Article 18 and the traceability needed for the purpose of other secondary or product-specific legislation**. In particular, they both emphasised that the traceability system foreseen by Article 18 aims to address food/feed safety incidents. In other secondary legislation (e.g. electronic animal identification, feed traceability and labelling, GMOs, certain labelling provisions in the context of the FIC Regulation[45]), there are additional traceability requirements tailored to specific needs and objectives other than food safety: e.g. in beef labelling, to ensure the origin and authenticity for safety (beef); in some product labelling (e.g. GMOs, fish, organic and quality products, other meats) to provide consumer information to support their purchasing decisions e.g. on sustainability (fish), method of production (organic/quality products), geographical origin (fresh meat) or GMO content.

The interviewed stakeholders and MS CAs did not consider that there were feed/food safety reasons to extend the traceability provisions of Article 18 beyond the 'one step back – one step forward' requirement horizontally across all sectors of the feed/food supply chain.

[44] For example, the retail and distribution sectors indicated that while in some MS authorities accept that transfers of goods between distribution centres and individual retail points of sales and/or warehouses of the same company are internal traceability and therefore not a compulsory requirement, in other MS authorities challenge this.
[45] Additional traceability requirements are set out in relation with the mandatory origin labelling of unprocessed meat in the context of Regulation 1337/2013.

Where specific requirements exist in certain product sectors, the stricter/more extended provisions of other secondary legislation are considered the appropriate approach as they allow specific traceability requirements tailored to the needs of each sector, in line with the provisions of Article 18(5).

Similarly, consumer associations noted that for the purposes of applying the geographical origin labelling provisions of the FIC Regulation, where the 'one step back – one step forward' approach is not sufficient, particularly in the case of longer and more complex supply chains, a more extended traceability requirement is necessary.

Regarding the stricter sector specific traceability required by beef labelling rules (Regulation (EC) No 1760/2000 establishing a system for the identification and registration of animals and regarding the labelling of beef and beef products), a recent (2015) evaluation assessed the impact of beef labelling rules for the meat supply chain, trade and consumers (AND International, 2015).

- **Extended traceability horizontally across all sectors:**

The focus has been on the aspect of **internal traceability**, which – as noted above - is not a compulsory requirement under Article 18 (with the exception of secondary feed legislation (Regulation (EC) No 183/2005 on feed hygiene) but tends to be subject to variable approaches amongst MS CAs.

The setting up of internal traceability (i.e. a system establishing a link between incoming and outgoing products which may also include records identifying how batches are split and combined to create particular products or new batches) and the ability of operators to operate in small batches is a production efficiency choice. It is noted that certain certified food safety schemes (e.g. those covered by the GFSI benchmark) also require internal traceability. **Stakeholders and most MS CAs noted that this efficiency assessment should remain a business decision, rather than a regulatory obligation.**

Efficiency issues are dictated by the size of batches, depending also on the specificities of the product sector (ranging from continuous to batch production), and this is balanced against the risk of incidents (which depends, *inter alia*, on the product sector). Two aspects are put in the balance: limiting financial damages with better targeted withdrawals/recalls in case of problems by producing in the smallest batches/lots possible vs. the efficiency gains of producing in large(r) batches. Internal traceability poses a particular challenge in the case of bulk products and/or products involving continuous (rather than batch) production processes, which is relevant for animal feed and several food products (e.g. sugar, flour, milk etc.). The challenge for operators is to achieve the smallest possible size of lot/batch that could be traced in cases of withdrawals/recalls as this would determine the size of the potential financial damage incurred in such cases. Several MS CAs noted that in cases of bulk products it is difficult to identify a lot, also in cases where a number of trading partners are involved, thus full (including internal) traceability is less achievable with bulk and more complex supply chains.

It is noted that, according to the SME panel results (**Annex 4**), three quarters of responding SMEs have put in place an internal traceability system within their organisation (Q7), with nearly two thirds of these set up at businesses' own initiative (Q8a). Nonetheless, only about a quarter of those businesses that have an internal traceability system in place indicated that this has provided additional benefits to basic traceability requirements (while a fifth of those businesses did not know) (Q8b). Nearly a third of respondents indicated that requirements to have a more detailed traceability system is often/sometimes imposed by private contractual obligations (contracts with suppliers or customers) (Q4e).

III.3.1.2 Impact and added value

The impact and added value of the traceability requirements are reviewed both with regards to the achieved outputs (improved tracing of food/feed for food/feed safety purposes) and the achieved outcomes (improved safety of food/feed), both of which also determine the cost-benefit balance of traceability.

The **requirement to implement one step back – one step forward traceability in the supply chain, as outlined in Article 18, has improved tracing of food/feed for food/feed safety purposes** in the EU, compared to the situation prior to the GFL[46] (survey results, Q12) (*indicator 14.1e*). In particular:

- For food supply chain operators, the introduction of Article 18 formalised a requirement for traceability along the full chain, making the application of the one step back – one step forward approach more robust and more systematic, as awareness increased amongst operators along the chain, based on principles enshrined in EU law and implementation verified during audits.
- For feed supply chain operators, not all sectors of the feed chain had a full traceability system in place prior to the GFL. Several stakeholders along the supply chain, as well as consumers, noted that pre-GFL incidents such as the dioxin crisis of 1999 – which led to tonnes of products being withdrawn from the market as the source of contamination could not be identified – highlight the traceability shortcomings before the GFL. According to most stakeholders, the management of incidents over the last 10 years has shown a significant improvement of the traceability systems along the feed chain, allowing faster identification of potentially affected products.

Article 18 enabled the feed and food supply chain more generally to have a well documented system set by EU law. The 'one step back – one step forward' requirement has improved the traceability of all manufactured goods, allowing for a quicker identification and response in case of a risk or hazard with regard to the withdrawal/recall procedure.

Both stakeholders and MS CAs highlighted that the traceability system foreseen in Article 18 is a 'passive' system, which comes into action in case of food/feed safety failure to trace potentially affected food/feed across the full supply chain. The benefit of the traceability system, in terms of output, is that the different parts of the supply chain can be linked to provide full chain traceability; this depends on the timely sharing of intelligence and information regarding food/feed safety incidents, both between operators along the supply chain and with the MS CAs. As discussed in section III.3.1.1, the need for a more extended traceability system was also investigated and this was not found necessary. Evidence from success cases (see below, *indicators 15.1c and 15.2b*) demonstrate that **the current traceability provisions have been sufficient to trace food/feed across the full supply chain**, i.e. the information provided at each part of the chain can be linked[47] to provide full chain traceability including in cross-border transactions (*indicator 14.3a*).

The current **added value** of the traceability requirement was investigated in particular in terms of the extent to which it has contributed to **improved safety of food/feed**. **The traceability provisions of Article 18 have had very positive impacts in ensuring food/feed safety in the EU**, according both to stakeholders and MS CAs (survey results,

[46] On a scale from 1 to 5, on average both stakeholders and MS CAs provided a rating well above 4 for traceability in both the food and feed sectors. It is noted that in the case of stakeholders the large number of 'don't know' responses on feed traceability (30 out of 67 responses) is partly attributed to the fact that many of the respondents did not have a view/are not involved in the feed sector.

[47] The extent to which the necessary traceability information is made available by operators when requested by MS CAs (*indicators 14.2a/14.2b*) is addressed in the context of withdrawals and recalls (EQ8).

Q51)[48] (*indicator 15.1b*). The benefits of traceability, in terms of achieved outcomes, are discussed further below.

In terms of the **EU added value of traceability** (*indicator 15.2a*), both MS CAs and stakeholders indicated that, **given the extent of cross-border trade in the internal market, only EU-level traceability can ensure the benefits** already highlighted above. EU-wide traceability is of critical importance for the single market. If there is no EU approach the traceability system has limited value. Not only is an EU-wide system more uniform, thus allowing a more level playing field across the EU, it also facilitates considerably the exchange of information between MS, thus playing a crucial role for identifying more rapidly the sources of incidents and affected products in cross-border trade.

Another indication of the positive impact of the traceability rules introduced by Article 18 can be obtained by comparing the EU and other third countries where no such system has been put in place. Literature reviews highlight the benefits and relative **superiority of the EU traceability system**, based on the harmonisation achieved by Article 18.

In a recent review of the food traceability regulations of 21 OECD countries[49] **EU MS ranked 'superior' in food traceability**, above other OECD countries. The ranking of EU MS was based on what was assessed to be the most comprehensive mandatory traceability system covering the full range of feed/food products and the full supply chain both for domestic and for imported foods under the provisions of Article 18 of the GFL. According to the rankings of the countries, EU MS are ranked as 'superior'[50] in that they have adopted mandatory traceability rules on the basis of Article 18. Canada is ranked as 'average', due to the presence of mandatory traceability for livestock through its animal identification system and the as-yet-unfinished development of a process for regulating other commodities. Similarly, Australia, New Zealand, Brazil, and Japan are ranked as 'average' due to having a mandatory system for specific, although not all, commodities. The US is also ranked as 'average' because it is still lacking regulations dealing with national traceability of food products in general despite the modernisation of the US Food Safety Act since 2011. Lastly, China is ranked as 'poor' because their specific traceability regulations are either limited or not yet fully implemented. The literature review showed that only some non-EU countries have mandatory traceability regulations; and where they exist, regulations are restricted to specific commodities. For example, in the US, traceability practices are mainly industry-led, e.g. the Produce Traceability Initiative (PTI)[51]; although, since the modernisation of the US Food Safety Act[52], the US government has been working on

[48] Average ratings above 4, on a scale from 1 to 5. None of the consulted stakeholders or MS CAs indicated a negative impact.

[49] Charlebois et al (2014).

[50] The review ranked the countries that have specific traceability regulations for all commodities, both domestic and imports, as "superior", while countries with less broad or stringent regulations were ranked as "average" and countries that were still in the developmental stage of mandatory or industry-led traceability requirements were ranked as "poor". This was an aggregate ranking based on a number of criteria. In particular, the countries were evaluated based on whether: mandatory traceability regulation(s) exists at the national level within a given country; regulations include imported products, and the nature of required documentation for imports; an electronic database(s) for traceability exists and, if present, its accessibility; and labelling regulations allow consumer access and understanding of traceability.

[51] The PTI is an industry-led, supply chain-wide initiative in the fresh North American fruit and vegetables sector, which is administered by Canadian Produce Marketing Association (CPMA), GS1 US, Produce Marketing Association (PMA, US) and United Fresh Produce Association (UFPA). The driver for this initiative, as stated by the PTI, is that North American industry leaders have recognised that a more systematic, industry-wide approach enhance overall supply chain traceability in speed and efficiency. According to the industry, the use of standards in the supply chain across the industry significantly enhance the ability to narrow the impact of potential recalls or similar problems, protecting both consumers and industry members.

[52] The US Food and Drug Administration (FDA) refers to the Food Safety Modernization Act (FSMA), signed into law on 4 January 2011, as the most sweeping reform of US food safety laws in more than 70 years.

establishing a traceability system along the lines of Article 18 of the GFL. In non-EU countries where mandatory traceability systems exist, these tend to cover mostly the supply chain of livestock products (from animal identification to product traceability), as is the case for example in Australia, New Zealand, Brazil and, more recently, China.

The authors of the above review note the importance of harmonising traceability requirements and regulations to minimise the potential for unnecessary costs and delays caused by difficulties in understanding each country's practices, to strengthen interoperability in order to overcome unintended trade restrictions, and to improve traceability of food products globally. Most of the consulted stakeholders and MS CAs in the context of the traceability case study highlighted that they have experienced precisely these benefits through the common framework established by Article 18.

The likely problems/gaps from a sub-EU-level approach (*indicator 15.2c*) are already highlighted by the benefits of the EU approach. Without an EU system, MS would probably close their borders as soon as an incident is identified for all similar products and mutual trust in the systems applicable at national level is considered likely to be low. The actual identification of the origin of incidents and affected products, and agreement of measures to contain the incident, would take longer and be less effective/efficient.

The analysis has also looked at the **costs and benefits of traceability** (*indicators 15.3a to 15.3c).* While the difficulties of providing cost and benefit analysis in the context of this study have been highlighted extensively in the challenges section, in this particular case this is due both to the time elapsed since the Article 18 provisions were implemented by operators, and to the diversity of business models and sectors covered by the traceability requirement.

Costs:

As there is no single model/system of integrating the traceability requirements of Article 18 (see *indicator 14.1c*), it is not possible to provide an overall estimate of the costs of providing 'one step back-one step forward' traceability according to Article 18 (e.g. as % of total production costs).

Traceability systems have been in place for over a decade now and are quite mature (given that these costs were incurred over a decade ago, there are no records or data from which to calculate the current costs). Food and feed supply chain stakeholders noted that traceability is now an integral part of their business process and therefore the costs incurred from fulfilling Article 18 obligations cannot be distinguished or segregated in terms of operational or administrative costs (and burden) from other process costs. Moreover, for operators affected by the specific additional traceability provisions of other secondary legislation and/or those applying internal traceability, the efforts needed to implement this cannot be separated from the basic traceability requirements foreseen in Article 18. Finally, considering the diversity of the supply chain, it is not possible to give a coordinated answer regarding traceability costs as a % of average operational or production costs.

As already noted, there is no linear correlation between size of business and traceability costs. Smaller companies tend to have an advantage when trading (buying/selling) locally and/or from a more limited number of long standing suppliers/customers, but tend to be disadvantaged when this is not the case and/or working with an extensive range of raw materials/products and/or suppliers/customers. According to SME panel results (Q12, **Annex 4**), nearly half of respondents indicated that record keeping for traceability purposes is one of the three most demanding administrative tasks carried out under EU food/feed law obligations. It is noted, however, that three quarters of responding SMEs have also set up

internal traceability systems, of which two thirds have done so at their own initiative (Q7/8).

Costs also depend on where an operator is positioned in the supply chain:

- At processing stage, an illustration of the current costs of providing 'one step back-one step forward' traceability according to Article 18, the processed aquaculture industry has indicated that, depending on the traceability software used, these can vary anywhere between €800 up to €10,000 /year of software maintenance per operator. In addition, there are labour costs for staff entering data, estimated at approximately €7,000-10,000/year (on the basis of 2 h/day, at €12/h). These costs are consistent in scale with estimates of new/additional traceability requirements in other food sectors from previous studies (e.g. FCEC 2013 and FCEC 2014).
- At distribution stage, traceability costs depend on the number of suppliers and clients (for wholesalers) that a given business has. This number varies considerably according to the specific business model of the individual operator determining the number of products which are part of the assortment and its sourcing practices. For example, a large retailer business can offer up to 50,000 product lines on a daily basis, while a regular size supermarket stocks between 10,000 and 30,000 product lines and has a couple of thousand suppliers[53].

In terms of the costs of providing additional traceability requirements, going beyond Article 18, there are additional costs through data recording, especially if the required databases are not interoperable with existing systems. In particular, where different legal traceability requirements apply – e.g. as established under other secondary legislation such as the FIC regulation or sector-specific labelling provisions - the main difficulty is the compatibility (interoperability) of the various IT systems, which could lead to duplication of IT efforts and increases the burden to extract, record and report the required information.

Benefits:

Overall, the consultation, both with stakeholders and MS CAs, has highlighted that the general traceability requirement of Article 18 ("one step back – one step forward" approach) in combination with own verification systems/procedures in place[54] have provided benefits in terms of achieving the following outcomes[55]: assisted in containing a food/feed safety problem (as well as in addressing a non-compliance problem with food/feed legislation (not safety-related)); ensured effective tracing of feed/food across the full 'farm to table' supply chain in the EU; ensured effective and efficient targeted withdrawals/recalls of unsafe food/feed; and, contributed to maintain consumer trust and confidence to the safety of a food/feed (survey results, Q13) (*indicator 15.1a*). In particular, these provisions, working in synergy, have conferred the following benefits:

- They have led to MS CAs aligning their procedures and communication to implement more uniform approaches (although in some cases current MS CA approaches to practical enforcement may be stricter than Article 18 requirements, e.g. on internal traceability, as discussed in section III.3.1.1).
- In case of an incident with one ingredient or one supplier (whether suspected or confirmed), they have made it possible to trace more rapidly all affected products. Before this requirement, such an investigation was tedious, could take days/weeks to carry out and could end up being unresolved because of lack of information in the supply chain. The impact of this is **improved food safety**.

[53] The number of product lines refers to a business rather than a store - number of products is a combination of stores by product lines.
[54] As analysed in section III.3.2.1
[55] Both MS CAs and stakeholders provided average ratings above 4, on a scale from 1 to 5.

- Similarly, in case of incidents, they have allowed to identify causes/sources of incidents and affected products with greater precision. This has enabled more targeted withdrawals of products and more focussed/effective recalls, **thus also reducing potential food losses**.
- Longer term, they have contributed in preserving business/product reputation, as well as consumer trust, given the potential damages of a food-related scandal both in terms of sales and lost consumer confidence.
- For consumers, the main benefit of the traceability requirement has been the fact that the faster provision of more targeted information has enabled differentiating more rapidly and more accurately from non-affected products (although, in practice this has not always been possible, despite the availability of more detailed information, in cases where consumers would not be in a position to differentiate between affected and non-affected products based on the available information).

These outcomes are also confirmed by SME panel results (**Annex 4**, Q6). A vast majority of respondents indicate clear benefits of the traceability system: it makes it easier to manage risk in food/feed safety incidents (85% of respondents); it helps identify which products need to be withdrawn from the market (83%); and, it maintains consumer trust by providing accurate information on products affected by a food safety incident (75%). A smaller majority of respondents indicated that the system prevents unnecessary disruption to trade (54%) and improves business management (60%), although a relatively important share of respondents do not know whether the traceability system has these particular benefits (23% and 13% respectively).

According to stakeholders, including consumer organisations, **various incidents that have occurred in the last ten years demonstrate that the current traceability set up has worked to rapidly contain a risk** (*indicators 15.1c; 15.2b*): examples quoted include dioxin, E.coli, organic eggs (PCB), melamine, and imported frozen strawberries (norovirus). The relatively recent E.coli incident (DE) demonstrates that traceability worked, although delays in this case were due to the context and circumstances surrounding the incident i.e. that parts of the supply chain did not communicate early enough. This contrasts sharply with the experience in pre-GFL incidents such as the dioxins crisis of 1999, which led to tonnes of products being withdrawn from the market as the source of contamination could not be identified. The more recent horsemeat scandal was also indicated by several stakeholders as well as MS CAs, as a case where the current traceability provisions of Article 18 allowed the rapid identification of the affected supply chain operators, leading to rapid withdrawals/recalls[56], once the source of a problem was established as being fraudulent activity; this is noteworthy as it runs contrary to a misconception and media reports that the horsemeat scandal provides evidence of failures in traceability.

It is important to also consider the **benefits of traceability in addressing issues recurring on a daily basis, e.g. salmonella**. Although the reduction in salmonella human cases is due to many factors, including better hygiene, improved technology, greater consumer awareness of handling products etc., and cannot be attributed to any single factor as such, improved traceability is a key contributing factor.

No cases of failures, in terms of achieved outcomes, due to the traceability systems set up in line with Article 18 were identified during the consultation and scope of this study.

Furthermore, the benefits resulting from the traceability requirement of Article 18 have considerably outweighed the costs of setting up and operating traceability systems, as required by the GFL, for over a third (37%) of stakeholders and have more or less

[56] These withdrawals/recalls were not performed on the basis of the GFL, as there was no safety concern.

outweighed costs for an additional 19% (survey results, Q15) (*indicator 15.3b*). Nonetheless 22% of stakeholders indicated that benefits have not for the most part outweighed costs while it is noted that 21% of stakeholders were not able to respond ('don't know'). As already discussed, a common observation of all groups of stakeholders was that it is impossible to measure not only the costs but also the benefits of traceability (as well as of the other GFL provisions). Consumer organisations and NGOs noted that *"it is clear that the safety and health benefits of the EU traceability rules are invaluable"*, adding that *"it is extremely challenging to measure and express in economic terms the benefits of avoiding illnesses and death triggered by the consumption of tainted food"*. Operators similarly noted that the benefits of traceability cannot be measured, neither for consumers nor for businesses. In qualitative terms, it is considered beneficial in limiting market/trade disruption in case of a problem and in preserving business/product reputation, given the potential damages of a food scandal in terms of sales and lost consumer confidence (see above, *indicator 15.1a*).

More generally, both the food and the feed manufacturing sector have indicated that, by definition, the businesses at the end of the supply chain that are the closest to consumers (business to consumer - B2C) stand to benefit the most from traceability.

Amongst those business operators who indicated that the benefits have not for the most part outweighed costs, specific factors have not allowed this to happen, including in most cases the need to adhere to traceability requirements that extend beyond Article 18[57].

The benefits of traceability in terms of the potential cost savings in case of withdrawals/recalls are generally expected to be higher for operators delivering to a large number of retailers or restaurants or exporting to different countries. Some representatives of the SME sector noted that, as this operational context is more typical of larger rather than smaller companies, the cost-benefit ratio is usually higher for larger operators. Smaller operators who sell their products to the final customer have to comply with the traceability obligations but their potential benefit in relation to the costs incurred from this obligation is lower if they are locally producing/selling, especially for those dealing with a limited number of ingredients/products and suppliers/customers and having long-standing business partners. Similar conclusions are drawn in the case of the implementation of the primary responsibility provisions of the GFL (Article 17), as outlined in the following section.

An indication of the potential direct costs and losses of food safety incidents is provided in the economic context of the sector (section I.1.1). For example, in the case of the Irish dioxin contamination incident in 2008, although less than 10% of pork products were potentially affected by the contaminated feed, 100% of products were recalled with an estimated cost of €200 million to the Irish industry (this incident affected the Irish market); the Parliamentary Committee examining the case concluded that, although the traceability system in place was in line with EU rules, a more detailed traceability might have reduced losses (Houses of the Oireachtas, 2009[58]). The 2011 *E. Coli* outbreak from sprouting seeds

[57] For example, the processed aquaculture products sector has noted that for EU importers of aquaculture and fisheries products traceability is not extended to the same level as for EU producers (unlike EU operators, EU importers only have the obligation to be able to identify at least the business from which the imported food was supplied). In their view, this has led to a lack of a 'level playing field' in this sector, as 70% of seafood products consumed in the EU are imported, and these products are perhaps only covered by the traceability of private third party certification schemes, such as Global Gap or Aquaculture Stewardship Council. Furthermore, the sector indicates that stricter sector traceability rules in feed have also increased EU feed costs. Businesses engaged in intra-EU cross-border trading are particularly affected as these businesses are more likely to have to compete with importers of products from third countries.

[58] More detailed facts and findings on this case are provided in the Report. With regard to traceability, according to the Irish authorities, the operators complied both with Article 18 (one step forward and one step back traceability) and with the EU identification rules for pigs. This traceability allowed the authorities to trace effectively from

cost more than 50 lives; losses for fruit and vegetable growers estimated to have exceeded €800 million, in addition to over €200 million of emergency payments on market support, and other costs/losses (European Commission, 2011a).

The adverse impact of poor traceability is also highlighted by incidents in countries where there are no compulsory requirements. In the US, the need for better traceability became clear after a national outbreak of salmonella in spring 2008 that sickened more than 1,300 people across the country erroneously identified tomatoes as the source, which according to the reviewed literature was partly due to poor record-keeping; the cost to tomato growers in Florida alone was estimated at about US$100 million (Charlebois et al (2014))[59].

III.3.2 Allocation of responsibilities *(EQ12/EQ13)*

Article 17 of the GFL defines the roles of food/feed business operators and the national CAs:

- Food/feed business operators have the primary responsibility for food safety. They must ensure compliance with the requirements of (EU/national) food law which are relevant to their activities and verify that such requirements are met. The scope of these requirements is the same as food law, in that they cover both the issues of feed/food safety (e.g. the hygiene legislation) and the protection of consumers' interests (e.g. food/feed labelling) (Article 17.1);
- National CAs monitor and enforce this responsibility through the operation of national surveillance and control systems (Article 17.2).

As such, Article 17 lays down the foundations of an allocation of responsibilities both along the food chain and between business operators and national CAs, which is based on the principle that food/feed business operators have primary responsibility for ensuring compliance with EU/national food law while national CAs are responsible for monitoring and controlling enforcement.

The allocation of responsibilities was examined with regards to the implementation both by business operators along the feed/food supply chain of their primary responsibility obligations of Article 17.1 to deliver 'chain responsibility', and by MS CAs of the provisions of Article 17.2 particularly in relation to official controls carried out by authorities, as well as penalties and infringements in place. The allocation of responsibilities amongst business operators is the backbone of the GFL; hence this issue was the subject of a dedicated case study, which examined how operator responsibilities under Article 17.1 were put into place, including self-controls, and what were the impacts.

III.3.2.1 Food chain: primary responsibility (EQ 12)

EQ12: How have the rules concerning the allocation of responsibilities in the food chain been applied? To what extent have they contributed to a consistent allocation of responsibilities in the field of food law across the EU (Article 17)? To

slaughter to farm, to feed supplier and then to customers of the feed supplier. Nonetheless, the 100% losses when compared to a 10% contamination rate were a consequence of the traceability system which was based on total day production recording at slaughterhouse level. While this traceability system would be efficient for the recall procedure for a contamination occurred in the slaughterhouse and/or cutting plant, it was inefficient for contamination that occurred upstream in the supply chain (in this case, feed). The Report concludes that a more detailed traceability system, such as that practised in the Danish pig slaughterhouse sector recording time slots of production during the day on a continuous basis, might have enabled a more refined targeting of the recalls.

[59] Initially, investigators at the FDA and the Centres for Disease Control and Prevention (CDC) identified tomatoes as the source, and warned the public against consuming them; more than a month later, FDA investigators correctly identified the source of the outbreak as peppers from Mexico. According to the FDA, the delay was partly because of the chaotic record-keeping of the growers, distributors, wholesalers and retailers.

what extent has this proved to be significant for achieving the objectives? Has the allocation of responsibilities produced efficient and effective results?

Key findings (EQ12):

Article 17.1 is considered to have led to the clarification/formalisation and more systematic application of measures and procedures that operators had in place prior to the GFL, to ensure their primary responsibility of compliance with the core requirements of EU/national food law in general. Operators – particularly larger companies - did not encounter any considerable constraints or difficulties to apply this obligation, which was also helped by the EU guidelines; problems stem rather from overlaps/contradictions with the requirements imposed in other secondary legislation. The findings point to the positive and effective contribution of Article 17 towards meeting the GFL objectives and intended outcomes, for consumers (high level of protection of human health and consumers' interests), and business operators (improved trust among supply chain partners, moreover in the single market context). In particular, Article 17.1 established 'chain responsibility' which is considered as a major novelty of EU feed/food law, compared to the pre-GFL fragmented individual responsibility approach.

Despite the overall positive feedback, several issues were raised in terms of the extent to which, in practice, compliance with Article 17.1 can be ensured along the full chain, also in a uniform manner across the EU, which ultimately defines the limits of the system in terms of its ability to deliver full 'chain responsibility'. These issues relate to the complexity of the supply chain, problems in the implementation of other secondary legislation and/or incomplete harmonisation (including on the allocation of liability which is not based on Article 17 but on a legal basis found in the national legal order (as foreseen in Article 21) and in the specific infringed legislation).

The rules laid down in Article 17 have also largely ensured an efficient allocation of responsibilities, both amongst operators and between operators and MS CAs, largely due to the non-prescriptive character of the provisions, which is appreciated by all consulted parties. There is evidence of efficiencies both at operator level (design of fit for purpose systems, integrated in quality management and certification schemes) and at authority level (in some cases, freed up resources to focus on enforcement). Article 17(2) is implemented through the Official Controls Regulation (EC) 882/2004, which aims to create an integrated and uniform approach to official controls along the agri-food chain to ensure harmonised enforcement. However, key obstacles to delivering a fully efficient system remain as follows: the non-acceptance/recognition of the operator own-control and verification systems by authorities in most MS; and, differences in understanding and implementation of controls carried out by national authorities between MS or even within MS (at regional/local level). Such differences in MS CA approaches are often attributed to understanding/ interpretation of the rules and control procedures by individual inspectors, rather than design of the official control plans as such which benefits from the harmonised requirements set out in Regulation (EC) 882/2004.

As in the case of traceability systems, systems and procedures to ensure compliance with the core requirements of EU/national food law existed prior to the GFL; these were determined by business needs, in particular the need to ensure an effective response to managing risks and minimise exposure both to financial damages and loss of reputation (*indicator 12.1c*). Thus, **Article 17.1 has not led to the development of new structures/systems, although it is considered to have led to the clarification/ formalisation and more systematic application of measures and procedures** that need to be in place as a minimum (*indicator 12.1d*). It is noted that the requirements of other secondary legislation (and, in non harmonised areas, national provisions), rather than Article 17.1, are determining the procedures and structures that food and feed businesses

need to have in place to ensure legal compliance with specific rules, including liability for failure to comply.

According to the industry, for the most part, **operators – particularly larger companies - did not encounter any considerable constraints or difficulties** with the application of Article 17.1. Issues that caused, and continue to cause, **problems stem rather from overlaps/contradictions with the requirements imposed in other secondary legislation**. Examples include: fragmented labelling provisions (provided in the FIC Regulation and also in sector-specific or other labelling-specific legislation)[60]; sampling and testing requirements imposed by other secondary legislation and the extent to which these are compulsory for all operators along the supply chain (including at the very beginning of the chain i.e. non-agricultural raw material suppliers and agricultural producers and at the end, i.e. final retailers or mass caterers). When it comes to smaller operators, Article 17.1 is considered to have resulted in a formalisation of pre-existing measures, through the adoption of more systematic procedures for delivering e.g. food safety and hygiene requirements (*see also indicators 12.3a to 3h on efficiency*).

The EU guidelines on the allocation of responsibilities between food/feed businesses and control authorities (Article 17) **have been largely useful** in assisting operators and MS CAs to comply with their respective obligations (survey results, Q52)[61] (*indicator 12.1g*.)

According to both stakeholders and MS CAs, feed/food business operators at all stages of production, processing and distribution are verifying (e.g. via their own internal controls) that the core feed/food law requirements (set out at EU and national level) which are relevant to their activities are met. However, the findings indicate **differences in implementation along the supply chain**: at one end of the spectrum, operators at the stage of feed/food processing are considered to be verifying the most and, at the other end, importers/transporters of feed/food to be verifying the least[62] (survey results: Q9)[63] (*indicators 12.1a, b and e*).

The form in which this verification takes place is specific to each stage of the chain, as well as being tailored to the profile and needs of each operator. Nonetheless, a common feature of most systems is their integration into private certification and quality management schemes/standards, which have considerably evolved over the last decade (*indicators 12.1f and 12.3c*)[64]. In particular:

- At food processing stage, operators apply systems that in principle combine good manufacturing practices (GMPs), HACCP and own verifications (**Box 1**), This base approach is further tailored, developed and formalised depending on the

[60] It is noted that the European Commission has launched a project to develop a database which will include all EU and national provisions on labelling, covering both general and sectoral rules.
[61] According to both MS CAs and stakeholders, rating average above 4, on a scale from 1 to 5. Only 4 of the 67 responding stakeholders did not find these guidelines useful, although it is noted that 16 stakeholders did not provide a response, largely because these guidelines are not applicable in their case (including consumer organisations and NGOs).
[62] It is noted that problems occur with the interpretation of the food/feed business definitions of Article 3 regarding the non-explicit inclusion of importers, (section III.2, **Table 3**).
[63] Both groups of respondents provided average rankings above midpoint (3.00), on a scale from 1 to 5. Among all stages of the supply chain listed, food/feed operators at the stage of processing received the highest average ratings (stakeholders: 4.14; MS CAs: 3.91). At the other end of the spectrum, transporters of food and feed received the lowest average ratings (stakeholders: 3.63; MS CAs: 3.26). The stakeholder responses may to some extent be tainted by the fact that the majority (35%) of stakeholder respondents are involved in food/feed processing, although it is noted that this is not necessarily their exclusive activity, and that MS CAs provided relatively similar scorings.
[64] The proliferation and central role played by private standards/schemes in the contemporary food safety governance system is discussed extensively in Bernd M.J. van der Meulen (ed.) (2011).

needs/requirements of: specific product sectors[65]; at MS level, defined by national associations; for certain specific issues, laid down in other secondary legislation[66]; and/or, integrated in wider quality management systems[67]. Typically, these systems, their use and implementation are audited by private certification bodies/standards and/or customers, and go beyond the requirements stated in legislation, including in terms of laying down rapid response and crisis management rules and procedures.

- At retail stage (sale to final consumer):
  - The primary responsibility obligation has been met by the set-up of regulatory departments, internal audits/third party audits, and dedicated quality management schemes. In larger retailers, the sales divisions have implemented quality management processes to ensure food safety and to comply with their responsibility; the process is documented in manuals and is compulsory for all stores, while staff training is based on this. These quality management processes are controlled by internal and external audits against worldwide benchmarks (e.g. GFSI[68]). While all large retailers do this internally as part of their quality management, smaller retailers do not always have this internal capacity and rely on audits by third party certified food safety schemes (e.g. BRC, IFS, FSSC22000). In many MS these schemes have become the standard business practice[69]. Some of these existing schemes, e.g. GlobalGap (which is relevant for primary production) and IFS are working together to provide a seamless coverage of the supply chain, from farm production to retail. It is noted that many of the retailer self-regulation tools, such as private standards and quality management systems, existed prior to the GFL, and were further developed over the last decade[70].
  - Retailer organisations have also emphasised that they increasingly have multiple roles as distributor, importer, but also as own-brand producer[71]. Therefore compliance with verification requirements may go beyond the distribution (sale to final consumer) stage as such. In this case, large retailers commission or conduct

[65] For example: Codes of practice developed by the EU vegetable oils industry (FEDIOL) to further ensure the highest level of safety and quality of products along the supply chain by preventing or limiting the occurrence of contaminants in vegetable oils and fats, meals and by-products. Examples include: Code of Practice & Quality Assurance Agreement on the purchase conditions of Fresh Bleaching Earth and Filter Aids for vegetable oils and fats refineries and integrated plants; Code of Practice for the transport in bulk of oils into or within the EU; EU guide on the manufacturing of safe feed materials. Also, in cooperation with other EU industry associations and the European Feed Ingredients Safety Certification (EFISC), FEDIOL developed a European Guide, providing guidance on crisis management, and in addition a feed incident and crisis management procedure, used by its members, in the situation of a feed incident.

[66] For example, the FDE Acrylamide toolbox and pamphlets, the FDE allergen guidelines.

[67] E.g. 'pre-requisite programmes' such as PAS 220. Prerequisite programs are programs and practices put in place to address the role the production environment plays in producing safe food products. GMPs would be part of prerequisite programs. PAS 220 (now ISO/TS 22002-1) provide specific requirements for food processors and manufacturers, which must be addressed by companies preparing for FSSC 22000 certification (food safety management system certification scheme - FSSC 22000 defines requirements for integrated processes to control and minimise food safety hazards.

[68] The GFSI (Global Food Safety Initiative) is the overarching benchmark for globally recognised food safety standards, including BRC Global Standards (British Retail Consortium: http://www.brcglobalstandards.com/), the IFS (International Featured Standards, developed by FR and DE retail organisations, first launched in 2003) and other private certification standards (for full list see: http://www.mygfsi.com/schemes-certification/recognised-schemes.html). These cover food retail procurement and processors; e.g. Manufacturer Food Safety Management Systems (practices and procedures) are BRC certificated which is a GFSI approved standard. More recently introduced, the GSSI reproduces for seafood the same concept as the GFSI for food.

[69] For example, the majority of UK retailers expect their direct suppliers to be BRC or equivalent accredited, or a third party certified scheme for EU/non-EU suppliers; similarly, for DE retailers and IFS. Both standards are globally available so businesses in the EU and third countries also have the opportunity to be approved.

[70] The practices of major retailers at the time of the GFL's introduction are described in Fulponi (2006).

[71] Private labels (retailer own brands) have increased in market share throughout the EU, while they no longer compete at low price levels only; for example, their current market share in Germany is estimated at 44%.

their own product specification for own brands products; in addition, smaller retailers often source from big retail certified suppliers.

- At trade (collection, storage and distribution[72]) stage, operators have in place fit for purpose systems, typically combining quality and control management such as ISO22000, ISO9001, with food practices (trading: GTPs; manufacturing: GMPs). Again, these systems are certified by independent, private certification and/or quality management bodies and/or customers, and can go beyond the requirements stated in legislation[73].
- At primary (agricultural) producer level, farmers/agri-cooperatives use a range of tools including good practices and private quality assurance or certification schemes, which are audited by independent and recognised third party certification bodies. Good hygiene and good agricultural and animal husbandry practices (GAPs) are applied by farmers[74]; these tend to be adapted to product characteristics and production processes, to ensure that they are practically implementable and tailor-made to their specific conditions on the farm, thus guaranteeing effectiveness and efficiency. This approach is implemented in different ways across the sectors, adapted to sector needs and characteristics (exposure to hazards and risks), within the general principle that "prevention is better than cure"[75]. Qualified professionals, such as veterinarians, agronomists and other farm technicians play an important role in providing up-to-date information to farmers relating to on-farm risk management, including disease and pest prevention, detection, control and eradication.
- The feed manufacturing industry (feed materials, compound feed and feed additives), in addition to HACCP systems[76], has implemented Feed Safety Assurance and third party certified systems, such as Fami-QS, which go beyond legal requirements to ensure compliance. The feed sector encompasses operators that are at the 'boundaries' of the feed/food supply chain in the sense that they produce/trade a diverse range of materials that are destined to multiple uses, not just feed, e.g. products sourced from the mining and chemicals industry. In this context, feed manufacturers have the role of 'gate keeper' for ensuring the safety of the entire supply chain, as feed materials sourced from operators outside the feed/food chain move into feed (e.g. limestone which is an important feed material: 10% of laying hen diet is composed of limestone)[77].

[72] Excluding retail sale to final consumer.

[73] For example: Good Trading Practice (GTP) codes and certification schemes developed by EU cereal/oilseeds traders (COCERAL) cover hygiene in trade, import, collection, storage and transport of food and feed materials. A guide of Good Hygiene Practices has been submitted to the COM together with Copa Cogeca and was accepted in 2008. The notion of guides has been introduced by the Hygiene package and has strengthened the Codes. The guide is regularly updated both to adapt to legislative evolutions and to evolving trading practices. Each company, depending on the specific operational conditions, origins of raw materials, etc. needs to undertake its own HACCP and risk analysis/management procedures and monitoring plans. Certified companies today represent more than 80% of traders. There is equivalence /mutual recognition of the Coceral Code with certain national schemes and some cooperation with other schemes of feed/food processors, such as with the EFISC code of FEDIOL, feed sector schemes, etc.

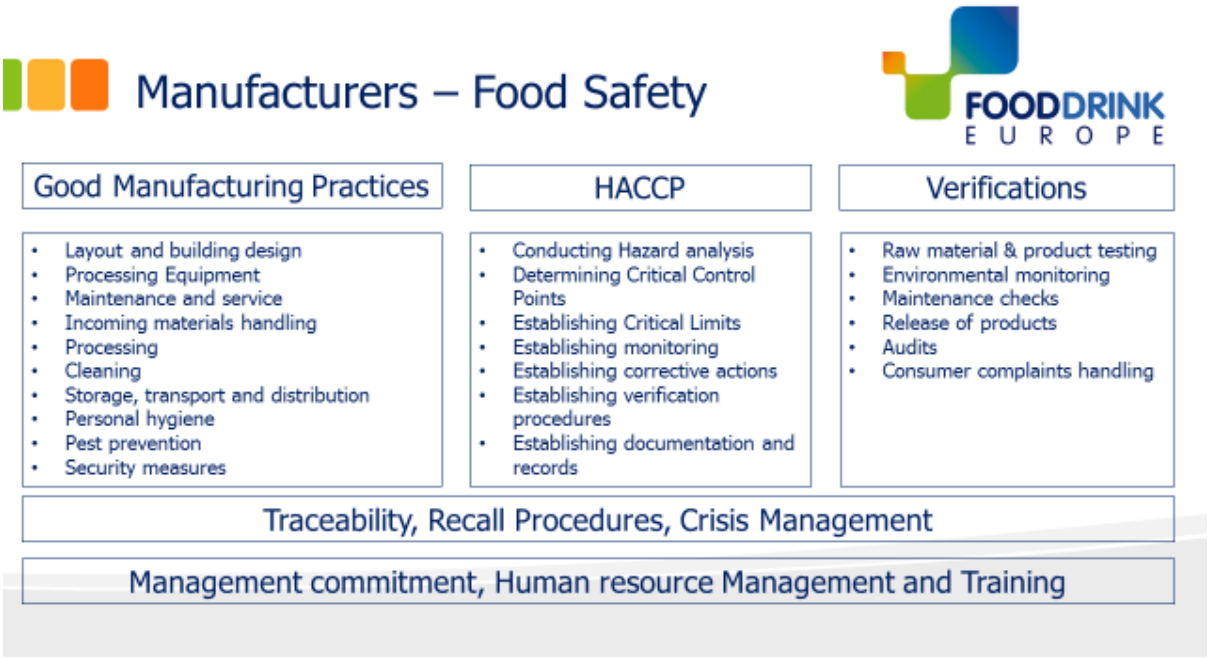
[74] As foreseen in Regulation 852/2004 on food hygiene, the application of hazard analysis and critical control point (HACCP) principles to primary production is not yet generally feasible. However, guides to good practice should encourage the use of appropriate hygiene practices at farm level.

[75] This more general principle can be found across EU policies, for example in the animal health sector, it is a fundamental principle of the EU Animal Health Strategy (2007-13).

[76] According to Regulation (EC) 183/2005 laying down requirements for feed hygiene, HACCP is required only for operations other than at the level of primary production (Articles 5, 6).

[77] In all these cases, any use of such materials in animal feed has to comply with the feed legislation concerned.

Box 1: Implementation of primary responsibility (Art.17.1) in the food sector



The findings of the consultation point to the **positive** and **effective** contribution of Article 17 towards meeting the GFL objectives and intended outcomes (*indicators 12.2a and b*). In particular, the allocation of responsibilities along the food chain as laid down in Article 17 has:

- For consumers: contributed to a **high level of protection of human health and consumers' interests** as regards feed/food products placed on the market (survey results, Q8)[78]. In particular, the obligation of Art. 17.1 for FBOs to perform their own verification (internal controls) and their responsibility to place safe food/feed on the market along with the other core requirements of the GFL (such as traceability and withdrawals/recalls) had a positive impact in terms of ensuring food/feed safety in the EU (survey results, Q51)[79].
- For business operators and authorities: facilitated the placing on the market of feed/food products, contributed to the effective functioning of the internal market, strengthened 'trust' along the 'farm to table' supply chain, and ensured a consistent implementation of the 'farm to table' policy (survey results, Q8)[80]. The share of responsibilities along the supply chain contributed to raise operator awareness of the responsibility to comply with the legal requirements at each level of the chain and across the EU. This allowed establishing a good baseline for **improved trust among supply chain partners, moreover in the single market context**. Several MS CAs noted that Article 17.1 established **'chain responsibility'** which is defined as the **collective responsibility of all operators at all stages of production, manufacturing and marketing**. This was a **major novelty of EU feed/food law, compared to the pre-GFL fragmented individual responsibility approach**. The

[78] According to both MS CAs and stakeholders, rating average above 4, on a scale from 1 to 5.
[79] According to both MS CAs and stakeholders, rating average above 4, on a scale from 1 to 5.
[80] According to both MS CAs and stakeholders, rating average above 4, on a scale from 1 to 5. Although MS CAs scored higher than stakeholders the contribution of Article 17 to the achievement of these outcomes, only few stakeholders (4-7, out of 67 responses) considered that the allocation of responsibilities along the food chain as laid down in Article 17 has not been positive or effective in terms of achieving the above outcomes.

extent to which chain responsibility is effectively and efficiently delivered depends on the allocation of responsibilities amongst operators, but also whether there remain any weak points in the system. In this respect, the feed/food chain can be seen as any other system approach, which can only be as strong as its weakest part/link.

Despite the overall positive feedback:

- Consumer organisations note that details of the outcome of the industry's own checks and controls are largely not communicated/unknown to the public. In DE, a review by the Federal Court of Auditors (Deutscher Bundesrechnungshofes, 2012) criticised the industry's self-controls; following a series of incidents, DE CAs have stressed the need for the industry to improve internal audits and checks. In general, transparency on both self-controls' and official controls' results is uneven amongst MS. Some countries, such as BE, DK, FI and the UK, have food hygiene rating schemes in place showing consumers how closely a business selling food (e.g. restaurant, cafes, takeaways, shops, etc.) is meeting the requirements of food hygiene law.
- Business operators note that, although the provisions of Article 17 have facilitated the placing of feed/food on the market and contributed to the effective functioning of the internal market, hurdles remain in that not all other secondary legislation is harmonised. Also, there are differences in the manner and extent to which controls are implemented by national CAs, with weaknesses often identified as highlighted in FVO reports and recommendations. Furthermore, the allocation of responsibility pertains ultimately to the attribution of liability, which is not regulated by GFL provisions as such, but by the national legal order (as foreseen in Article 21) and the specific infringed legislation.

Based on the findings of the consultation, **several issues were raised in terms of the extent to which, in practice, compliance with the primary responsibility obligations of Article 17.1 can be ensured along the full chain, also in a uniform manner across the EU**. As already discussed, this ultimately defines the limits of the system in terms of its ability to deliver full 'chain responsibility'. The issues identified below demonstrate the **complexity of the supply chain and are often caused by problems in the implementation of other secondary legislation and/or incomplete harmonisation**[81]:

- Importers/traders: several issues were raised:
  - Feed/food manufacturers have questioned the extent to which authorities perform verification of imports, while some MS CAs have indicated that further guidelines on import verification – in particular of non animal origin food - would be welcome in terms of the allocation of responsibilities between operators and control authorities for performing such verification.
  - As regards feed imports, the establishment of a list of approved third counties and third country operators, as foreseen in the Feed Hygiene Regulation, has not yet been completed.
  - Some operators who do not see and do not own the goods, such as those involved in trade and storage/distribution logistics, are not clearly/always identified as operators of the feed/food chain, in the implementation of other secondary legislation by authorities (e.g. hygiene requirements)[82].
  - International contracts tend not to include guarantees of compliance with all legal requirements of the importing countries but rather a presumption of compliance; this has a bearing on importer responsibilities.

[81] This includes in some cases difficulties in reconciling the provisions of the GFL and those of other secondary legislation, also in terms of definitions (see section III.2).

[82] It is noted that in Regulation (EC) 183/2005 on feed hygiene, Article 17 refers explicitly to feed business operators "which act solely as traders" as regards some exceptions, from which it derives that they are basically covered by the requirements of the Regulation, within the broader definition of the GFL for 'placing on the market' (Article 3.8).

  - On the other hand, traders note that some issues arise from the fact that it is not always clear whether the traded products are to be destined to food, feed or technical uses, although it is generally assumed in the legislation that the use of a product is always known[83]. This leads to a tendency by operators/control authorities to attribute responsibility to traders/importers, as the first link of imported material, for any non-compliance identified further down in the supply chain involving that material (e.g. when a contamination is detected further down the chain - this is complicated by the fact that contamination may occur at processing or any other step of the supply chain).
- E-commerce: it is not clear at present how internet selling platforms, including more general those run by businesses that are not strictly speaking classified as food/feed business operators, comply with the GFL responsibilities.
- Retailers: extent to which retailers are required to carry out sampling/testing on products they sell (whether own brand or not), in line with the provisions of other secondary legislation, and extent to which they are covered by liability provisions (see below).
- Farmers: buyers of raw materials complain of a certain lack of engagement of primary producers in the verification process. The development of harmonised assurance schemes for farmers across the EU and/or global assurance schemes is considered essential to ensure supplies comply with legal requirements.
- Feed sector/raw materials (feed): operators at the boundaries of the feed chain are not always registered as feed business operators, partly as the final destination of their products (raw materials/ingredients destined into feed, but also other uses) is not always predetermined, and leave it to their customers to ensure the safety of their products; furthermore, the exemption from HACCP requirements at the level of primary production of feed is often perceived as exemption from monitoring requirements[84]. In this sense, feed manufacturers assume the role of "gate keeper" for ensuring the safety of the entire supply chain, also from feed to food, and this can have a disproportionate burden on their part of the 'chain' responsibility[85]. In certain countries (DE, BE, FR etc.), collective monitoring systems have been established to allow better characterisation of generic risks for the various feed ingredients, while global assurance schemes have helped reduce the burden. Similar issues are identified in the case of such products destined to food (see next point).
- Raw materials (food): there is some reluctance amongst upstream operators in the food chain, in particular those supplying non agricultural raw materials/ingredients to the food industry, to accept full responsibility of compliance to food law as food business operators. For example, operators of the chemical industry (e.g., suppliers of processing aids) for whom the food sector is a small market, do not always provide users of their substances the necessary information so that they can themselves meet their obligations.

[83] This is not due to the definition of food and feed in the GFL, which is considered to be fine but other secondary legislation (e.g. Regulation 767/2009 on the placing on the market and use of feed) which takes the approach that it is always clear whether a product is to be destined to food, feed or for technical uses. Depending on the use, different legal requirements will apply. This is especially the case in the bulk trading sector where traders do not always know the destined uses of raw materials with multiple market destinations, e.g. grains/oilseeds can be re-destined to food or feed (or used for technical purposes) at many stages along the chain. Generally speaking, standards applicable to food are more stringent than feed, which means that downgrading a product from food to feed is, in most cases, possible whilst upgrading a product for food use is in principle not possible.

[84] The industry attributes the mixed picture of the actual implementation of the feed legislation, which is sometimes depicted in the FVO inspection reports, to these issues.

[85] Broadly speaking, up to 50 - 60 % of feed ingredients come from farming, while up to 40-50 % of feed material are imported including additives. This puts a heavy burden on small producers/importers. Global assurance schemes have helped to reduce this burden.

The above highlight certain areas where actions taken by national authorities in relation to the attribution of operator responsibilities along the chain (Article 17.2) have been implemented differently across MS. For instance, the extent to which the responsibility of retailers is fully covered by the interpretation of Article 17.1 has been a source of contention until now. This could improve with a recent (November 2014) judgement of the Court of Justice[86] which, in the absence of specific provisions on operator liability in the relevant secondary legislation, made specific reference to the general requirement of Article 17.1 that operators, at all stages of production, processing and distribution within the businesses under their control, must ensure that foods satisfy the requirements of food law relevant to their activities. In this particular case, based on the objectives and relevant provisions (Art. 17.1) of the GFL, the court said that the EU rules apply to "*products placed on the market during their shelf life*" and ruled that this definition includes retail sale. Thus, according to the Court's judgment, food retailers and other distributors could be prosecuted (pending on national provisions, see below) if they have sold meat that has been unfit for human consumption (in this case, meat containing salmonella at levels which breach EU rules)[87]. As such, the ruling has wider repercussions on attributing responsibility to retailers in all areas of food safety[88], and sets a precedent for more harmonisation across the EU on the application of the GFL provisions to all actors along the feed/food supply chain including retailers, given that considerable differences currently exist amongst MS.

The above ruling is also in line with more targeted provisions on the responsibilities of operators introduced subsequently to the GFL, in particular in the context of the Food Information to Consumers (FIC) Regulation (EU) 1169/2011. Article 8.3 of the FIC Regulation introduces (limited) liability for those selling to the final consumer as regards the provision of information on prepackaged foods: retailers must not sell food products if they know/presume that they do not comply with the FIC requirements[89]. There is already evidence of a certain transfer of responsibility along the supply chain following these provisions: during the consultation it was indicated that the stricter application of retailer responsibility for labelling provisions in the FIC Regulation has resulted in a situation where retailers request food manufacturers to put their name on retailer own-branded products.

Finally, a further issue that arises in terms of ensuring a harmonised approach across the EU is that, from a legal perspective, the **GFL provisions do not regulate the allocation of liability among the different links of the food chain**. As mentioned by the above Court decision, it is for the national court to examine the proportionality of the penalties to be applied. Thus, the liability proceedings are not based on Article 17 but on a legal basis to be found in the national legal order (as foreseen in Article 21) and in the specific infringed legislation. As outlined in section III.3.2.2, this is an area of considerable differences in approach between MS. For instance, while in some MS penalties often apply to retailers, in compliance with Article 17.2, in other MS existing legislation is less strict (while in some MS there are no specific provisions implementing Article 17.2: see EQ13).

Thus, although Article 17 is considered to have ensured an efficient allocation of responsibilities, the above differences in MS approaches - including of rules not laid down in Article 17 but in the national legal order (allocation of liability) - explain why according to

[86] European Court of Justice ruling: Judgment of the Court (Fourth Chamber), 13 November 2014, Case C-443/13 (Ute Reindl v Bezirkshauptmannschaft Innsbruck).
[87] Regulation No 2073/2005 sets the microbiological criteria with which foodstuffs must comply at all stages in the food chain. The regulation does not contain any provisions relating to the liability of FBOs.
[88] For example, if EU campylobacter limits were set for poultry, given that in some MS about two thirds of products on sale contain the pathogen.
[89] The approach of Article 8.3 of the FIC Regulation is in line with the outcome of a case decided by the ECJ in 2005: European Court of Justice, Case C-315/05, Lidl Italia Srl v. Comune di Arcole (VR). With reference to food labelling, Article 8.3 introduced the principle of liability for fault instead of objective liability.

some of the consulted parties, in particular supply chain stakeholders, the allocation of responsibilities along the food chain as laid down in Article 17 has not been efficient. These issues are discussed further below.

Overall, the findings indicate that the **rules laid down in Article 17 have ensured an efficient allocation of responsibilities** (*indicator 12.3a*). In particular it has: ensured a fair and clear distribution of responsibilities amongst feed/food business operators along the 'farm to table' supply chain, as well as between feed/food business operators and MS CAs; created a level playing field for all feed/food business operators in the EU; reduced administrative burden (e.g. by avoiding unnecessary repetition of operators' self controls along the 'farm to table' supply chain); and, freed up resources at MS CA level to focus on the enforcement of feed/food law (survey results, Q8)[90]. However, stakeholders scored lower than MS CAs the contribution of Article 17 to the achievement of these outcomes, while a relatively important number of supply chain stakeholders (8-18, out of 67 responses) indicated that the allocation of responsibilities along the food chain as laid down in Article 17 has not been efficient in terms of achieving the above outcomes.

As already discussed, **the GFL does not prescribe how controls should be carried out along the supply chain, whether at operator (Article 17.1) or at MS level (Article 17.2)**. It only provides the end objective - to ensure compliance - with legal responsibility given to every part of the chain as a means to that end. In this context, it should be noted that the Official Controls Regulation (EC) No 882/2004, by establishing a set of general rules for the organisation of such controls, provides for some degree of harmonisation in terms of enforcement of (amongst others) food law. Regulation (EC) 882/2004 and its current revision is the most harmonised area as far as market surveillance is concerned. This sets out the requirements for the national enforcement authorities[91], who are responsible for checking businesses operators' compliance with food and feed legislation (as well as animal health and welfare). This set up aims to allow MS CAs to take into account operators' own checks in their risk profiling in order to better (i.e. more effectively and efficiently) target their control plans. The benefits of this approach (i.e. Article 17 prescribing the end objective – food safety – rather than the tools/means) for all involved are also highlighted in literature e.g. Leon-Guzman, M. (2011).

This set up is generally appreciated by operators in that it provides the basis for an efficient allocation of resources: it allows the flexibility, while making it a legal responsibility, for operators to design optimal, fit for purpose own check systems. In this sense, Art. 17.1 can provide the most cost-effective solution for operators to ensure the intended outcome of feed/food safety (*indicator 12.3b*). Similarly, some (but not all) MS CAs noted that assigning the primary responsibility to operators to ensure compliance with feed/food law has to some extent freed up resources at the level of authorities to focus on enforcement, as prescribed by the regulatory framework on official controls outlined in Regulation (EC) 882/2004.

[90] According to both MS CAs and stakeholders, rating average above midpoint (3), and in some cases above 4, on a scale from 1 to 5. On average, MS CAs scored higher than stakeholders, for all outcomes.

[91] Key elements of the Regulation on official controls are as follows:

- official controls should be carried out regularly, on a risk basis and with appropriate frequency;
- official controls should be carried out at all stages of the food chain on domestic produce, as well as on imports and exports;
- CAs may delegate specific tasks to official control bodies, under certain conditions;
- specific rules are laid down for official controls carried out on imported products;
- regular training for competent authority staff is an obligation for the Member States;
- training programme for CAs' staff is funded by the European Union (Better Training for Safer Food);
- framework for the designation of EU Reference Laboratories;
- rules on the design and implementation of multi-annual national control plans prepared by Member States to ensure the effective implementation of the Regulation; and,
- possibility of coordinated control plans on an ad-hoc basis.

Operators highlighted that **integrating legal requirements within existing** (albeit, adapted/evolved) **quality management and certification schemes/standards has been an important cost-mitigating factor** that has helped to accommodate the costs associated both with the traceability and the primary responsibility obligations of the GFL. As already outlined, **adherence to private schemes/standards**, including notably those developed by retailer organisations, **has over the last decade** been reinforced and has now **become the common/standard business practice** (*indicators 12.1f and 12.3c*). Private schemes/standards tend to require strict verification procedures for food processors. Such private schemes/standards used to be very different between MS but have considerably harmonised including through global benchmarks (e.g., the GFSI) and mutual recognition. Retailers tend to be a key driver in promoting their private schemes/standards to the rest of the food chain, motivated by the need to: avoid costs associated with cases where products are found to be non compliant; ensure that controls by authorities do not lead to any problems; and, maintain the integrity of their reputation. In most sectors, certified operators today represent an important share of the market: for example in the cereals/oilseeds trade sector, more than 80% of traders are certified with the industry standard; in some MS, food processors are virtually excluded from selling to large retailers unless they are certified according to recognised standards. In the feed sector, Feed Safety Assurance schemes have been implemented on request of downstream operators in the supply chain; although they resulted in additional costs, these could be compensated to a certain extent by a reduction of supplier audits/ controls on purchased feed ingredients from certified suppliers.

According to operators, a **key obstacle to delivering a fully efficient system is that the own check and verification systems that have been put in place by operators are not recognised by authorities in most MS**, even when independent third party auditing/certification is performed. For example, the fact that suppliers are certified by a third party is not considered by most control authorities as a relevant parameter for the design of the risk management system at the customer level. As it currently stands, MS CAs do not consistently take into account operators' own checks in their risk profiling and control plans; only in a minority of MS, control authorities adopt such an approach. This is seen by the industry as a major limitation to the optimisation of the costs related to own checks along the chain, and is the reason why Article 17 has had a neutral impact in terms of administrative burden reduction, according to supply chain stakeholders; it is also a hindrance to achieving a level playing field for operators across the EU, as operators face different costs depending on the approach followed by national authorities.

However, it is noted that the variable approach taken by MS CAs in risk profiling their official controls system also reflects differences in the reliability of own checks (even when these are certified). The official controls system should take into account the reliability of operators' own checks to base the frequency of the official controls as provided for by the Regulation (EC) 882/2004 (Article 3.1(c)).

Furthermore, Article 17.1 should be put in the wider context of Article 17. First, the rationale of requiring operators to perform own verification checks is to reinforce the primary responsibility of operators. Every single operator in the feed/food chain must ensure that requirements are met (rather than pass on responsibility to other elements in the chain). Second, the liability factor needs to be taken into account with regard to drawing conclusions on the application of Article 17. As noted in section III.3.2.2 liability/sanctions remain national law/jurisdiction: variable national approaches to sanctions and liability interfere with the ability of the current set up to ensure a uniform approach, thus not allowing the full benefits of the allocation of responsibilities as foreseen in Article 17. Article 17 is only one constituent of the current system which allocates responsibilities to operators and foresees that MS have in place measures and penalties applicable to infringements.

Some national systems also take into account the fact that appropriate checks have been performed by the operator to assess liability issues (due diligence).

More generally, the approach to controls carried out by national authorities can be different between MS or even within MS (at regional/local level) (*indicator 12.1h*). As with most other GFL provisions, survey results indicate that there have been differences in the implementation of Article 17 by MS, in particular the allocation of responsibilities between FBOs and control authorities, although for the most part these have not been systematic (survey results, Q53)[92]. Supply chain stakeholders indicate that the approach taken by some MS regarding official controls is stricter than in other MS: the frequency and depth of controls varies between MS; some methods of detection used in some MS are more sensitive than those used in others; other areas of discrepancy concern the actual hygiene and food safety requirements inspected within food/feed premises; there can also be different interpretations on what is a "safe" level (e.g. for presence of contaminants/ undesirable substances in feed/food), and even zero tolerance in some MS as a standard approach. Several operators have indicated that they have been forced to use private tools/self-regulation to reduce legal uncertainty and unnecessary burdens resulting from diverging implementation at national level; thus, certification systems going beyond GFL principles have been implemented to alleviate those issues and ensure further harmonisation across MS.

It is noted that the harmonisation and consistency in the design of the official control plans by the authorities benefits from the harmonised requirements set out in Regulation (EC) 882/2004 which *inter alia* foresee detailed rules on the drawing and implementation of multi-annual control plans by national authorities. **During the consultation, differences were often attributed to interpretation of the rules and implementation of the control procedures by inspectors rather than design of the official control plans by the authorities as such**. For example, SME representatives in one MS indicated that *"there are around 460 CAs employed by local councils; these do not always have the same interpretations of the food hygiene legislation"*. Similarly, farmers' organisations commented that national CAs do not promote or stimulate the establishment and use of flexible, fit-for purpose solutions, such as e.g. the possibility to adapt hygiene requirements on the construction, layout and equipment of establishments, which is due to *"lack of understanding by local authorities … often, problems arise due to the fact that legal requirements are interpreted differently by individual inspectors or veterinarians"*.

The differences in the implementation of controls between MS were also acknowledged by several of the consulted MS CAs. These differences are due to different approaches followed by national authorities rather than the legal provisions of the GFL as such. Article 17.2, with its general requirements, and Regulation (EC) 882/2004 (including its current revision: COM(2013) 265 final) are considered to have the potential to allow authorities to develop a more harmonised[93] and a better targeted, risk oriented approach to official controls. It is considered particularly relevant, in the current context of financial resource constraints, to ensure that the allocation of responsibilities between businesses and MS CAs is both

[92] While there are a large number of 'don't know' responses (58% of stakeholders and 13 of the 26 responding MS CAs), overall the differences identified are for the most part not systematic ('yes systematically' responses were provided only by 3% of stakeholders, while 36% of stakeholders and 9 MS CAs replied that differences existed to some extent/in some cases or only to a limited extent).

[93] Harmonisation in this context refers to the harmonised application of a risk-based approach to controls across the EU, rather than uniform controls across all types of business. It is important to note that Regulation 882/2004 specifically requires that MS CAs carry out controls on a risk basis; all MS are therefore required to implement the risk based approach to controls. However, in the context of official controls the definition of risk is wider than that of the GFL as it does not only include health risks but it also takes into account the actual characteristics of each business, including compliance records, having in place reliable systems of self-controls etc. The intention therefore is for controls to be tailored to the specific risk profile of each type of business/business sector.

effective and efficient. More generally, however, MS CAs point out that Article 17 is only one constituent of the whole system; as long as there are 28 different national sanction systems within the EU and there is no functional administrative assistance and cooperation among the MS, Article 17 is unable on its own to ensure the intended outcomes.

The **differences in MS CA approaches were also noted by the recent report of the FVO on the state of implementation of HACCP in the EU**, which also reviews the implementation of official controls carried out by MS CAs to verify that operators have put in place HACCP systems and principles (European Commission, 2015). The review concludes that, although generally MS CAs have in place risk-based audit systems to verify the implementation of HACCP based procedures followed by operators, there is wide variation in the approach to controls in terms of frequency and content, lack of clear understanding and national policies for flexible implementation (e.g. with regards to: consideration of third party Food Safety certification schemes such as ISO 22000; application of flexibility for SMEs), as well as different approaches and interpretations by individual control staff. The implication of these differences is that controls are not efficiently/consistently applied. The report notes that *"improved training for official control staff would improve the consistency of the approach to controls, ensure a more consistent interpretation of national requirements and improve the overall efficiency of HACCP systems."*

It should be noted that a better harmonisation of the MS approach to official controls is one of the objectives of the Commission's proposal to revise the existing rules of Regulation (EC) No 882/2004 on official controls (COM(2013)265 final), by modernising and simplifying the current system of controls and by extending its rules to sectors and activities of the agri-food chain that are not currently covered (e.g. official controls on the implementation of legislation on plant health, plant reproductive material and animal by-products).

Consumer organisations and NGOs recognise the need for an efficient allocation of responsibilities between businesses and national CAs, but stress also the need for public authorities to maintain oversight and control – especially in the context of supply chains becoming ever more globalised – for which governments must allocate sufficient resources.

Several MS CAs noted that authorities have a difficult balancing act in that, on the one hand, there is pressure of budgetary cuts and savings in the use of their resources, while on the other, the supply chain has become increasingly complex and globalised and the general public as well as many operators still think that, ultimately, MS CAs are responsible for food/feed safety.

As already discussed, in a context of globalised, complex supply chains and highly technical issues, it has become fairly standard business practice that the various verification and control systems put in place by business operators in line with the primary responsibility obligation of Article 17.1 extend beyond compliance with the basic legal requirements (stipulated in other secondary legislation) to encompass rules and standards laid down in third party certified schemes/standards and/or contractual obligations (*indicators 12.1f and 12.3c*). These play an important role in ensuring a fairer allocation of responsibilities vis-a-vis suppliers and customers and managing/reducing the impact of potential liability issues. For example, in the case of bulk commodity traders, in addition to official controls traders have monitoring/verifying systems to control the safety of their products based on best practices of sampling and testing for contaminants at levels which are predetermined in their contracts with buyers (customers); the standard contracts provide for arbitrage systems which include provisions on legal/penal responsibilities in case of non-compliance[94].

[94] Sampling of large bulk consignments can lead to false positive results leading to a wrong rejection of a safe lot/cargo and huge financial losses. This is exacerbated by generally very low levels of tolerance against very high

The costs for business operators emanating from the requirements of Article 17.1 (*indicator 12.3e*), as also implemented through other secondary legislation, include the costs of own verification controls, verification controls of suppliers, costs associated with the official controls carried out by national authorities (own business costs, excluding fees paid to MS CAs, if any) and providing evidence to national authorities and customers. Business operators were not in a position to quantify these costs (e.g. as % of total production costs), largely for the same reasons as in the case of traceability costs. Notably: these costs were incurred over a decade ago; compliance with Article 17.1 formed part of a more comprehensive approach to quality management including traceability and other regulatory requirements and, in some cases, certification systems and contractual obligations.

As the approach taken to comply with regulatory requirements was designed to fit each operator's specific profile and needs, these **costs are specific to each operator**. Findings also confirm that **costs are not influenced by individual factors** - such as business type or size or extent of cross-border trading or sector or product/supplier/customer range - **but rather by a combination of these factors as it applies to each business operator**. Nonetheless, size is an important determinant of costs when all other factors are equal: in relative terms, smaller operators typically face higher costs in relation to their turnover when compared to larger companies producing a similar range/type of products and with a similar range of suppliers/customers.

Results of the SME panel (**Annex 4**) indicate that the GFL requirement that most (nearly half) of SME respondents often/sometimes find the hardest to meet is carrying out own checks to ensure compliance with food/feed law requirements (e.g. labelling, safety, product specifications) (Q2); one third of SME respondents have (at some point) hired an external consultant to help them comply with EU food/feed law (Q3), as also confirmed during interviews with the SME sector. Smaller operators often commented that they have difficulties to comply with all EU regulations, while they also tend to be mostly in direct and long-standing contact with their customers and, to ensure customer loyalty within what is typically a competitive environment, it is important to offer products of consistently high safety/quality. The administrative burden for such companies is that many regulatory obligations which would have been observed in any case (e.g. frequency of checking refrigerator temperatures for hygiene purposes), with regulation have to be recorded formally. In other words, prior to the application of responsibilities foreseen in Article 17.1, smaller business operators tended to have in place (lower cost) measures rather than (higher cost) "procedures". Hygiene and food safety topics were integrated as a matter of course in the daily work, while now smaller operators complain that they have to write down every "detail". So, the administrative burden on smaller operators after the GFL has not been reduced and is expected in fact to have increased in many cases. However, more general feedback from respondents suggests that this emanates from the combination of specific requirements laid down in other secondary legislation and/or implementation in the MS, rather than the GFL as such.

Private standards are adding to the sector's burden. Retailers overcautious to avoid any potential scandals, but also driven by effort to market what consumers are interested in, lead to a competitive environment where voluntary 'nice to have' requirements are mixed with and become mandatory 'must have' requirements (e.g. where the product comes from).

level of uncertainty with sampling (this issue is not due to the GFL). Therefore it is vital that monitoring/verifying systems accompany testing and sampling with appropriate risk management strategies. The sample and sampling technique is defined and agreed in the contract between traders and their buyers. Every part of the chain should perform controls. Sampling ideally is defined in the contract so that it is accepted by both parties. But there can be an issue when splitting a big consignment into smaller batches e.g. from vessel to barges/containers/trucks.

The findings confirm that the intended benefits of having the primary responsibility obligations laid down in Article 17.1 for all business operators along the full supply chain – in combination also with the traceability provisions of Article 18 - are largely achieved, i.e. better targeted identification/prevention of potential risks/early response, withdrawals and controls (*indicator 12.3f; see also indicator 15.1a*[95]). Although it has not been possible for operators to quantify/estimate the benefits, they are in principle considered to be very important, hence the extensive uptake of own verification and control systems on a voluntary basis already prior to the GFL.

For the same reasons as in the case of the traceability provisions, stakeholders were not able to provide any evidence on the costs and benefits of the primary responsibility provisions (Art. 17) or to estimate the cost-benefit ratio in broad quantitative terms. Despite the caveats in quantifying those, the benefits resulting from the primary responsibility provisions (Art. 17) of the GFL have more or less outweighed the costs of setting up and operating systems and procedures to meet this requirement (e.g. via own internal controls) for nearly a third (33%) of stakeholders and have considerably outweighed costs for an additional 19% (survey results, Q10[96]). Nonetheless a quarter of stakeholders indicated that benefits have not for the most part outweighed costs while it is noted that a quarter of stakeholders were not able to respond (*indicators 12.3g and 3h*). Similarly, according to SME panel results (Q14, **Annex 4**), when comparing the benefits and costs of EU food/feed law more generally, 18% of SME respondents indicated that benefits outweigh costs, 24% that benefits break even with costs, while for 32% of respondents benefits do not outweigh costs; nonetheless, nearly a quarter of respondents indicated that they do not to know.

Amongst those FBOs that found benefits had outweighed costs, the main comments were that the primary responsibility provisions have been essential for feed and food businesses, although benefits are mostly felt by those trading within the internal market as they can benefit from the harmonisation of provisions. As such, those that found benefits had not outweighed costs tended to be smaller and craft enterprises that do not export their products and do not rely on imports for their raw materials, and therefore do not benefit from the harmonised requirements of the internal market, but have to cope with the additional administrative burden, particularly that stemming from other secondary legislation. Those SMEs dealing with a large number of non-standardized products and mostly trading within national/regional/local markets are particularly at a disadvantage in this respect. At the other end of the spectrum, large scale operators dealing with a limited number of standardized products/ingredients but selling throughout the EU market thus achieving a high turnover and economies of scale stand more to benefit from harmonisation. However, given the diversity of the sector, it cannot be concluded that harmonisation benefits larger companies more than smaller companies, as in practice a large range of operational contexts can prevail.

III.3.2.2 Public authorities: penalties and measures applied to infringements (EQ13)

EQ13: To what extent have the public authorities applied penalties or other measures for infringements of EU food law (Article 17.2)? What impact did those have on effectiveness of the implementation of the Regulation?

[95] Overall, the general traceability requirement of Article 18 ("one step back – one step forward" approach) in combination with own systems/procedures in place to provide relevant information to the CAs has provided benefits in terms of achieving these outcomes (survey results, Q13) (*indicator 15.1a*).
[96] FBO responses only.

Key findings (EQ13):

According to the consultation with MS CAs, most MS have in place in their national legal systems some form of measures and penalties against infringements in food and feed law. For the most part rules existed prior to the GFL and changes only partly occurred with the adoption of the GFL (i.e. on the basis of Article 17.2). In certain MS Article 54 of Regulation (EC) 882/2004 is applied directly as the legal base for such measures. Where MS CAs indicated that new rules/provisions have been introduced/changed following the GFL, both penalties and measures are considered by MS CAs to have been an effective tool to deter feed/food business operators from committing further infringements. Where these have not been effective, this is attributed to several reasons, including lack of resources to pursue the infringing parties, insufficient training for CA staff, and/or because national legislation needs updating/improving. Furthermore, several MS indicated that the current levels of fines are in some cases considered not sufficiently high, and one of these MS is currently working on the adjustment of national legislation to review penalty levels. Therefore, as the current legal systems stand, the form, specificity and severity of the measures/penalties, hence their effectiveness to act as a deterrent, continue to vary considerably between MS. The effectiveness of the national judicial system in terms of the time required for a final judgment also affects the dissuasive effect of the penalties.

Most MS have in place in their national legal systems some form of measures and penalties against infringements in food and feed law (survey results, Q20) (*indicator 13.1a*). For each of the identified core obligations[97], between 20 and 24 of the 25 responding MS CAs (depending on the obligation) indicated to have measures and penalties in place to address infringements.

The **form, specificity and severity of the measures/penalties currently in place tend to vary considerably between MS** both in terms of the provisions of the GFL to which they apply, and whether they involve administrative measures and/or penalties and/or criminal prosecution/imprisonment (details provided by MS CAs, survey results, Q20)[98]. **It is noted that criminal penalties are only foreseen in some MS (see also section III.8.1.2**). The range/severity of criminal sanctions actually applied varies, and imprisonment is exceptionally applied in cases linked to food law. This depends on the severity of cases (e.g. extent of public health implications), but also to some extent on legal/constitutional reasons. For example, the SE CA indicated that, as regards criminal penalties, imprisonment was removed from national food law for legal, technical and constitutional reasons; it is still possible that non-compliance can be considered a crime against general criminal law (e.g. fraud or causing injury etc.) and lead to a prison sentence but this is only likely to be applied in very serious cases.

In terms on the extent to which new rules have been introduced in MS on the basis of Article 17.2 as such, survey results indicate that **for the most part rules existed prior to the GFL and changes only partly occurred with the adoption of the GFL** (Q21a). In

[97] The identified core obligations are: placing only safe food/feed on the market (compliant with food/feed safety legislation); establishing one step back – one step forward traceability at all stages of production, processing and distribution; notifying public authorities in case of food/feed at risk; collaborating with public authorities on actions taken to avoid or reduce risk in food/feed; and, verifying that the relevant requirements of food/feed law are met (Article 17(1) of GFL).

[98] It is noted that in some cases the national measures indicated by MS CAs are taken on the basis of Article 54 of Regulation (EC) 882/2004 ('remedial measures').

particular no change occurred in 12 of the 25 responding MS with regards to criminal penalties, in 9 MS on administrative penalties, and in 6 MS on measures other than remedial measures (i.e. other than measures taken on the basis of Article 54 of Regulation (EC) 882/2004). For a second group of MS, rules existed prior to the GFL but new provisions have nonetheless been introduced at the time of the adoption of the GFL on the basis of Article 17.2. This has been the case for administrative penalties in 9 MS, for measures other than remedial measures in 6 MS and for criminal penalties in 5 MS. **In MS where rules did not exist prior to the GFL, some have adopted new rules on the basis of Article 17.2 while others (2 of the 25 MS) have not and therefore have no measures in place to date**.

It is noted that:

- Between 4 and 8 MS CAs did not answer this question; it was established during interviews that the lack of a response in some of these cases was because MS had not introduced any new rules on the basis of Art. 17.2. For example, the UK CA indicated that the UK Food Safety Act (1990) already had a well-defined set of rules and sanctions in place.
- Several MS CAs indicated that they apply Article 54 of Regulation (EC) 882/2004 directly as the legal base for such measures, hence it has not been not possible to make a distinction from the remedial measures foreseen in that Regulation.

No data/information was made available in the course of the consultation on the trend of penalties/other measures applied, during 2003-13, or an explanation of any observed trends; other existing literature (e.g., FVO reports) provide some data in some cases, but not on a systematic basis (*indicator 13.1b*).

Nonetheless, where new rules/provisions have been introduced/changed in MS' national legislation as a result of the GFL, both penalties and measures (other than remedial measures) are largely considered by MS CAs to have been an effective tool to deter feed/food business operators from committing further infringements (survey results, Q21b) (*indicator 13.2a*).

Where penalties and measures (other than remedial measures) are not considered to have been an effective method to deter feed/food business operators from committing further infringements, MS CAs indicated that this was due to the following reasons (*indicator 13.3a*): CA does not have sufficient resources to pursue penalties or other measures on infringements; more training for CA staff is necessary e.g. on legal requirements, judicial processes etc.; and because national legislation needs updating/improving (each of the above reasons was provided by 3 of the 20 responding MS CAs) (survey results Q21c). Furthermore several MS indicated that the current maximum fine is in some cases considered not to be sufficiently high, and one of these MS is currently working on the adjustment of national legislation to review penalty levels. Finally, the effectiveness of the national judicial system in terms of the length of time required for a final judgment also affects the dissuasive effect of the penalties.

III.3.3 Determining food safety, withdrawals and recalls of unsafe food *(EQ8/EQ9/EQ10/EQ11)*[99]

Article 14 of the GFL prohibits food being placed on the EU market if it is unsafe. Food is 'unsafe' if it is: injurious to health; or, unfit for human consumption. In general, to

[99] These EQs have been analysed together as they address interrelated aspects of the performance of the same provisions of the GFL, in particular Articles 14 (determining food safety), 15 (determining feed safety), Article 19 (operator responsibilities for food) and Article 20 (operator responsibilities for feed).

determine if a food is unsafe, one should take into account its intended use, the normal conditions of use of the food and the information provided to the consumer. To determine whether a food is 'injurious to health', one should take into account: (a) the short- and long-term effects of consuming such food; (b) the probable cumulative toxic effects; and, (c) the particular health sensitivities of a specific category of consumers when the food is intended for that category of consumers. To determine whether a food is *'unfit for human consumption'*, one should consider whether it is unacceptable for human consumption according to its intended use[100].

Article 15 prohibits feed being placed on the EU market or fed to any food-producing animal if it is unsafe. Feed is unsafe if it has an adverse effect on human or animal health or makes the food derived from food-producing animals unsafe for human consumption.

Articles 19 and 20 oblige food/feed business operators to withdraw or recall unsafe food/feed, notify accordingly national CAs and collaborate fully on any further action taken to avoid or reduced risks posed by a food/feed supplied:

- Withdrawal is the process by which a product is removed from the supply chain, with the exception of a production that is in the possession of consumers.
- Recall is the process by which consumers (food) or users (feed) are asked to take the product back to the place of purchase or destroy it.

EQ8: To what extent have the obligations on food/feed business operators and public authorities [to: place only safe food/feed on the market (compliant with food/feed safety legislation) (Articles 14, 15); verify that food/feed is compliant with relevant legislation (Article 17.1); withdraw/recall food/feed at risk (Article 19.1, 19.2, 20.1 and 20.2); and, notify public authorities in case food/feed considered at risk (Articles 19.3 and 20.3)]: a) ensured a high level of protection of consumer's health; and, b) gradually contributed to the performance of fit for purpose withdrawals and recalls by food/feed business operators?

EQ9: To what extent have the provisions of the GFL and their implementation contributed to improving cooperation between authorities and operators and thereby made actions taken to avoid or reduce risks posed by food/feed placed on the market more efficient and effective? (Articles 19.2, 19.3, 19.4 and 20.2, 20.3 and 20.4) How has this contributed to achieving the objectives?

EQ10: To what extent has the provision that food/feed is deemed safe when it complies with specific EU provisions, or in their absence to specific national provisions, governing food/feed safety proved sufficient in order to achieve the objective of protection of health of consumers (Article 14.7 and 9 and 15.4 and 6)?

[100] The Commission's guidelines on the GFL (January 2010) clarify: *"The central concept of unfitness is unacceptability. Food can be rendered unfit by reason of contamination, such as that caused by a high level of non-pathogenic microbiological contamination (see Article 14(3) and (5) of the Regulation), by the presence of foreign objects, by unacceptable taste or odour as well as by more obvious detrimental deterioration such as putrefaction or decomposition."*

EQ11: To what extent and how efficiently and effectively have the public authorities taken further actions when food/feed was discovered unsafe despite its conformity with the legislation? (Articles 14.8 and 15.5) How significant has this been in terms of achieving the objectives?

Key findings (EQ8/EQ9/EQ10/EQ11):

All of the indicators used to assess the performance of withdrawals and recalls, as implemented by business operators and MS CAs, and to determine the contribution of the relevant GFL requirements to achieving the objectives (ensuring a high level of protection of consumer's health), have demonstrated positive results. Overall, operators have for the most part complied with the actions foreseen in the context of withdrawals and recalls when such actions were necessary, while the cooperation between operators and authorities is generally functioning well (as envisaged by Article 19: food; Article 20: feed). This has largely led to fit for purpose withdrawals/recalls and ensured a high level of protection of consumer's health. Compared to the situation prior to the GFL, the implementation of harmonised provisions has led to more effective and efficient withdrawals and recalls, according to all consulted parties, as also evidenced by the improvement both in the speed and costs of actions taken.

Despite an overall positive feedback, several shortcomings have been identified. An important issue of concern remains the variable level of implementation of withdrawals/recalls between MS, including in terms of determining the course of action to be taken in similar cases, cooperation between authorities and operators, and informing consumers/transparency (further discussed under EQ23). An underlying factor accounting for such differences relates to some inherent difficulties in interpreting the legal provisions to determine the safety of feed/food, with regards both to Articles 14 and 15 and to secondary legislation. Particular problems have been encountered in areas of secondary legislation where the harmonisation of legislation is incomplete and in areas where there is no scientific basis for assessing safety risks or the balance between scientific assessments and other legitimate factors is not clear. These difficulties come into play particularly when interpreting Articles 14.7/9 and 15.4/6 (food/feed compliant with EU/MS legal provisions is deemed to be safe), and Articles 14.8 and 15.5 (food/feed suspected to be 'unsafe' despite legal compliance). More generally, in interpreting the concept of non-compliance to legislation versus assessing safety for human health, it is difficult for authorities to establish a clear balance when no objective/science-based criteria exist, e.g. when 'unsafe' is established on the basis of Article 14.2(b) i.e. 'unfit for human consumption' or current legislation is not harmonised (e.g. contaminants), thus often leading to differences/non-uniformity in implementation. Such differences in interpretation/implementation can have considerable cost implications for operators, while they undermine the consistency in ensuring fit for purpose withdrawals/recalls and the effective protection of consumer health. In this context, the application of objective and transparent criteria to establish safety, such as in the approach currently applied to determine the safety of food products exceeding MRLs for pesticides residues, is an important factor determining the effectiveness of the legal provisions (GFL and secondary legislation) in protecting consumer health.

III.3.3.1 Overall assessment of food safety and withdrawals/recalls (EQ8/EQ9)

EQ8: To what extent have the obligations on food/feed business operators and public authorities [to: place only safe food/feed on the market (compliant with food/feed safety legislation) (Articles 14, 15); verify that food/feed is compliant with relevant legislation (Article 17.1); withdraw/recall food/feed at risk (Article 19.1, 19.2, 20.1 and 20.2); and, notify public authorities in case food/feed

considered at risk (Articles 19.3 and 20.3)]: a) ensured a high level of protection of consumer's health; and, b) gradually contributed to the performance of fit for purpose withdrawals and recalls by food/feed business operators?

EQ9: To what extent have the provisions of the GFL and their implementation contributed to improving cooperation between authorities and operators and thereby made actions taken to avoid or reduce risks posed by food/feed placed on the market more efficient and effective? (Articles 19.2, 19.3, 19.4 and 20.2, 20.3 and 20.4) How has this contributed to achieving the objectives?

All of the indicators that were used to assess the performance of withdrawals and recalls, as implemented by food/feed business operators and MS CAs, and to determine the contribution of the relevant GFL requirements to achieving the objectives (ensuring a high level of protection of consumer's health), have demonstrated positive results.

According to MS CAs, overall, **operators have complied with all the actions foreseen in the context of withdrawals and recalls** when such actions were necessary (as envisaged by Article 19: food; Article 20: feed) (survey results, Q16) [101] (*indicators 8.2f and 9.1a*). In particular, for the most part, operators comply with the following key requirements (listed in order of average ranking): they destroy unsafe feed, unless the competent authority is satisfied otherwise (this appears to be the most observed obligation); they (retailers or distributors) withdraw unsafe food/feed from the market, pass on relevant information necessary to trace unsafe food/feed and cooperate with other relevant operators along the food chain; they recall unsafe food from consumers when other measures are not sufficient to achieve a high level of health protection; they immediately withdraw a food/feed from the market when they consider or suspect that it is unsafe (i.e. injurious to health or unfit for human/animal consumption) and has left their immediate control. Also, for the most part, operators fulfil their obligation to **immediately inform the authorities** when: they take action to address the potential risk arising from a food/feed, according to Articles 19.3 and 20.3; they consider or suspect that a food/feed placed on the market is "injurious to health", and/or take action to prevent risks to the final consumer in such cases, regardless if the food/feed is under their immediate control; and, they withdraw a food/feed from the market. Furthermore, for the most part, operators **have not prevented or discouraged any person from cooperating with the authorities** in the actions taken.

With regards to the information/notification obligations, only in a few cases, some MS CAs indicated there were incidents that were identified by authorities *a posteriori*, e.g. authorities were informed by RASFF rather than directly by operators. There has been some debate between operators and authorities, on authorities having more information to enquire on products upstream in the supply chain, for products where there is no obligation as such to notify e.g. products that were never put on the market. Also, the question can be raised on who has to notify: e.g. if the retailer does the withdrawal on their own initiative and/or has organised this with their supplier, is the retailer still obliged to do the notification? Authorities indicated there are many examples of operators informed by their suppliers about withdrawals of products supplied to them; in such cases, as operators put in place actions that have been decided by their suppliers, they generally do not proceed to a notification. These issues also relate to the attribution of liability between operators along the chain: while the implementation of the provisions of Articles 19 and 20 raise cost

[101] Average ratings higher than midpoint (3), on a scale from 1 to 5 (MS CAs). Only 1-2 MS CA have indicated that some of these provisions are not always fulfilled by FBOs. It is noted, however, that 1-3 MS CAs did not provide an answer, and for the last point (whether FBOs have prevented or discouraged any person from cooperating with the authorities) 13 MS CAs indicated 'don't know', but no further explanation/comment was provided.

implications for operators, liability issues are not addressed by the GFL as such (as also discussed under the allocation of responsibilities: EQ12/13).

The **action posing more problems**, although compliance is still achieved according to a majority of MS CAs, is the requirement for operators to effectively and accurately **inform consumers** of the withdrawal of unsafe food, when such products might have reached them: 6 of the 25 responding MS CAs indicated that operators do not comply with this requirement (while 2 MS CAs did not provide an answer) (survey results, Q16) [102] (*indicator 8.2f*). This is largely because informing consumers in the case of withdrawals is not seen as relevant as in the case of recalls, but also due to different levels of awareness amongst operators of their obligations under Articles 19 and 20. Several MS CAs noted that there are difficulties at times in reconciling the definition of 'placing on the market' and the obligations of operators under Article 19 and 20 (for goods under their 'immediate' control). This is, for example, where the product in question is still under the control of the operator who produced it but has been transported to another establishment which may or may not be owned by that operator e.g. central distribution/warehouse. Nonetheless, it is noted that the Commission guidelines on the implementation of these Articles (European Commission, 2010a) provides further explanatory information on this issue.

Consumer organisations have confirmed that not all MS have the same level of transparency when it comes to consumers' access to information from authorities on a food withdrawal/recall: some national organisations indicated that the GFL mostly ensures the withdrawal of unsafe food/feed from the market but does not always ensure a high level of protection of consumers' health as recalls are not always conducted and, if they are, are not always well communicated to consumers; the lack of (or perceived lack of) transparency on product withdrawals does not help improve the situation. In this context, a best practice example of transparency is that, after a series of food and feed crises, CAs in the DE federal states have cooperated to rapidly publish all results of warnings, withdrawals and recalls on a central webpage[103]. By contrast, in some other MS there are more difficulties in getting access to relevant information that would be useful for consumers[104], including for example brand names (this issue is discussed further under 'transparency').

In terms of the **cooperation between operators and authorities**, the majority (62%) of operators that responded to the survey have sought assistance from MS CAs in the case of withdrawals and recalls; of these, one third has done so always/in most cases, and two thirds not systematically (*indicator 9.1b)*. When this has been the case, according to operators, MS CAs have for the most part provided the necessary assistance (55% of operators have indicated this has happened, or 85% of those that have sought assistance, of which about a quarter 'always/in most cases' and three quarters 'yes but not systematically') (survey results, Q18)[105]. Operators specified that, as the provisions of Articles 19 and 20 are quite strict on the obligations of operators, in practice, these tend to seek assistance from authorities quite systematically, also to ensure that they are covered

[102] Average ratings higher than 3, on a scale from 1 to 5 (MS CAs). Only 1-2 MS CA have indicated that some of these provisions are not always fulfilled by FBOs. It is noted, however, that 1-3 MS CAs did not provide an answer, and for the last point (whether FBOs have prevented or discouraged any person from cooperating with the authorities) 13 MS CAs indicated 'don't know', but no further explanation/comment was provided.

[103] www.lebensmittelwarnung.de

[104] To some extent, particularly when there is not sufficient information, consumer organisations have also challenged the rationale and motives of withdrawals but no recalls in case when products might have reached consumers, referring to them as '*quiet recalls*'. Operators have defended '*quiet recalls'* on the basis that not all information on withdrawals is relevant/actionable for consumers, while providing too much information can be counterproductive is that it dilutes focus from what is important/actionable information which is typically the case of recalls.

[105] The large number of 'don't know' responses is noted (30%-34%), which is to some extent due to the profile of responding stakeholders for some of whom this question was not applicable.

in any event by their insurance policy[106]; however, in practice, authorities in certain MS leave full responsibility upon operators to decide whether or not to withdraw/recall a product. Operators have commented that there are differences in the assistance provided and more generally cooperation with authorities, with authorities in some MS more ready to cooperate and to provide constructive/helpful assistance than in other MS, but also differences experienced within MS at regional/local level; several operators noted that it can often depend on the relationship/level of contact and trust with local authorities. To some extent, the differences in the level of cooperation between MS are attributed to cultural reasons, i.e. the extent to which traditionally there has been cooperation/dialogue between industry and authorities. SMEs particularly complained that in many cases MS CA officials do not appreciate their particular needs and are "*more keen on enforcement than assistance*", but sometimes also lack industry experience and emphasise theoretical as opposed to practical measures to be taken.

MS CAs have also confirmed that they have assisted operators when requested in the case of withdrawals and recalls, always/in most cases (14 of 25 MS CAs), or have done so but not systematically (8 MS CAs) (survey results, Q17) (*indicator 9.1c*). They have also confirmed that they have on occasion taken action where operators were unwilling/not in a position to cooperate with the authorities and/or take the required action commensurate with the risk to ensure the protection of public health. Several MS CAs have indicated that they provide assistance to operators depending on the case, but there can be variations in readiness/knowledge to assist and/or implementation at regional/local level. Nonetheless, it remains challenging for authorities to determine the right moment to take action, as ultimately the primary responsibility should remain with operators and action should not be taken too early by authorities. Given the variation in the level and quality of the assistance provided by authorities, operators would welcome more guidance/training on this. One best practice example indicated by some operators was the initiative of the BE Federal Agency for the Safety of the Food Chain (AFSCA) who provide assistance to BE food processors during practical seminars with simulation-type exercises dedicated to the management and communication aspects in the event of incidents related to food safety.

More generally, the main negative issue raised by stakeholders is the **variable level of the implementation of withdrawals/recalls by MS CAs**. This is both in terms of how provisions on the withdrawal/recall of feed/food by operators are implemented by authorities and for the withdrawal/recall of feed/food by authorities themselves. Legal experts have confirmed that although Article 19 and 20 have made a positive contribution in that they have for the first time laid down harmonised rules for operators' own withdrawal/recall procedures, harmonised rules for the withdrawal/recall of food/feed by the authorities as such are missing, and this, in practice, leads to different implementation between MS[107]. It is noted that Regulation (EC) 882/2004 in cases where non-compliance is identified, requires MS CAs to ensure that the business operator remedies the situation and that includes, amongst others, ordering the withdrawal of non-compliant food/feed (Article

[106] In most cases, insurance companies only compensate recalls/withdrawals ordered by MS CAs. It is not always clear whether a recall/withdrawal is requested by the CA or not, especially in cases where the non-compliance is not clear (e.g. in case of emerging hazards or analytical results exceeding slightly the maximum limit) as the CA may not wish to assume the responsibility if the products are eventually deemed to be safe. This issue is compounded by issues surrounding the attribution of responsibility and liability along the supply chain. In the feed sector for example, suppliers of feed materials do not provide a guarantee to feed manufacturers that the raw material complies with EU legal limits; in absence of guarantee, in theory this would require testing to prove, but the cost of performing the series of tests that would be required to check compliance with the full set of rules would be prohibitive/not realistic. E.g. in DE testing for mycotoxins and active substances/pesticides (chemical risks) [i.e. excluding microbiological risks] was estimated by the feed industry at €2.5 billion (compared to €7 billion turnover of the DE feed industry).

[107] As a comparator, safeguard measures for non-food business operators are horizontally laid down in the General Product Safety legislation (and its ongoing recast).

54). MS retain the discretion to decide what the most appropriate remedial action to take is. However, the Commission's proposal on Official Controls (COM (2013) 265 final) will offer the possibility to introduce via tertiary legislation a greater harmonised used of some remedial actions, including withdrawals/recalls.

An underlying factor accounting for differences in the implementation of withdrawals/recalls (Articles 19/20) between MS is the **interpretation of legal provisions to determine the safety of feed/food by MS CAs**, with regards both to Articles 14/15 and to other secondary legislation. Several operators commented that authorities in different MS can take different courses of action when applying the same food safety criteria, which leads to a non-even playing field between operators: companies having multiple sites of production across Europe are frequently confronted with different national approaches. Furthermore, as also confirmed by MS CAs, establishing a link between non compliance and food safety is a grey area, and the course of action with regards to product recalls/withdrawals can vary between MS CAs depending on the extent of the link, as also seen with RASFF notifications (see below). This is not the case only in non harmonised fields (e.g. contaminants where MS apply different tolerance limits), but also where harmonised rules are in place (e.g. pesticide residues, where the applied analytical methods may differ between MS).

Related to this, there is an issue of the **sensitivity of analytical methods**, which can differ between MS and/or may not be always appropriate, while they have generally become increasingly sensitive over time. For example, business operators indicated that in one MS fruit and vegetable products may not be placed on the market or may be withdrawn as soon as a pesticide MRL (but not necessarily the acute reference dose) is exceeded[108], while in other MS this may not be the case because analytical methods differ and/or the assessment of the analytical results takes into account a higher level of uncertainty. MS CAs may use different methods of sampling/analysis, some more sensitive than others (while some cases were identified where MS CAs used methods that were not valid for a specific food of feed matrix). Moreover, there is a trend – driven by scientific/technological advances - towards the development of more sensitive analytical methods able to detect increasingly miniscule exceedance of legal limits compared to the situation 10 years ago. These issues create considerable scope for different interpretation/enforcement between MS CAs, including on the action required in terms of withdrawals/recalls (several cases identified during the consultation), according to operators as also confirmed by several MS CAs and legal experts. The availability of appropriate tools (e.g. analytical methods) is therefore an important prerequisite for harmonised implementation/enforcement. **These issues, which pertain to the implementation by national authorities of official controls[109], are discussed further under EQ10 and EQ11 below**.

Although the above shortcomings point to the scope for improvements, overall the framework established by the relevant GFL provisions is appreciated by all consulted parties for bringing an **increased harmonisation in the way withdrawals and recalls are performed compared to the situation prior to the GFL**. The available evidence indicates that the **GFL provisions have largely contributed to the performance of fit for purpose withdrawals and recalls** by food/feed business operators. Fit for purpose refers both to the effectiveness and the efficiency of withdrawals and recalls. In particular:

[108] Maximum residue levels (MRLs) are the upper legal levels of a concentration for pesticide residues in or on food or feed based on Good Agricultural Practices (GAPs) and the lowest possible consumer exposure. The results from field trials would only be used to establish MRLs if the estimated intake of residues did not exceed the acceptable daily intake (ADI) or acute reference dose (ARfD). However, the MRL is not linked to the ADI or ARfD, and could result in intakes considerably below the ADI/ARfD. Residue levels above the MRL may therefore not necessarily result in an intake that exceeds the health based limits. Toxicological reference values (pesticide specific) are used to establish the link to health.

[109] Regulation (EC) 882/2004 and the pending proposal for a new Regulation – COM(2013) 265 final.

- The requirements on **withdrawals/recalls** of food/feed at risk (Art 19.1, 19.2; Art. 20.1, 20.2) have largely contributed to fit for purpose withdrawals and recalls, according to the vast majority (85%) of stakeholders and 23 of the 25 responding MS CAs (survey results, Q4c)[110] (*indicator 8.2c*). All consulted parties, including legal experts, have noted that the introduction of harmonised withdrawal/recall procedures by the GFL has been an important step compared to the situation prior to the GFL.
- The combination of the requirements for operators to **place safe food/feed on the market** (Articles 14 and 15) and to **verify that food/feed is compliant with food law** (Article 17.1) have contributed to fit for purpose withdrawals and recalls, according to the vast majority (87%) of stakeholders and 23 of the 25 responding MS CAs (survey results, Q4a)[111] (*indicator 8.2a*).
- Similarly, according to the vast majority (90%) of stakeholders and 24 of 25 MS CAs, the requirement of Article 18 to **establish one step back - one step forward traceability** has contributed to fit for purpose withdrawals and recalls (survey results, Q4b)[112] (*indicator 8.2b*). Consistently with these findings, survey results (Q13) also indicate that the traceability requirement of Article 18, in combination with own systems/procedures in place to provide relevant information to the CAs, ensured effective and efficient, targeted withdrawals/ recalls of unsafe food/feed, according to both stakeholders and MS CAs[113] (see *indicator 15.1a*).
- The requirements of Articles 19.3 and 20.3, for **operators to notify public authorities** in case food/feed considered at risk, **and to collaborate with public authorities** on actions taken to avoid or reduce risk, have contributed to fit for purpose withdrawals and recalls, according to the vast majority of stakeholders (82% and 90%, respectively, for each requirement) and 24 of the 25 responding MS CAs (survey results, Q4d[114] and Q4e[115]) (*indicator 8.2d*).
- The combined application of the provisions on determining the safety of feed/food, both in terms of traceability and withdrawals/recalls, has for the most part **ensured targeted withdrawals/recalls of unsafe food/feed**, according to both stakeholders and MS CAs (survey results, Q19)[116] (*indicator 8.2e*). Furthermore, for the most part MS CAs and stakeholders agree that the combined application of the relevant provisions of the GFL has <u>not</u> resulted in withdrawals/recalls of <u>safe</u> food/feed.

Beyond this semi-qualitative assessment, which is endorsed by all consulted parties, it is not possible to draw comprehensive conclusions on the basis of the analysis of trends in

[110] Average ratings, on a scale from 1 to 5: for stakeholders, higher than midpoint (3); for MS CAs, higher than 4. 20 of the 25 responding MS CAs provided a rating higher than 4. Amongst stakeholders, the number of negative responses is relatively marginal (5 out of 67 stakeholders scored '1' or '2').

[111] Average ratings, on a scale from 1 to 5: for stakeholders, higher than midpoint (3); for MS CAs, higher than 4. 20 of the 25 responding MS CAs provided a rating higher than 4. Amongst stakeholders, the number of negative responses is relatively marginal (3 out of 67 stakeholders scored '1' or '2').

[112] Average ratings higher than 4, on a scale from 1 to 5, both for stakeholders and MS CAs. In the case of stakeholders, 41 of the 67 responding stakeholders provided a rating higher than 4. Similarly, in the case of MS CAs, 19 of the 25 responding MS CAs provided a rating higher than 4. Amongst stakeholders, the number of negative responses is relatively marginal (3 out of 67 stakeholders scored '1' or '2').

[113] Average ratings higher than 4, on a scale from 1 to 5, both for stakeholders and MS CAs. In the case of stakeholders, 49 of the 67 responding stakeholders provided a rating higher than 4. Similarly, in the case of MS CAs, 22 of the 25 responding MS CAs provided a rating higher than 4. Amongst stakeholders, the number of negative responses is relatively marginal (3 out of 67 stakeholders scored '1'); 9 of the 67 stakeholders did not provide an answer largely because they were not in a position to know.

[114] Average ratings, on a scale from 1 to 5: for stakeholders, higher than midpoint (3); for MS CAs, higher than 4. In the case of MS CAs, 22 of the 25 responding MS CAs provided a rating higher than 4. Amongst stakeholders, the number of negative responses is relatively small (7 out of 67 stakeholders scored '1' or '2').

[115] Average ratings, on a scale from 1 to 5: for stakeholders, higher than midpoint (3); for MS CAs, higher than 4. In the case of MS CAs, 20 of the 25 responding MS CAs provided a rating higher than 4. Only 1 out of 67 stakeholders provided a negative response ('1').

[116] Average ratings higher than 4, on a scale from 1 to 5, both for stakeholders and MS CAs.

incidents of withdrawals/recalls (*indicators 8.3a to 8.3c*), as such data is not consistently collected and cannot be uniformly interpreted, whether at MS CA level or at EU level such as RASFF[117]. Difficulties with comparing and interpreting trends on the basis of RASFF data[118] partly relate to the non-uniform approach followed by MS CAs in the notification of similar incidents as an 'alert' or 'information' (which require different courses of actions in each case)[119].

In terms of their overall contribution to achieving the objectives, the key requirements for operators as laid down by the GFL (Articles 14, 15, 17, 18, 19 and 20) **have largely ensured a high level of protection of consumer health** (*indicator 8.1a*; as also outlined under EQ3, in particular *indicator 3.1e*).

As already discussed under traceability (Article 18: EQ14/15) and allocation of responsibilities (Article 19: EQ12/13), the harmonised provisions of the GFL have played a **key role in ensuring a more effective and efficient targeting of withdrawals/recalls** compared to the situation prior to the GFL (*indicators 9.2a and 9.2b*). Both traceability (in particular when further enhanced by internal traceability, where this is voluntarily put in place by operators), and cooperation between operators and MS CAs (including the exchange of helpful advice and good practices[120]) are two key factors that improve both the effectiveness and the efficiency of withdrawals/recalls. Both of these factors are found by all consulted parties to have greatly improved over the last decade, due to the GFL. In particular:

- In terms of **efficiency**, according to estimates provided by the industry, having internal traceability in place (to the extent feasible, e.g. less feasible for bulk products and continuous production processes) can result in reducing the potential costs of withdrawals by a factor of 10. It was not possible to compare data on the costs of recalls/withdrawals as such before and after the GFL[121]. Nonetheless, according to industry estimates, the cost of the dioxin crisis back in the late 1990s was estimated at nearly €1 billion, while the cost of the dioxin contamination in Ireland in 2008 was estimated at €200 million[122] and of the aflatoxin crisis in 2012 was estimated at €100 million. The evaluation of the RASFF (FCEC, 2015) estimates the cost of the recall following the 2010 incident involving glass fragments in instant coffee to have reached

[117] Trend on withdrawals and recalls: there are no systematically collected data on withdrawals and recalls. Some cases are documented in RASFF, however, these are only cases with implications for several MS; if a case affects only one other MS, only the MS CA in question tends to be notified (unless, when an incident is feared to have wider implications).

[118] RASFF notifications provide data to 2014. However, RASFF data are not systematic to provide trend and there are caveats in interpretation – see also challenges section. In particular, data on the number of notifications do not provide information on the extent (level) of the risk involved; furthermore, each 'notification' may refer to one or more consignments. Therefore, trend analysis or comparison between MS, between products, and between hazard categories does not provide conclusive evidence on the improvement in food safety levels.

[119] In the context of RASFF, an **'alert notification'** is sent when a food, feed or food contact material presenting a serious risk is on the market and rapid action is or might be required in another country than the notifying country; products subject to an alert notification have been withdrawn or are in the process of being withdrawn from the market (MS have their own mechanisms to carry out such actions, including the provision of detailed information through the media if necessary). An **'information notification'** concerns a food, feed or food contact material for which a risk has been identified that does not require rapid action either because the risk is not considered serious or the product is not on the market at the time of notification.

[120] In the context of good practices, operators also appreciate the EU guides and national guidance provided on good hygiene practices (Regulation (EC) 852/2004), as registered by the Commission: http://ec.europa.eu/food/food/biosafety/hygienelegislation/register_national_guides_en.pdf

[121] Collecting data on costs would have required specific analysis of incidents, which was not possible in the scope of this study. Furthermore, several factors concur to contribute to costs, hence it is not possible to attribute cost increases to a single factor as such. For more general caveats on costs analysis, see challenges section.

[122] Although less than 10% of pork products were potentially affected by the contaminated feed, 100% of products were recalled with an estimated cost of €200 million (Houses of the Oireachtas, 2009).

over €23 million[123]. Although these cases are not fully comparable[124], according to the industry, there has been a reduction in terms of costs of risk/crisis management which *inter alia* can be attributed to the enhanced and harmonised traceability system in place.

- Similarly, in terms of **effectiveness**, according to all consulted parties, the speed of reaction has greatly improved over the last decade. During the 1999 dioxin crisis, it took several weeks to get traceability information both upstream and downstream the supply chain; now it is possible to get information to trace the products (one step up - one step down) in hours and this enables the effective (speedier; more targeted) conduct of any subsequent inspections by CAs and more effective and efficient actions by operators and authorities. For example, in the case of the 2011 E. Coli outbreak, traceability information was rapidly provided once the source of the outbreak was correctly identified; also, the evaluation of the RASFF (FCEC, 2015) notes that throughout the outbreak the RASFF was used as a tool for information exchange, which contributed significantly to the traceability exercise.

Despite these improvements, there is scope to address certain identified shortcomings, in particular those stemming from differences in the approach followed in similar cases by MS CAs, as outlined above. The implications of such differences in approach can have considerable cost implications for operators. For example, based on an actual case where two MS followed a different approach in addressing non-compliance[125], the destruction of the products in one MS is estimated to have resulted in costs > €0.4 million (value of affected products), while in the other MS costs were minimised by re-exporting the products where authorised. Compounded with the limitations and differences of the sampling/analysis methods used (as discussed above), such cases can easily occur at present. It is noted that the proposed new Regulation for official controls (COM(2013) 265 final) aims to address some of the above shortcomings pertaining to differences in implementation of the official controls by MS CAs, including foreseen improvements in relation to sampling, analysis, testing and diagnosis to allow a more uniform application of rules.

III.3.3.2 Assessment of specific provisions (EQ10/EQ11)

EQ10: To what extent has the provision that food/feed is deemed safe when it complies with specific EU provisions, or in their absence to specific national provisions, governing food/feed safety proved sufficient in order to achieve the objective of protection of health of consumers (Article 14.7 and 9 and 15.4 and 6)?

Article 14.7 and 9 (food) and Article 15.4 and 6 (feed) foresee that food/feed is deemed safe when it complies with specific EU food/feed law (i.e. the GFL and other secondary legislation), or in their absence to specific national provisions, governing food/feed safety. The withdrawal obligations set out in Articles 19 and 20 are implicitly linked with these provisions (and, more generally, Articles 14 and 15), in that they cover products considered to be non-compliant with food safety requirements (as defined in Articles 14 and 15, and in

[123] Because of the nature of the incident, a restriction to particular production codes or best before dates was not possible leading to a substantial traceability and recall exercise of the products concerned, in 30 countries, in order to remove them from the market.
[124] There are considerable differences in the methodologies followed for the estimation of the costs of a feed/food safety crisis, including the range of costs taken into consideration (e.g. whether these include the direct costs of withdrawals/recalls, and indirect costs of losses from market disruption and fall in consumer demand/trust; furthermore, the baseline and assumptions on which any of these costs are calculated can differ). In addition, the context and circumstances of each particular incident have specific impacts on costs.
[125] This case involved non-compliance with regards to an imported product with low level presence of an unauthorised GMO event; the product in question is used as ingredient/raw material in a large range of food products.

other secondary legislation), as also confirmed by the COM guidelines on these Articles. As such, these provisions act together to ensure that food placed on the market is safe, in order to protect consumers' health.

Overall, these provisions have proved effective in protecting consumers' health for all the main areas of other secondary legislation, according to both stakeholders and MS CAs (survey results, Q6a) (*indicators 10.1a to 10.1d*)[126]. Stakeholders indicate that they have been particularly effective in the areas of food hygiene and foods for specific groups; MS CAs corroborated on the high effectiveness of the provisions in these two areas, but also highlighted their high effectiveness in the area of food improvement agents, GMOs and feed legislation (feed labelling, feed additives, and feed hygiene)[127].

In general terms and on the basis of the current knowledge, stakeholders and MS CAs agree that compliant food can be considered to be safe. For example, the annual report from EFSA on pesticide residues demonstrates that food compliant with relevant EU legislation is safe[128]. The EU feed legislation is also considered to set a very high safety standard, as proven by the fact that all feed safety incidents with possible adverse human health effects (i.e. resulting in non compliant food of non animal origin) were identified to be connected to a non-compliance with EU feed safety law[129]. The question that arises however is whether non-compliant food is necessarily unsafe, particularly in cases where: the risk to health cannot be scientifically established; and/or where – in the absence of harmonised rules - non-compliance is assessed differently across the EU.

The key reasons why the **provisions of Articles 14.7/9 and 15.4/6 are considered not as effective in other key areas of EU legislation**, according to stakeholders and MS CAs[130], relate to the **underlying shortcomings** discussed elsewhere in this report. In particular, these can be summarised as follows: incomplete harmonisation in some fields; and/or, concerns over the basis for assessing safety versus non-compliance, whereby stakeholders call into question whether non-compliance of a food/feed necessarily means that the food/feed is not safe (and therefore must be withdrawn). For example, in the case of enriched food, an underlying shortcoming is that no harmonised maximum levels have been set for the addition of vitamins, minerals to foods[131]; divergent national limits exist, but the established levels cannot be explained by science-based risk assessment alone. In the case of food improvement agents, novel foods and GMOs, stakeholders commented that non conformity with the legal requirements does not necessarily mean that a food is not safe, if the legislation has been based on a risk management decision where the balance between science and other legitimate factors is not clear. In the area of food supplements, major differences exist between MS on the approach and rules applying to botanical products, in relation to whether they are considered food supplements or medicinal products, and the extent to which certain products are safe (e.g. botanicals presenting

[126] Average ratings higher than midpoint (3), and in some cases of other secondary legislation higher than 4, on a scale from 1 to 5, both for stakeholders and MS CAs.
[127] Average ratings higher than 4, on a scale from 1 to 5, in all these cases.
[128] The last EFSA report (published in March 2015) contains findings from tests carried out in 2013 on more than 80,000 samples – showing that overall 97.4% of these food products were within the maximum residue levels (MRLs) of pesticides permitted in the EU. For the EU-coordinated program covering 12 food commodities, the results showed even higher compliance: 99.1%. MRLs are a strict trading standard under which cut-off points are set well within acceptable safety levels.
[129] All cases of recent feed safety incidents involved a breach of existing legal provisions, e.g. non-compliance with maximum levels for contaminants (called 'undesirable substances' in the feed legislation, see Directive 2002/32/EC) or missing registration/approval of establishments.
[130] Despite some differences in average ratings between stakeholders and MS CAs, the outlined shortcomings are generally accepted both by stakeholders and MS CAs.
[131] Furthermore, in the case of other substances, stakeholders have commented that the procedure of Article 8 of Regulation (EC) 1925/2006 is not uniformly applied, and MS still decide the distinction between foods and medicines.

serious adverse effects). Similar issues arise in other areas where harmonised rules are missing, including contaminants, microbiological criteria in feed of plant origin (e.g. salmonella in feed), and rules for novel feed. Finally, in the case of food irradiation, one MS CA noted that the current legislation needs updating in light of the latest international standards (Codex and ISO) and scientific developments; as the legislation currently stands, it is considered to impede the use of this technology and thus its potential contribution to a reduction in the levels of food-borne illness.

Most stakeholders and MS agreed that in most of the above areas the **effectiveness** of the legal provisions of the GFL and of other secondary legislation in protecting consumer health **can be improved by continuous science-based scientific assessments systematically feeding into the risk management process**. This is clearly the intention of the legislator, as also explained in the COM guidelines on Article 14.7: although the assumption is that food not compliant with specific legislation is unsafe, it is possible after a risk assessment to conclude that a certain product is safe despite that non-compliance with the relevant legislation. There is some evidence that the **application of objective and transparent criteria to establish safety** is delivering where applied. A best practice case is the approach applied for pesticides residues by some MS: products that exceed MRLs (which are set at harmonised levels) are withdrawn only when the toxicological reference value of the pesticide exceeding the MRL has been exceeded, thus indicating that the acute reference dose may be exceeded[132]. In such cases, an objective measure of 'dangerous' to health is being applied order to decide to withdraw or not a product from the market, rather than non-compliance to the legislation as such. The problem is that where science, and appropriate tools such as analytical methods, are incomplete/lacking such an approach cannot be applied[133].

Where objective/science-based criteria are lacking, MS CAs confirmed that **it is difficult for authorities to establish a clear balance in interpreting the concept of non-compliance to legislation versus assessing safety for human health**, thus often leading to differences/non-uniformity in implementation.

A case where this frequently occurs, according to the various consulted parties (supply chain stakeholders, MS CAs, experts) is when 'unsafe' is established on the basis of Article 14.2(b), i.e. 'unfit for human consumption'), which typically includes cases where there are no clear objective criteria, despite the existing Commission guidelines (2010) on these provisions [134]. The consultation has found that, in practice, there is a wide range of cases, leading to differences in the approaches taken not only by authorities but also by business operators. Furthermore, there appear to be cases of '*excessive'* implementation where foods can be deemed unfit for consumption although not necessarily unsafe. Such cases can range from, e.g. retailers withdrawing fruit of lower visual quality (that is unfit but not unsafe) and/or products close to expiry date, to authorities deeming as unfit/unsafe products that pass over a limit set in legislation (e.g. maximum levels for contaminants or food additives). Another area where no clear objective and harmonised criteria exist in current legislation is

[132] This is a practice that is only followed by some MS, as this remains a non harmonised area. While in some MS products are withdrawn from the market only when the toxicological reference value of the pesticide exceeding the MRL has been exceeded, in other MS products are withdrawn in case the MRLs are exceeded without any health risk being identified. The lack of harmonisation in this area is also outlined in **Table 4**.

[133] For example, in the field of pesticide residues, the Commission/EFSA have been systematically reviewing all existing maximum residue limits under Art. 12 of Regulation (EC) No 396/2005. Since more than 400 active substances are in this review programme and there are more than 300 MRLs for each substance to be reviewed, priority has been given to those substances where potential health concerns exist. EFSA has also been working on a methodology that will allow the assessment of cumulative risks from different pesticides, which is to be taken into account when setting future MRLs.

[134] Unlike pesticide residue MRLs, where (as discussed under EQ10) in some MS, clear and objective, science-based criteria have been set as to how authorities in these MS should proceed when MRLs have been exceeded.

for contaminants (e.g. cadmium, mercury, mycotoxins etc.); thus, in practice, a case by case approach is taken by MS CAs and this can lead to different approaches to recalls, depending on authorities' own assessment of potential safety risk for human health[135].

Consumer organisations emphasised the effective contribution of the GFL provisions (Articles 14.7/9 and 15.4/6; and, implications on withdrawal obligations as foreseen in Articles 19 and 20), **as currently applied, to ensuring a high level of protection of consumer health, given the scientific knowledge gaps in certain areas** (e.g. safety of nanomaterials) and or contradictory/inconclusive scientific opinions in other areas (e.g. GMOs; novel foods).

EQ11: To what extent and how efficiently and effectively have the public authorities taken further actions when food/feed was discovered unsafe despite its conformity with the legislation? (Articles 14.8 and 15.5) How significant has this been in terms of achieving the objectives?

As already discussed establishing when a food is unsafe is difficult to define; hence the approach taken in Articles 14.8 and 15.5 which provide a safety net for authorities to take further actions when food/feed is discovered unsafe despite its conformity with the legislation.

Indeed, a majority of MS CAs (14 of 25 MS CAs) have, in some cases, **restricted the marketing or required the withdrawal/recall of compliant food/feed from the EU market**, because there were reasons to suspect that the food/feed was unsafe (as foreseen in **Articles 14.8 and 15.5**); 8 MS CAs indicated that there have not been such cases in their country while 3 MS CAs did not know (survey results, Q7) (*indicators 11.1a and 11.1b*). MS CAs indicated several cases of food/feed products withdrawn on the basis of Articles 14.8/15.5. Many of the provided examples relate to the absence of harmonised EU rules/maximum limits as such. For example, suspicion of high presence of histamine in pet food in one MS and in seafood preparations in another, or a number of withdrawals/recalls of shellfish for presence of Norovirus although products were compliant with biotoxin and E. coli limits[136]. Other cases where, according to MS CAs, Articles 14.8/15.5 have been invoked include restrictions by some MS CAs on authorised GMO crops, and suspected contamination from food contact materials (e.g. packaging containing BPA; presence of ITX, a chemical substance released from the print ink on (dairy) packaging; migration of heavy metals (lead and cadmium)).

III.4 Risk analysis

The obligation to apply the risk analysis principle when adopting food and feed safety measures derives from Article 4 of the GFL. The approach to be taken to apply this principle is laid down in Article 6, taking into account the definitions of the risk analysis process and its components in Article 3. Article 6 requires that national and EU measures on feed/food should be based on risk analysis, except where this is not appropriate to the circumstances or the nature of the measure. As defined in Article 3, **risk analysis** is composed of three interconnected, yet independent and distinct, components, which are further described in Article 6:

[135] For contaminants every finding of non-compliance has to result in a withdrawal of the non-compliant feed/food from the market. That is a clear criterion for withdrawal of food from the market. However, there is no clear criterion in which situations in addition to a withdrawal also a recall of the food should be carried out.

[136] Histamine: no limits of histamine have been set for feed at EU level, although limits exist for food (in this particular case, the levels for feed were higher than the maximum limits for food). Norovirus: there are no legislative limits for Norovirus in European legislation.

(a) **Risk assessment**: to be carried out in an independent, objective and transparent manner on the basis of available scientific information and data (Article 6);
(b) **Risk management**: to be distinct from risk assessment (Article 3) – it needs to take into account the results of the scientific assessment as well as other legitimate factors and, where relevant, the precautionary principle (Article 6); and,
(c) **Risk communication**: to involve the interactive exchange of information and opinions throughout the process between all relevant parties involved (Article 3).

As laid down in Article 7, the **precautionary principle** should be triggered in specific circumstances where a risk to life or health exists and scientific uncertainty persists.

The risk analysis principles and procedures laid down in the above Articles of the GFL apply **globally** to all EU/national measures of food and feed safety (i.e. addressing chemical, biological or physical risks). **Additional specific procedures** are laid down **in other secondary legislation** regarding product authorisations (e.g. food improvement agents; food contact materials; feed additives; GMOs), the authorisation of health claims[137], and the setting of maximum limits (MLs) (e.g. contaminants; undesirable substances (feed); residues; microbiological criteria). These procedures are not *per se* measures on food and feed safety but create a specific framework within which decisions can be taken (e.g. to authorise or not a certain product), in line with the risk analysis principles laid down in the GFL, to address the specific needs of these sectors[138].

Thus, the extent to which the risk analysis and precautionary principles are applied, and the analysis of specific cases, are analysed within the framework of the above Articles of the GFL and other secondary legislation. The purpose of the study has been to analyse the impacts (positive and negative) of the relevant GFL provisions, including their implementation in other secondary legislation, the extent to which they have been of added value/benefit, whether or not positive impacts outweigh negative impacts, and their overall sufficiency and effectiveness for ensuring food and feed safety and public health.

III.4.1 Application of risk assessment and risk management *(EQ20)*

EQ 20: To what extent has the principle of risk analysis been applied efficiently, coherently and consistently in drawing up food law measures and in their application (Article 6)? Have the three components of risk analysis (risk assessment, risk management and risk communication) been clearly defined and consistently, efficiently and effectively applied? How did the separation of and the interface between risk assessment and risk management function in practice? To what extent have other legitimate factors been taken into account in the risk management process? What were mostly those legitimate factors? How has this influenced achieving the objectives?

[137] Unlike product authorisations, the authorisation of health claims refers to claims rather than products. Thus, a rejection of a claim does not constitute a ban of the product itself from the market. Moreover, to use authorised health claims the product must be in compliance with all EU ad national regulatory requirements applicable to it, including product authorisation under relevant legislation.

[138] In the specific area of authorisations linked to food/feed, additional legal procedures in line with the principle of risk analysis have been provided by other secondary legislation to address specific needs such as the obligation for applicants to submit a dossier for authorisation, to whom and how these dossiers are delivered, how they are evaluated and against which criteria the authorisation is given. In all cases, the risk analysis process requires a prior risk assessment (scientific opinion) by EFSA and validation by PAFF. In a number of cases the authorisation procedures provide some clarifications about some other legitimate factors that have to be taken into account by risk managers (e.g. food additives cannot be misleading). In the context of specific procedures laid down in other secondary legislation, although all areas where such procedures exist were covered, the study focussed on: the authorisation procedure for food contact materials, food additives, and feed additives; and, determination of MLs for undesirable substances/ contaminants in food and feed.

Key findings (EQ20):

Globally, since the entry into force of the GFL, EU measures managing microbiological, chemical and physical risks linked to food and feed have been adopted on the basis of risk analysis, in line with the general principles laid down in Article 6. Furthermore, most of the secondary legislation (basic acts) laying down additional specific procedures (authorisation/setting of MLs) have been revised/modernised, including the design of harmonised procedures in most sectors, in line with the GFL risk analysis principles. The adjustment process has been gradual both at EU and at MS level. The separation of the risk assessment and risk management functions at EU level has improved considerably over time and is generally functioning well in practice; risk assessment by EFSA is considered to be independent, objective and transparent. Also at the level of MS, in most MS that contributed to the case studies, there have been considerable adjustments to apply risk analysis at national level as laid down in Article 6, including the functional and/or legal separation of risk assessment from risk management; the adjustment process has taken many years and is still in progress today. The implementation of risk analysis principles, as laid down in Article 6, is widely acknowledged, both during this consultation and confirmed by literature, to have improved the scientific basis and transparency of measures adopted both at national and EU level, in all areas of feed/food law. It has also increased efficiency, in terms of: a) cost savings from the central approach followed at EFSA (thus reducing the need for national risk assessments, particularly in smaller MS that cannot afford to invest in the required scientific capacity); and, b) the pooling of scientific resources involved in EU/national assessment bodies. Where national and EU measures on feed/food have been adopted on the basis of a risk analysis, positive outcomes have been achieved and measures have been effective and proportionate. In particular, the risk analysis process, including consideration of other legitimate factors is acknowledged by all consulted parties to have had a substantial positive impact on consumer health and protection. It is noted that the positive impact of Article 6 as such cannot be isolated from other relevant concurrent developments, in particular the establishment of EFSA and the increased level of harmonisation in EU feed/food law.

Despite the continued progress in the application of the risk analysis principles of Article 6, our consultation has highlighted certain persisting problems/difficulties. These are partly linked to the complexity of the risk analysis process as such but also the complexity/diversity of the field of application, particularly in the case of partially or non-harmonised areas (where lack of harmonisation accentuates the scope for divergence in application). They are also linked to the diversity in focus and perspectives of the different stakeholders on the outcome of the process: according to the case at stake and stakeholder interests, it is sometimes expected that only the results of risk assessment are taken into account and sometimes that legitimate factors are also taken into account. Thus, a common theme that came out in the consultation is the consistency of consideration of 'other' legitimate factors, besides the risk assessment as such, in the final risk management decision and how these have been weighted. Although both risk assessment and other legitimate factors consistently tend to be taken into account in EU/MS risk management process, as foreseen by Article 6, in view of the diversity of sectors, the exact range of factors varies on a case by case basis, according to needs. Although the case by case approach is considered inevitable, this creates a certain lack of 'certainty' which, based on the feedback received from the industry, hampers innovation, in view of the high costs involved (e.g. authorisation procedures).

Notes:
Although EQ20 specifically refers to Article 6, as noted above, the obligation to apply risk analysis derives from Article 4, while risk analysis and its three components are defined in Article 3; therefore the analysis below covers all three Articles. ***The analysis below covers measures taken both at EU and at MS level****. Where harmonisation is more complete, the application of Article 6 in measures taken at EU level is more relevant; where it is not complete, the application of Article 6 in measures taken at MS level becomes more relevant. It is noted that* ***issues arising from a certain lack of harmonisation are neither linked***

nor a consequence of the implementation of the risk analysis principle *as such. Nonetheless, these issues are also analysed in this section, because they have implications for the application of the risk analysis principle at MS level.*

III.4.1.1 Application of risk analysis at MS/EU level

a) Application at EU level

Globally, EU measures managing risks linked to food and feed (microbiological, chemical, physical risk) **have been adopted on the basis of risk analysis**, as laid down in Article 6, according to the majority of stakeholders and MS CAs (survey results, Q28) (*indicator 20.1a*). Nonetheless, while for MS CAs this has occurred always/in most cases (16 of 25 MS CAs), the majority of stakeholders (69%, i.e. over two thirds) indicate that this has not occurred systematically.

All of the consulted parties have highlighted that a risk analysis approach was already applied before the GFL for the adoption of EU measures on feed and food safety, even though this was not based on a defined formal framework[139]. The application of the risk analysis principles of the GFL should therefore be seen as a step further in the continuity of what was done before, enhancing the consistency of the process on the basis of a harmonised set of principles. At EU level, the major step taken in this direction by the GFL was the establishment of the European Food Safety Authority (EFSA), an autonomous agency responsible for the delivery of independent risk assessment. This aimed to ensure that Article 6 could be correctly implemented both with regard to the independent, objective and scientific basis of risk assessments and for the separation of the risk assessment and risk management functions (see section III.4.2). Since the entry into force of the GFL, a large body of EU feed/food legislation has been adopted or reviewed, in line with / on the basis of the risk analysis principles as set out in the GFL. Moreover, the harmonisation of EU feed/food law has progressed further. As it stands today, globally, most areas of feed/food law are harmonised.

When it comes to **additional specific procedures laid down in other secondary legislation (authorisation/setting of MLs)**, since the entry into force of the GFL, most of the other secondary legislation (basic acts) **has been revised or modernised**, including the design of harmonised procedures in each sector **in line with the GFL risk analysis principles**. In many food sectors, procedures for EFSA opinions and provisions for application dossiers have been formalised, and programmes for the reassessment of substances (reviewing old scientific opinions) have been introduced into new regulations. Guidance documents explaining how to implement basic legislative acts or determining the risk assessment methodology have also been produced.

Despite the continued progress in the application of the risk analysis principles of Article 6, our consultation has highlighted certain persisting problems/difficulties. These are partly linked to the **complexity of the risk analysis process**, which is also reflected in the divergence of what is commonly understood as *'adopted on the basis of risk analysis'*. They are also linked to the fact that **stakeholders have diverse perspectives** on the outcome of the process. This becomes evident from reviewing the cases of EU measures

[139] Risk assessment was performed by the Scientific Committee on Food (SCF) and by the scientific committee on veterinary measures relating to public health (SCVPH). SCF opinions were often based on opinions of international organisations (JECFA, JMPR). Regarding risk management, regulatory measures were taken by the regulatory Committee on the basis on the SCF/SCVPH opinions, other legitimate factors and the results of interactions with interested parties.

that, according to stakeholders, have not been adopted on the basis of risk analysis (**Table 4)** (*indicator 20.1b*). In fact, a closer examination of most of these cases indicates that the risk analysis process has been followed, although they highlight the complexity and problems in applying it as follows:

- **Complexity of the process**: The complexity of the three components of the risk analysis process is a starting point to explain the problems that occur in practice. As the issues covered by the process are underpinned by considerable scientific/technical complexity, the application of risk analysis is not always fully understood by stakeholders (e.g. in terms of the need for more scientific evidence) and/or may be perceived not to be consistently applied (e.g. in terms of the weighting of the various legitimate factors). Furthermore, as specified in Article 6, risk analysis is applied only when appropriate to the circumstances (e.g. not applicable for the adoption of labelling provisions that do not require to be based on a risk assessment since they are not managing a risk); this partly explains some of the stakeholder/MS CA responses why '*it has not occurred systematically'*.
- **Complexity/diversity of the field of application**: The complexity of the process is accentuated by the diversity and complexity of the scientific/technical fields of other secondary legislation to which risk analysis is applied. Risk assessment to be performed needs to be based on robust scientific evidence and in the case of new complex or emerging scientific fields, evidence is usually only partly available and new evidence needs to be collected. When it comes to additional specific procedures laid down in other secondary legislation, given that there is a number of authorisation/ML setting procedures that are not standardised in terms of criteria, this creates specific operational difficulties for the risk assessor (these are described further in section III.4.1.2c).
- **Consideration of other legitimate factors**: A common theme that came out in our consultation with the different parties (see **Table 4**) is the extent to which 'other' legitimate factors, besides the risk assessment as such, have been taken into account in the final risk management decision and how these have been weighted. Thus, in a number of cases it was indicated that the risk analysis principle was not (consistently) applied because, depending on the point of view of different stakeholders, the risk managers (unduly) put more weight on other legitimate factors or put more weight on the risk assessment results.
- **Risk communication and level of understanding**: Our findings indicate that the above observation is due to the following reasons: the risk communication component was not well/sufficiently performed; and/or, stakeholders did not well understand the risk management process; and/or it reflects divergent viewpoints and interests amongst stakeholders. The difference between consumer groups/NGOs and industry in what is expected to be the risk management outcome is generally evident in most cases.
- **Level of harmonisation**: The above complexities increase in the case of partially or non harmonised areas, where lack of harmonisation as such creates the scope for divergence in application. Despite the advanced level of harmonisation in most areas of feed/food law, some areas remain partly harmonised such as contaminants, food contact materials, and microbiological safety criteria. In the specific case of legislation laying down authorisation/ML setting procedures, harmonisation continues to be more advanced/complete in certain sectors (e.g. food improvement agents, including additives, flavourings, enzymes; feed additives) and less in others (e.g. food contact materials; contaminants)[140] (**Annex 6.D**).

[140] Many of the pre-GFL scientific opinions reached at EU level (SCF/SCVPH) are still today the scientific basis of food law (e.g. additives that have not yet been reassessed, substances used in the manufacturing of plastic food

Although the review of the cases put forward by the industry (**Table 4**) highlights the complexities/difficulties of applying the three phases of risk analysis in practice in the different fields of EU feed/food law, these **cases do not identify systemic inconsistencies in the application of Article 6 as such**. The only area where some inconsistency was identified was in the risk analysis approach for feed additives versus feed materials (this issue is further analysed under negative impacts, section III.4.1.3).

Table 4: Cases of EU measures not adopted on the basis of risk analysis, according to industry stakeholders *(a)*

	Background
'Southampton -6' food colours *(b)* :	EFSA assessed the results of a UK study by McCann et al. (2007) (Southampton University) on the effect of six synthetic colours (azo dyes) and sodium benzoate on children's behaviour, and concluded that the findings of the study cannot be used as a basis for altering the ADI of the respective substances. The UK had used the findings of the study to recommend the phasing out of these food colours. The adoption by the Commission of rules imposing a warning label on food and drinks that contain such colours (azo dyes), in the context of Regulation 1333/2008 (mandatory labelling that these colours 'may have an adverse effect on activity and attention in children'), used the 'other legitimate factors' clause as part of the risk management procedure. *Note: The EU risk management decision took into account both the risk assessment and other legitimate factors. What seems to be less clear is how these factors were weighted.*
Aluminium-containing food additives	In 2008 EFSA assessed the safety of aluminium from dietary intake and concluded that the proposed *"Tolerable Weekly Intake of 1 mg/kg bw/week is likely to be exceeded in the significant part of the European population"* due to the variety of sources and main contributors to the aluminium content of a particular food and dietary aluminium exposure. Despite the conclusion of the EFSA opinion, it was considered appropriate to amend the conditions of use and reduce the use levels for aluminium-containing food additives (Commission Regulation (EU) 380/2012). *Note: The EU risk management decision took into account both the risk assessment and other legitimate factors. This will be then further monitored to check if the intake is not exceeded. What seems to be less clear is how these factors were weighted.*
Health claims	The industry argues that while issues related to labelling may arise in risk management, they cannot justify the delay and final decision in various cases in relation to health claims: Effects of vitamin D: in 2011, the EFSA Panel on Dietetic Products, Nutrition and Allergies adopted a scientific opinion concluding a cause and effect relationship between the intake of vitamin D and the reduction in the risk of falling. Despite this positive opinion, in September 2014 this claim was not adopted. *(d)* Effects of glucose: Commission Regulation (EU) 2015/8, rejects the authorisation of certain glucose related health claims. EFSA had given a positive opinion on the scientific support for these claims and confirmed that the claimed benefits were favourable to health. However, the European Commission rejected the authorisation due to general considerations that such claims would convey a conflicting and confusing message to consumers because they would encourage consumption of sugars, which is inconsistent with generally accepted scientific advice. It is argued that the Commission did not present any evidence and that the opinion was mainly based on a concern rather than facts. *(e)* Effects of caffeine: despite the EFSA assessment confirming the safety of caffeine (latest published May 2015), health claims are not yet approved. *(f)* *Note: The EU risk management decision took into account both the risk assessment and other legitimate factors. What seems to be less clear is how these factors were weighted and/or communicated. In practice, although delays are observed in some of the above cases, action is promptly being taken in others (e.g. effects of caffeine). An important factor for the speed of the decision making process is the complexity of the case (e.g. effects of vitamin D; effects of glucose and potential contradiction with general principles).*
Bee health, ban on neonicotinoids	One of the possible contributing factors of the root causes of bee diseases and their unusually declining numbers in parts of the developed world (Western Europe, North America) which are examined by scientists is the increased use of a class of pesticides known as neonicotinoids. Doubts have been raised on the assessment delivered by EFSA which – although acknowledging a high level of uncertainty in its evaluation and the multiple causes of bee

contact materials; first legislation on microbiological criteria), while these opinions were used by EFSA as the starting point for further updating/reviewing risk assessments.

	Background
	diseases - formed the basis of the EU decision to ban neonicotinoids. Nonetheless, EFSA continues to work intensively in this area: in line with its strategy to consider risk assessments in a wider, more integrated manner so as to provide risk managers with comprehensive advice on which to base their decisions, EFSA established in May 2012 an internal task force to compile a state-of-the-art review of its own work in this area, as well as the current activities conducted by MS; furthermore, in early 2015 EFSA launched a major project aiming to develop a holistic approach to risk assessment of multiple stressors in honeybees (MUST-B). *Note: The EU risk management decision took into account both the risk assessment and other legitimate factors. In addition, EFSA keeps under review complex scientific issues in order to update its risk assessment. This work is expected to feed further into risk management. In its decision to ban the three neonicotinoid insecticides (Regulation (EU) No 485/2013), the Commission has undertaken to review the conditions of approval of the three neonicotinoids, to take into account relevant scientific and technical developments.*
Use of pesticide MRLs in assessing the risk of dual use substances:	It is argued that MS decided to apply the pesticides MRLs to substances that are not used as pesticides and that do not result from use of PPPs, without addressing whether the substances in question could correctly be deemed "pesticide residues", and thus whether Regulation (EC) No 396/2005 should be applied *(c*). This has been the case for the following dual use substances, the residues of which are managed through default pesticide MRLs: • **Quaternary ammonium compounds**, which are used to disinfect raw materials and processing lines. • **Chlorate**, a known by-product of potable water disinfectant hypochlorite. Chlorate, listed as pesticide until 2008, can be present in foods rinsed with potable water (due to the addition of chlorine compounds in processing water). This issue is expected to be addressed at EU level when more precise occurrence data become available. *Note: This is mainly a legal issue; in fact, temporary measures setting up MRLs were taken on the basis of Article 16 of Regulation (EC) No 396/2005, which provides for temporary MRLs (for up to 10 years) in exceptional cases, in particular where pesticide residues may arise as a result of environmental or other contamination or from uses of PPPs.*
MRLs for pesticide residues in food	Two further issues with the use of pesticide residue limits have been raised by operators *(source: industry):* • Commission Regulations (EC) 178/2006 and (EU) 212/2013 (and other regulations) modify certain MRLs for pesticide residues: operators have indicated that no rationale is provided, why certain MRLs were modified and what were the considerations *Note: this appears to be mainly a risk communication issue. Explanations are provided in the recitals, e.g. of Regulation (EU) 212/2013, on the changes made but the industry does not consider these explanations sufficient and/or would had welcome some prior consultation.* • Discrepancy between MRLs and Acute Reference dose (ARfD) (which determines acute dietary intake assessment of pesticide residues) leads to MRLs considered as 'unsafe' and large differences in risk assessment between MS. *Note: this relates to practical issues that usually occur when managing rapid alerts/ emergencies, when risk managers in practice apply the risk analysis principle, in this case by determining risk on the basis of the acute reference dose and consumption data. The particular issue raised here is mainly technical and relates to the speed of updating the consumption data required to determine the risk of exposure. An important element to calculate ARfD rates is the consumption rate of a product which varies by MS; to address this, EFSA have developed the European Primo model which is using consumption data submitted by MS. When a new EU MRL is established the (worst case) consumption figures from the EU Primo model are used to determine if the MRL is safe. However, updating Primo has a considerable lag-time; therefore, MS use in the risk assessment their own consumption data and are unfamiliar with the actual consumption figures of other MS. This can result in considerable differences in risk assessment between MS. It is noted, nonetheless, that the MS WG on RASFF is working on a more harmonised approach for such practical issues of risk management, including through the development of standard operating procedures (SOPs).*

(a) Notes highlight the actual risk analysis process followed in each case.

(b) The 6 colouring agents are: sunset yellow (E110), quinoline yellow (E104), carmoisine (E122), allura red (E129), tartrazine (E102) and ponceau 4R (E124)

(c) Regulation (EU) 528/2012 lays down rules for active substances to be used as biocides (e.g. disinfectants) and biocidal products. Regulation (EC) 396/2005 establishes a list of "pesticide" substances and determines MRLs for these substances in given commodities; the definition of "pesticide residues" in this Regulation includes active substances currently or formerly used in plant protection products (PPPs), including those which may arise as a result of use in veterinary medicine and as a biocide. Default pesticide MRLs are applied to active substances falling within the scope of Regulation (EC) No 396/2005, for which no specific MRLs are set.

(d) Effects of vitamin D: the EFSA opinion was published in September 2011 when all the resources of the Commission were focused in the last steps for the establishment of the list of permitted general function

(article 13) health claims. When the discussions with the MS were launched on Vitamin D and the risk of falling, there was difficulty to agree on the most appropriate conditions of use for this claim.

(e) *Effects of glucose: the Commission was taken to court on this case. EFSA has explained that the applicant wanted initially a claim on endurance but no specific evidence was provided. In its opinion EFSA states that "in the context of the information provided, and in the context of the clarifications provided by the applicant during the validation of this application, the Panel notes that the clamed effect refers to the contribution of the food constituent to energy-yielding metabolism". The conditions of use proposed by EFSA are that a food should be a significant source of glucose based on the reference intakes for sugars. However, the Commission considered it confusing for consumers on the one hand having a claim promoting the intake of sugars while at the same time national and international authorities advise consumers to cut down their sugar intake. There are also other cases where the Commission rejected claims despite a positive assessment "due to other legitimate factors", e.g. sodium and maintenance of normal muscle function, as this claim is contrary to the general principles for health claims (the use of this claim is considered misleading as it contradicts generally accepted scientific advice, European, national and international authorities informing the consumer to reduce salt intake).*

(f) *Effects of caffeine: the Commission requested EFSA to undertake a safety assessment of caffeine intake in February 2013. Until then, the safety of the overall caffeine intake, from all sources, and acceptable use levels was never assessed. EFSA published its scientific opinion on the safety of caffeine on 27 May 2015. The Commission discussed this opinion and the concerned claims on caffeine (which were put on hold pending EFSA's safety assessment) in the context of the latest two working Group meetings (June and November 2015). Following the consensus of the MS, the Commission is now proceeding with internal procedures before tabling these claims to a future meeting of the Standing Committee PAFF for an opinion.*

Source: Agra CEAS, based on findings from the consultation

b) Application at MS level

As already discussed, national measures tend to be adopted in areas that are not harmonised. The process of harmonisation as such has continued since the adoption of the GFL, so that today most of the areas of feed/food law are harmonised. This context needs to be taken into consideration when assessing the application of Article 6 for measures taken at MS level.

According to the feedback received by MS CAs, prior to the introduction of the GFL, most MS applied some form of risk analysis, albeit non systematically, on a case by case basis (*indicator 20.1c*). For the most part, there were neither binding national legal provisions nor internationally recognised documents that defined risk analysis. Although, in some cases, the principle that food law shall be based on risk analysis existed in national food law, and separation of risk assessment from risk management was applied (**Table 5**), the principle and its three components were not legally defined and binding as is the case in the GFL. However, the work of certain international organisations[141], including Codex Alimentarius, helped MS to familiarise with the concepts of risk management, risk assessment and risk communication[142]. The contribution of these international bodies/fora in the development of awareness and understanding of the risk analysis principles amongst risk assessors and risk

[141] Examples of such work were provided by MS CAs, as follows:
- Application of risk analysis to food standards issues, Report of a Joint FAO/WHO
- Risk management and food safety, Report of a Joint FAO/WHO Consultation Rome, Italy, 27 to 31 January 1997
- Application of Risk Communication to Food Standards and Safety Matters, report of a joint FAO/WHO Expert Consultation, Rome, Italy, 2-6 February 1998
- Principles of risk assessment of food and drinking water related to human health, ILSI Europe, 2001
- The preparatory work of the Codex Alimentarius that led to the adoption and publication of the working principles for risk analysis for application in the framework of the Codex Alimentarius in 2003 and later the working principles for risk analysis for application by governments in 2007.

[142] Including through the 2007 Codex guidelines "*The Working Principles for Risk Analysis for Food Safety for Application by Governments*". These are intended to provide guidance to national governments for risk assessment, risk management and risk communication with regard to food related risks to human health.

managers played a key role particularly in the new MS that joined the EU after the adoption of the GFL.

In the feed sector, the application of risk analysis in the MS was even more piecemeal; where it existed it tended to be applied more in the case of feed additives. Not only many of the consulted MS had no national legal provisions or other reference document that defined "risk analysis", but also at international level – notably Codex Alimentarius - there were in that time no reference documents referring to risk analysis in terms of animal feed. However, it should be noted that, since the 1970s there was EU legislation in place for feed additives (Directive 70/524/EEC) in which a reference to prior risk assessment by an independent scientific committee (reference to the Scientific Committees of the European Commission), therefore partly implementing the risk analysis approach, was explicitly foreseen[143].

As a general conclusion, **there was neither a common framework nor harmonised application of the risk analysis principle amongst MS before the GFL**, and even taking into account the best practice examples of **Table 5**, responsibilities were often divided amongst different CAs, while separation of risk management and risk assessment, consideration of other legitimate factors and stakeholder consultation/exchange was not systematically applied (in particular the risk communication component was not formally addressed).

Table 5: Application of risk analysis in MS, prior to the GFL (examples) ***(a)***

MS	Situation prior to the GFL
BE	The principle that food law shall be based on risk analysis was stated in Belgian Food Law since 1964. Furthermore, the principle that national food legislation shall be based on science was laid down and in Law of 24/01/1977 concerning the protection of consumers' health. The scientific opinion of the Superior Health Council (SHC), established in 1849, was required for setting legal rules regarding food additives, contaminants, food contact materials, detergents, dietetic food, nutrients and other substances added to food. The SHC was an independent scientific body, fully separated from risk management. Management decisions regarding food law (except in the veterinary legislation regarding hygiene of food from animal origin) were taken by the General Food Inspectorate within the Ministry of Health; these decisions had to be based on the SHC scientific opinions, and had to take into account other legitimate factors, following also stakeholder consultation ("Advisory Commission on Food"). This approach was applied in the case of national (non harmonised) legislation in the above areas. In the feed sector, although the base Law (Law of 11/7/1969 dealing with raw materials for agriculture, horticulture, forestry and animal husbandry) did not explicitly foresee risk analysis, authorities could impose a mandatory approval or registration for raw materials (e.g. feed additives, feed materials) used in animal feed. However, there was no distinction between risk assessment and risk management (i.e. no designated independent national scientific body for risk assessment), and stakeholder consultation/exchange was more limited. Following the 1999 dioxin crisis, the organisation of the food safety in Belgium was extensively reviewed with new structures set up and implemented in 2000, i.e. prior to the adoption of the GFL. In particular, the law of 4 February 2000 established the Federal Agency for the Safety of the Food Chain (AFSCA) that is competent for the official control and the risk management, and the Royal Decree of 23 May 2001 created the Federal Public Service of Health, Food Chain Safety and Environment Competent authority for policy and food/feed legislation. Risk assessment continues to be performed by the SHC.
FI	Prior to the GFL, risk analysis was applied in Finland (FI) but not systematically. However the risk management decisions were based on some kind of risk assessment (in a narrower sense), involving scientific evidence from national risk assessments, the EC Scientific Committee of Food, and FAO/WHO. There was separation of risk management from risk assessment, although not as clear as today, some consideration of other legitimate factors and stakeholder consultation and exchange. This approach was applied in the case of national (non harmonised) legislation on food additives, contaminants, food contact materials and feed additives.
FR	The Decree of 15 April 1912 taken for application of the law of 1 August 1905 on fraud and falsification contained, although not-formalised, the principle of separating risk management and risk assessment, for which assessment bodies were appointed to be the Conseil Supérieur d'hygiène publique de France

[143] Also, in the case of undesirable substances in feed (former Directive 74/63/EC), a procedure was laid down for taking into account developments in scientific and technical knowledge (Article 6).

MS	Situation prior to the GFL
	and the l'Académie Nationale de Médecine. France has supported this organization, which led to the creation of AFSSA (Agence Française de sécurité sanitaire des aliments) by Law No. 98-535 of 1 July 1998 on the strengthening of health surveillance and monitoring of the safety of products intended for humans. The establishment of AFSSA* in 1998 aimed to apply the requirements of transparency, independence and scientific and technical quality of the risk assessment, in line with the principles of risk analysis. Thus, at the time of the adoption of the GFL, the organization in France was already based on a separation of risk assessment and risk management. Other legitimate factors were taken into account, e.g. in food additives the technological interest in the use of the additives. There was also stakeholder consultation and exchange of information. This approach was applied in the case of national (non harmonised) legislation in areas such as food additives, processing aids, food contact materials etc. ** The current national food safety authority ANSES (Agence nationale de sécurité sanitaire de l'alimentation de l'alimentation et du travail) was created in 2010 by merger of the AFSSA and the French Agency for Health Safety Environment and Labour (AFSSET).*
SK	The risk analysis (except risk communication) was applied in the Slovak Republic since 1976, on the basis of the principles laid down in Codex Alimentarius. Risk assessment was already based on available scientific evidence provided in an independent, objective and transparent manner. Risk assessment was separated from risk management: the Research institute for preventive medicine was responsible for risk assessment as the basis for risk management in the food area. The Research institute for feed and the Institute for experimental veterinary medicine were responsible for independent risk assessment for feed. National Food legislation adopted by the Ministry of Health has been based on risk analysis principles since 1976, including national legislation for food additives, contaminants, food contact materials, and pesticide residues in food. In the feed sector, legislation was adopted by the Ministry of Agriculture, and every new feed additive was under pre market control (case by case), with the authorisation based on risk assessment prepared by the relevant scientific bodies (the Research institute for feed and the Institute for experimental veterinary medicine).
UK	The framework for science governance, as summarised by the UK Food Safety Authority (FSA) pre-existed the GFL and envisaged all the base principles of Article 6: separation between risk assessment and risk management, stakeholder consultation and exchange, and consideration of other legitimate factors. The process is further described in the FSA website: http://www.food.gov.uk/sites/default/files/multimedia/pdfs/governance-framework.pdf

(a) The Table draws on examples of best practice, based on the evidence provided during the consultation by MS CAs (survey and case study). In this sense, it represents the situation in (selected only) MS prior to the GFL, where this relatively closely resembles the main elements of the risk analysis as defined in Article 6.

Source: Agra CEAS Consulting, based on MS CA consultation

In most MS that contributed to the case studies, there have been considerable adjustments to apply risk analysis as laid down in Article 6 (*indicator 20.1d*). Considerable effort was necessary to achieve this, including through the establishment of new structures/bodies, adaptation of existing structures, systems and procedures, development of appropriate research methodologies, and training/workshops. The adjustment process has taken many years and is still not fully achieved today.

According to the consulted MS CAs, each of the risk analysis steps can present difficulties, depending also on the issue in question. The main challenges were: for risk assessors, to integrate the risk assessment principles into the scientific process and to collect the data required for risk assessment purposes (e.g., occurrence data and consumption data); for risk managers, to raise the appropriate questions and interpret/use the outcomes of risk assessments to reach management decisions; and, to develop risk communication.

The observed challenges include any combinations of the following: restricted available resources and shortage of staff with the required specialist training; lack of sufficient or representative data; insufficient scientific background (e.g. risk assessment of emerging risks; complex issues such as cocktail effects and multi-sources of endocrine disruptors; application of appropriate risk assessment methodologies[144]); insufficient time available to

[144] For example, quantitative risk assessment (deterministic or probabilistic) or newer methodologies such as BMDL (Benchmark Dose (Lower Confidence Limit), MOE (margin of exposure) (i.e. how large does the MOE/MOS need to be to be safe). The required scientific knowledge also leads to difficulty to choose the appropriate risk assessment methodology.

complete all risk analysis steps; insufficient/outdated national legislative framework; and, consideration of other 'legitimate' factors. The intensity of these challenges varies on a case-by-case basis, depending on the issue in question. More generally, it has been difficult to manage the large and increasing number of substances to evaluate and to respect the different regulatory procedures and deadlines applicable in the different areas.

All these areas were already challenging for MS when trying to apply risk analysis prior to the GFL, and were not due to Article 6 as such. If anything, by laying down general principles rather than a fixed method of application, Article 6 allowed a more tailored approach to the application of risk analysis in the different areas, which is largely seen as positive. In some cases and for various reasons, the adjustments carried out at MS level were a parallel process, and it was possible to integrate newly formed structures in the adjustment process to ensure a continuum (e.g. BE following the 1999 dioxin crisis; DE following BSE; in the new MS in preparation for accession; in FR following the appointment of AFSSA in 1998) (**Table 6**).

In particular, the extent to which adjustments were necessary depended on two factors: the baseline situation at which MS were found prior to the GFL (**Table 5**); and, the extent to which MS considered it important to proceed to a full implementation of Article 6 for their own purposes. The latter was determined by the extent to which national risk assessments were considered relevant and necessary, given the growing harmonisation in feed/food law and the provision of risk assessment by EFSA, against the considerable investment required for establishing a fully independent and competent scientific risk assessment function.

An important element of MS' adjustment process was the establishment of independent scientific bodies, effectively separating risk assessment from risk management (**Table 6**). This has been a long process (the current organisation of food safety bodies in MS is described in the latest EU Food safety Almanac, 2014). The establishment of scientific bodies to carry out independent risk assessments has been neither desirable nor feasible for all MS. The costs of risk assessments can be very high, given also the data collection needs (e.g. consumption data, occurrence data in the food chain, toxicological data)[145]. As an illustration, the DE BfR had a budget of nearly €68 million in 2013 for its statutory tasks; since its establishment in 2010 the FR ANSES had a budget of about €130 million; even in smaller MS, e.g. BE and FI, budgets of national risk assessment bodies have been very considerable[146]. Although these bodies secure some funding from participation in research programmes, and in some cases income from regulatory functions (e.g. fees charged to FBOs for performing official controls), the majority of their budget comes from state funding.

[145] This is an important problem for consumption data that require high budgets to conduct regular Food Consumption Surveys among the population, among specific groups of the population (pregnant women, infants and young children, elderly, immigrants…) or for specific food/niche products (food supplements, enriched foods, flavourings, additives etc.). This partly explains data gaps in these areas.

[146] The budgets provided here are for illustration purposes only and are not directly comparable, as these bodies have different structures, tasks and roles. It is not possible either to compare the budgets devoted to this function before and after the GFL given that some of these structures were only created after the GFL, while before the GFL the risk assessment function was in many MS divided between different authorities/services.

Table 6: Adjustments in MS to apply risk analysis as laid down in Article 6 (examples) *(a)*

MS	Changes following the GFL
AT	The GFL has brought an integrated food chain approach and has been the driver/inspiration for the creation of the Austrian Health and Food Safety Agency (AGES) in 2002 as the single institution to carry out risk assessment from farm to table (previously food safety was dealt with by a number of institutions). This has allowed a more harmonised approach for risk assessment compared to the situation prior to the GFL. Also, food and feed areas were better integrated. The approach towards other legitimate factors remained similar.
BE	The main changes to the national structures (establishment of two separate CAs, with their own scientific advisory bodies and advisory platforms, including AFSCA) happened in 2000 following the 1999 dioxin crisis. Prior to this, the national risk analysis already followed some of the key risk analysis principles (see previous Table). Thus, the entry into force of the GFL in 2002, and the application of article 6, was largely a continuity of what already existed. Nonetheless, several further adjustments were necessary, as a result of Article 6, as follows: a) Establishing cooperation agreements, coordination procedures and communication channels between the newly created CAs; b) Putting in place cooperation structures and procedures with EFSA, as well as communication channels: representation in the Advisory Forum and its working group on communication, establishment of the Focal point, building of the network of article 36 organisations; c) The establishment of a national platform to collect data on and coordinate the investigation of foodborne outbreaks; d) In response to criticism by certain stakeholders, rules were further strengthened in 2013: the Law of 21/12/2013 aims at strengthening transparency, independence and credibility of the decisions taken and advice delivered in the areas of public health, food chain safety and environment. Implementation of that law into practice is still on-going.
CZ	Administrative structures were fundamentally changed in 2001, in the context of the country's pre-accession process. Thus, the entry into force of the GFL, and the application of article 6, was largely a continuity of these new structures. The new structures were developed based on the Czech Food Safety Strategy (Governmental decree No. 1320/2001 of December 10, 2001). The Food Safety Coordination Unit (risk management), national scientific committees (scientific advice) and Food Safety Information Centre (risk communication) were established. An independent body carrying out risk assessment for the feed/food chain has not been established in the Czech Republic; a body dealing with human health risk assessment already existed prior to application of GFL (National Institute of Public Health). More generally, risk assessment is not sufficiently financially supported in the Czech Republic.
DE	In Germany, scientific risk assessment is the competence of the Federal Institute for Risk Assessment (BfR) and risk management falls under the competence of the Länder authorities and the Federal Office of Consumer Protection and Food Safety (BVL) and the Federal Ministry of Food and Agriculture (BmEL). The creation of BfR (November 2002) followed the lessons learnt from the BSE crisis, in a similar timeframe and for the same reasons that inspired the creation of EFSA (separation of risk assessment from risk management) at EU level.
FI	Considerable adjustments were necessary to adapt existing structures, systems and procedures in order to integrate risk analysis in the food sector. The Finnish Food Safety Authority Evira was established in 2006. The field of operation of Evira includes laboratory operations, risk assessments and scientific research as well as controls.
FR	No particular adjustments were necessary. The separation of risk assessment and risk management already existed within AFSSA. The establishment of ANSES from the merging of two competent risk assessment bodies in 2010 allowed it to have an approach to risk and health issues that was more integrated and wider scope (covers expertise for the assessment of occupational risks) than that of EFSA. This is particularly the case for the risk assessment of substances that can be employed in various uses, which at EU level are the responsibility of various agencies (ECHA, EMA).
IT	Prior to the GFL, there was no separation between risk assessment and risk management. With the GFL, a law was adopted in 2005 to ensure the separation. Three different bodies apply risk assessment in their respective sectors: national Committee for Food Security (CNSA) (not an agency); Istituto superiore di sanità (ISS); and, Consiglio Superiore di Sanità. Although risk assessment was already applied in the past this was not systematic, for example, not applied systematically in the areas of feed additives and veterinary medicinal products.
SK	Following the GFL, a network of 26 groups of national scientific experts was established, which are coordinated by the Food Safety and Nutrition Department at the Ministry Agriculture.

(a) The Table draws on examples of adjustments, based on the evidence provided during the consultation by MS CAs (survey and case study).

Source: Agra CEAS Consulting, based on MS CA consultation

On the other hand, further harmonisation in some sectors and the central role of EFSA in providing risk assessments, has reduced the need for risk assessment activities at national

level and has led to cost savings. For example, further harmonisation in 2002 in the sector of feed additives and undesirable substances in feed means that these are no longer evaluated at national level, which according to MS CAs was previously a very important workload.

The cost savings from the central EFSA approach have been particularly important for smaller MS with limited financial and scientific resources, as it allowed them to rely on EFSA's scientific opinions and risk assessment in most cases (facilitated by the increased harmonisation of EU legislation and central role played by EFSA in these cases). Nonetheless, some MS that do not have dedicated scientific bodies in place for this function indicated that although risk assessment is not financially sufficiently supported in their countries, they are still examining options for developing an independent risk assessment body by using/consolidating existing structures.

Three main drivers continue to generate the need for national risk assessments:

a) The need to provide the scientific basis for MS measures in non-harmonized areas (e.g. processing aids) or partially harmonised areas (food contact materials, contaminants in food, food supplements).
b) Factors of exposure to risk (e.g. from contaminants) can be very different at national level compared to the EU average, determined *inter alia* by consumption levels/patterns for different foods as well as production systems.
c) Maintaining and/or expanding national scientific risk assessment capacity allows MS to offer/supplement the expertise available to EFSA. Where necessary, EFSA asks additional data/scientific information from MS through the dedicated scientific networks and/or EFSA national contact points, including during the development of scientific opinions. The EFSA model is actually based on the functioning of this EU-wide risk assessment network and is highly dependent on the expertise available in MS. Most experts who are members of EFSA's Scientific Committee/panels and the various EFSA Working Groups are employed by national scientific agencies. Thus, the EFSA model effectively pools the available expertise across the EU.

Following the GFL, according to 81% of stakeholders and 21 of the 25 responding MS CAs, national measures on feed and food have been adopted on the basis of risk analysis, as laid down in Article 6 (survey results, Q29) (*indicator 20.1e*). Nonetheless, while according to MS CAs this has occurred always/in most cases (14 of 25 MS CAs), the majority of stakeholders (57%) indicate that this has not occurred systematically.

As already discussed, as a result of further harmonisation in EU feed and food law, risk analysis in the context of feed/food legislation is mainly applied at EU level (risk assessment by EFSA; risk management by DG SANTE regulatory Committees). With the completion of the harmonisation process in nearly all areas of feed and food legislation (leading to the repeal of many pieces of national legislation) and following the establishment of EFSA, there has been a continuous decrease in necessity of national risk assessments at the basis of food law. Thus, for the most part, MS rely mostly on EFSA opinions to participate in the risk management process at EU level and, in certain cases, also to take decisions at national level[147].

Nonetheless, there is still need of national scientific risk assessments to support national risk analysis in areas which are not yet fully harmonised (e.g. food contact materials, food

[147] For the most part, EFSA opinions feed into the EU level risk management. There can be cases where MS have asked for EFSA opinions on non-harmonised issues or also cases where EFSA provided general guidance on how to assess safety issues within certain non-harmonised areas, e.g. the safety of food supplements.

contaminants, etc.); in addition, this capacity is used to support other activities where a scientifically based approach is required to assess risks[148]. Stakeholders, including consumer organisations, noted that, the food/feed safety considerations of Articles 14 and 15 act as a driver for the adoption of national legislation, through the scientific appraisal and/or the risk management response given in different MS (e.g. Bisphenol A, contaminants, salmonella in feed, trans fats)[149].

Regarding animal feed (additives/undesirable substances), the EU legislation has been fully harmonised in 2002 (Directive 2002/32/EC regarding undesirable substances in animal feed) and 2003 (Regulation 1831/2003 regarding feed additives) based on the principles of risk assessment as foreseen in GFL (central role of EFSA). This means that MS rely on the outcome of EFSA's risk assessments and do not undertake any specific risk assessments anymore at national level.

For the most part, the non systematic application of risk analysis as the basis for national measures is attributed by MS CAs to the difficulties and constraints associated with the implementation of fully fledged risk analysis. As outlined above, key difficulties/constraints for risk managers (not only at MS level but also at EU level) relate to the complexity of issues, staff capacity/budget required, and data needs/existing data gaps to perform risk assessment. These difficulties/constraints prevail throughout the process, such as when:

- Performing a full risk assessment, as generally required to justify national measures taken in application of Article 14 (food considered unsafe because of the presence of a harmful substance where there is no European legislation);
- Raising the appropriate questions to the risk assessor. The first stage in the risk analysis process is the formulation of the request and mandate for risk assessment. This determines whether the outcome of the risk assessment is fit-for -purpose;
- Understanding, interpreting and using the outcomes of risk assessments in management decisions. This is especially the case when new methodologies are used[150], and when dealing with the uncertainties outlined in scientific opinions;
- Dealing with the pressure (politics, media) when a food safety issue is identified and there is a risk for public health while trade is disrupted[151];
- Dealing with the more extended timeframe required by risk assessors to provide scientific opinions that are conform with risk assessment methodologies.

Certain national MS measures, according to stakeholders, are not adopted on the basis of risk analysis, leading in some cases to an excessive application of the precautionary principle by MS, which does not reflect fully the principles of Article 7 (*indicator 20.1f*). Nonetheless, although stakeholders have experienced certain differing standards between MS (e.g. on contaminant limits), they were not in a position to judge on what basis these were established nationally. Stakeholders indicated that in some cases, for example salmonella in feed, national measures have not been based on the assessment of risk, but rather of hazard.

[148] Providing scientific support is used in practice, for example, to better define the official control activities by risk ranking (risk-based control program), or to better manage cases of incidents, involving alert and recall procedures and tracing back the source.

[149] Similar safety considerations may have acted as a driver for measures taken by MS before the GFL, but Article 14 provided a common reference point for taking into account such considerations.

[150] For example, when no indication is given on the required/acceptable MOS/MOE limit. Examples:

- Smoke flavourings: MOS of 300 was the general guidance but it is actually case by case depending on different factors. (EFSA opinion http://www.efsa.europa.eu/en/efsajournal/pub/1325.htm) However it is difficult for risk managers to judge these factors such as the quality of toxicological data.
- Cadmium and arsenic EFSA opinions: the conclusion gave no indication on the required MOE level.

[151] Examples include: perchlorate in fruits and vegetables, e-coli in sprouts (outbreaks in Germany that affected other Member States).

MS CAs indicated that for the most part national measures are adopted on the basis of risk analysis, as long as this is considered appropriate to circumstances (as provided by Article 6) and/or is possible according to the available evidence and time limits for reaching a decision. For example, France indicated that it has defined without recourse to the principles of risk analysis the labelling rules on GMO-free food, as this was not applicable in this case (the application of risk analysis is not required for measures such as labelling where the objective is to inform consumers and not to protect health by managing a risk). There is some evidence that where national measures were not adopted on the basis of risk analysis they were subsequently withdrawn/amended (e.g. GR, amendments to legislation regarding the production and distribution of bakery products).

The issue is complicated by the extent to which MS take measures on the basis of the precautionary principle within the meaning of Article 7 (see EQ21). Food contact materials (e.g. BPA), contaminants, and trans fatty acids were examples where MS CAs also indicated that the precautionary principle was used in some MS (**Table 7**).

Table 7: Cases where the basis of national MS measures is questioned *(a)*

	Aspects that are being questioned
food contact materials (BPA)	The differing national approaches towards bisphenol A (BPA) are questioned by industry stakeholders and several MS CAs, when the risk assessment by EFSA should be the basis for EU-wide legislation. Since 2011, Belgium, Denmark, Sweden and France have all initiated national legislation restricting bisphenol-A in food contact materials, all applying different rules. France has issued national legislation banning BPA in all food contact materials in France with a date of enforcement as of 1st January 2015. The French authorities took this decision despite the fact that the final Scientific Opinion on the safety of BPA had not yet been published by EFSA (published in January 2015). The EFSA opinion is now available (EFSA Journal 2015;13(1):3978) and does not support the actions taken by France. An indicator of the extent of the problem in the field of food contact materials more generally is that other MS appear to be considering the introduction of national measures; e.g. Germany is considering national legislation on printing inks and mineral oils from recycled paperboard; Belgium is considering national legislation on coatings.
contaminants	Another area where legislation is not fully harmonised and operators have expressed concerns on whether national measures have been taken on the basis of risk analysis or on a precautionary basis are contaminants. Moreover, even for contaminants where limits are harmonised, operators indicated that there are differences in implementation between MS. According to operators, authorities in some MS sometimes apply stricter maximum limits (MLs) for contaminants in food and undesirable substances in feed than the ones recommended at EU level. For example, in one MS the national food association expressed doubts on whether the stricter maximum regulatory limits applied in that MS as regards certain contaminants in food (e.g. lead), compared to the EU legislation, is based on a risk analysis. Associations representing the retail, distribution and trade sector indicated there are often differences between national limits on some contaminants which cannot be justified.
salmonella in feed	Several stakeholders representing operators indicated that the management of salmonella risk in feed, which is not harmonised across the EU, is an area of concern. Whether the measures are always based on risk analysis taking into account the risk assessment was questioned, in particular given that certain MS consider all salmonella serotypes in feed to be a concern for public health whereas other MS do not. Stakeholders indicated that this is an example where measures have not been based on the assessment of risk, but rather of hazard.
trans fats	Consumer organisations argue that although scientific evidence on trans fatty acids shows that they are harmful, there is no political action on this at EU level. As a result, some MS have taken action, e.g. Denmark has introduced legal limits on industrially-produced trans fatty acids in food, but such national measures are being questioned by some industry stakeholders.

(a) The Table draws on examples of cases of national MS measures being questioned, by business operators and/or MS CAs (source indicated in each case), based on the evidence provided during the consultation by MS CAs and stakeholders (surveys and case study).

Source: Agra CEAS Consulting, based on consultation

III.4.1.2 Separation of risk management and risk assessment process in practice

a) Separation at EU level

As already noted, a major element introduced by the GFL has been the separation between risk assessment and risk management at EU level, as foreseen in Article 6. This was made effective with the creation of EFSA, as an autonomous agency to carry out risk assessment, separated from the risk management function of the Commission. This separation created the need for continuous dialogue and interface between EFSA and the Commission to ensure the coherence of the risk analysis process. At Commission level, this need was addressed by the creation of a dedicated Unit within SANTE ensuring daily interaction with EFSA. These arrangements ensure compliance with Codex standards, which foresee a legal and functional separation of the risk assessment and risk management phases of risk analysis while maintaining interconnection. Thus, at EU level, the GFL has created the separation with the establishment of EFSA but dialogue with the Commission has been ensured (interconnected).

All consulted parties agree that the **separation of the risk assessment and risk management functions at EU level**, as described above, **have improved considerably over time and is generally functioning well in practice** (*indicators 20.4a and 20.4b*). Although there are certain areas which are functioning less well, these are addressed by ongoing initiatives, as described further below.

In terms of boundaries and difficulties encountered with following the definitions of risk assessment, risk management and risk communication, **establishing such boundaries, in practice, is a difficult act of balance**. For example, some consulted parties commented that EFSA's scientific opinions sometimes extend beyond the boundaries of risk assessment, into risk management. EFSA has clarified that the Agency cannot get involved in setting protection goals, which is the responsibility of the risk manager; EFSA is only involved when risk managers ask EFSA's advice on the setting of protection goals. According both to business operators and MS CAs, **in most cases the boundaries have been respected**[152].

Risk assessment by EFSA is generally considered to be independent, objective and transparent. EFSA has the most advanced/robust system in place amongst European agencies to ensure independence and transparency of the risk assessment process and outputs, which is explicitly laid down in its policy and rules of procedures (see EFSA website), and is confirmed in independent reports[153]. This system is applied consistently in the various sectors of EU food law. EFSA's workload today involves more regulated products (i.e. covered by EU authorization and approval systems: food/feed additives, nutrient sources, food enzymes, food contact materials, health claims, flavouring substances, GMO and novel foods) compared to the time when the GFL came into force[154].

Beyond the overall positive feedback, there are calls to overcome certain weaknesses related to the effectiveness and efficiency of EFSA, as follows:

- The European Economic and Social Committee recently issued an opinion on the role of EFSA[155], outlining its major contribution in preventing health risks in Europe but also

[152] Nonetheless, operators noted some controversial cases where EFSA's provision of recommendations is perceived to fall more into the remit of risk management. For example, this was noted in the context of EFSA scientific opinions on the safety and efficacy of the use of certain compounds (e.g. cobalt compounds; zinc compounds) as feed additives. (cobalt compounds: EFSA Journal 2012;10(7):2791); zinc compounds: EFSA Journal 2015;13(4):4058).

[153] 2012 report of the second EFSA external evaluation; 2012 of the European Court of Auditors on the management of conflict of interest in selected EU Agencies.

[154] According to the consulted experts, EFSA work on regulated products has increased from an estimated 20% to more than 60-70%. These figures could not be verified by other independent sources.

[155] CES NAT/633: Opinion of the European Economic and Social Committee on the current system guaranteeing food safety and security of the food supply in the EU and ways to improve it. Rapporteur: M. Igor ŠARMÍR, 18 March 2015 (NAT/633 – EESC-2014-02479-00-00-AC-TRA (FR) 1/11).

highlighting areas that need addressing such as more transparency of the procedure for assessing new products to ensure consumer confidence[156].

- The latest (2012) independent evaluation of EFSA, although generally positive about most of EFSA's processes, made certain observations and recommendations to improve efficiency [157] . The EFSA Management Board included many of the report recommendations in the EFSA Multiannual Plan 2014-2016[158].

The above concerns were reiterated by the industry during the consultation. The industry has raised various concerns which fall in two major areas: a) deficiencies in communication between EFSA and industry, leading to unpredictability, lack of clarity in terms of e.g. data requirements, delays and additional regulatory costs; and, b) development of mandates (by the Commission) and their impact on EFSA opinions (see below). Regarding communication between EFSA and applicants, the industry notes the striking difference between the more limited opportunities for applicants to interact with EFSA, compared to the more extensive opportunities to interact with other EU risk assessment agencies, such as the European Medicines Agency (EMA) and the European Chemicals Agency (ECHA). The impact of these communication problems and delays is that, concretely, the authorisation process is still too slow/cumbersome. For example, although the re-evaluation programme of approved food additives was adopted in 2010 (Regulation (EU) 257/2010) only around 10% of food additives have been revaluated to date.

There are **ongoing exchanges between EFSA, the Commission and industry** [159] with a view to improving EFSA's risk assessment process of regulated products. EFSA has launched an initiative to increase the efficiency, clarity and consistency of the assessment of regulated product applications, by the entry into force of new timelines for submitting additional or supplementary information to EFSA in May 2014 (EFSA Scientific Report - "stop-the-clock" guidance document, January 2014)[160].

Risk management - EU measures taken at the Standing Committee PAFF - is generally considered to **duly take into account the results of risk assessment and in particular the opinions of EFSA, as well as other legitimate factors**. However, as already noted in section III.4.1.1, the balance between science and other 'legitimate' factors in the final decision tends to be more questioned by stakeholders, considered not to be always transparent or consistent. This is linked both to the particular viewpoints of different interest groups, but also the technical complexity of issues and the sufficiency of risk communication

[156] *"For example, statutory studies submitted by manufacturers, which must prove that the product concerned is harmless, are not published in scientific journals and not only does the scientific community not have routine access to the raw data from these studies, but trade secrecy has been overtly invoked in several cases."* CES NAT/633 – EESC-2014-02479-00-00-AC-TRA (FR) 1/11, 18 March 2015.

[157] The EFSA evaluation (2012) noted that *"…the capacity to meet the industry's needs should be improved, balancing the need to respond effectively to industry needs with its independence and taking into account that applications cover more than 60% of EFSA's output."*

[158] The Plan states that EFSA *"…aims to provide food and feed operators with a more predictable regulatory environment and enhanced interaction….and to review its efficiency in handling applications within the context of existing legal frameworks and good administrative practice as well as streamlining its working processes."*

[159] Industry efforts on this are coordinated by an informal group of 17 associations representing different sectors (the so-called Parii Group).

[160] These so-called 'stop the clock' provisions establish the period of time granted to applicants to provide additional or supplementary information needed to complete the risk assessment. Industry stakeholders have called for further provisions on timeline/procedures for EFSA promising feedback to applicants which, according to them, is a step of the risk assessment process that currently results in delays and lack of information. They have also called for EFSA to refrain from adopting an inconclusive scientific opinion on an applicant product in case supplementary information has not been provided within the timelines defined in the guidance, given that the preparation of data/documentation may require more time and budget than envisaged by the document. They finally point out that the guidance documents are prepared without sufficient prior consultation and this is essential for ensuring that data requests and timelines can be respected (normally, EFSA is launching public consultation before adopting guidance documents).

to explain and justify the basis for the risk management measures. In terms of the latter, industry stakeholders have indicated that in some cases relevant information can only be found in: recitals of EU food regulations, but these only give some brief indications/explanations of how the decision was taken and what were the factors, other than science, that were into account; and/or, the minutes of the Standing Committee PAFF reports, but these are very concise and do not usually contain any explanation.

Although there is no EU framework for transparency of the risk management process (i.e. clearly explaining how the risk assessment and other factors were weighted, leading to the final decision), there are procedures in place to ensure a certain transparency. In most cases, the Commission carries out public consultation, consultation in relevant working groups (WGs) and, in some cases of potential high impact measures, impact assessments. In some cases, information on the decision making process is published on the website of the Commission.

Some general principles of risk management appear clearly and transparently in other secondary legislation. Examples include the ALARA principle[161] (contaminants), the principle of positive lists (food improvement agents)[162].

As already highlighted, most questions on management risks addressed to EFSA come from the Commission. The industry has complained about the relevance of the mandates developed by the Commission as this impacts on the outcome of EFSA opinions; several MS CAs have also raised the fact that they are not consulted on the mandate drafting although called to vote for the final decision at the Standing Committee PAFF. The formulation of these questions is important because it determines the adequacy of the risk assessment outcome and its relevance for addressing the needs of the decision making process at the Standing Committee PAFF; as discussed above, ongoing initiatives and discussions between EFSA, the Commission and industry aim to address this weakness.

Risk communication as such is not defined in Article 6 of the GFL, but a general definition is provided in Article 3.13, as the interactive exchange of information and opinions among all interested parties. Principles of risk communication are laid down in international contexts, including Codex Alimentarius, the WHO and the FAO [163]. As discussed above, according to most of the consulted parties and experts, risk communication is considered to be one of the weakest elements of the risk analysis process. Several of the consulted parties point to, sometimes, conflicting communications from European vs. national risk assessors, and also discrepancies between EFSA, the Commission (COM) and national level communications. This is considered to lead in some cases to a lack of clarity in the final decision-making particularly on the balance between risk assessment and other legitimate factors.

In April 2012, the Heads of MS Agencies endorsed a report on the transparent use of risk assessment in decision making. The objective was to develop transparency and rigour in the decision-making process comparable to that in the risk assessment process, so that the basis for risk management and the information and analysis used in this is clear, rational

[161] ALARA: "as low as can reasonably be achieved by following good practices at all the stages". This principle applies for setting maximum limits for chemical contaminants, and exists since Regulation (EEC) No. 315/93.
[162] The principle of positive lists applies for the authorisation of food improvement agents. Three additional authorisation criteria exist for food additives and enzymes: absence of safety concern on the basis of the available scientific evidence; reasonable technological need; and, not misleading for consumers (Regulations (EC) 1333/2008 and 1332/2008). The principle of reasonable technological need is not foreseen for flavourings (Regulation (EC) No. 1334/2008).
[163] FAO (1998): The application of risk communication to food standards and safety matters. Report of a Joint FAO/WHO Expert Consultation on the Application of Risk Communication to Food Standards and Safety Matters, 2-6 February 1998, Rome.

and justifiable, in line also with Codex Alimentarius principles[164]. A second report was adopted in September 2014 with the aim to identify actions for the development of frameworks and approaches to transparency in risk management decisions. However the recommendations have not yet been applied at national or EU level in food/feed legislation[165].

The above issues lead to a certain perception, amongst stakeholders, that there is lack of / insufficient transparency and consistency. In particular they question the way in which EFSA scientific opinions are further addressed, which can lead to delays or even perceived inconsistencies in the risk management process. Examples include those provided in **Table 4**. An area where the balance of 'other legitimate factors' versus science in the risk management decisions is often questioned by the industry as not being 'transparent' is the case of GMOs (**Box 2**). According to the industry, EU and national decisions on GMOs are to some extent driven by interplay between political considerations and public perception of the risks involved, and this has an impact in terms of potential supply disruptions.

Box 2: Case where the balance of 'other legitimate factors' in risk management is not clear – GMOs (source: industry)

In terms of GM import authorisations in the EU, while the risk assessment phase carried out by EFSA is making the EU authorisation system one of the strictest in the world. During the management process, some MS regularly do not take decision (abstain). This results in a "no-opinion" situation in both the Standing and Appeal Committees, and the final decision has therefore to be taken by the College of Commissioners, which is supposed to proceed without excessive delay (although there is no precise timeline for this).

There are currently 13 GM import authorizations (Maize MON 87460, Rapeseed GT 73, Soybean 305423, Soybean MON87708, Soybean MON87705, Soybean BPS-CV127-9, Maize T25, Cotton T304-40, Maize NK603, Rapeseed MON 88302, Cotton LL25xGHB614 and Cotton MON 88913) awaiting final decision by the EU College of Commissioners, following completion of the EFSA scientific assessment and EU risk management process. The final decision of some of these 13 GMOs is on hold since October 2013 (for example, MON 87460 is pending final decision since 21 October 2013).

The technical solution, which introduces harmonized rules for testing with the definition of methods for sampling and for analysis, applies in feed but not in food. The technical solution sets the "technical zero" at 0.1% (mass fraction of GM material in the tested material) at which results can be interpreted robustly.

Source: Agra CEAS Consulting, based on consultation with the industry

b) Separation at MS level

As already noted, there are differences in the organisation of food safety structures between MS, which suit the particular contexts and traditions/cultures in each country and reflect the historical diversity of food policy development in the MS. For example: food safety authorities can be part of the Ministry of Agriculture, or Health or Economy; some MS divide competences between Ministries by sector (e.g. food, agriculture, animal health, plant health, human health); some MS divide competences in terms of policy, inspection/controls between Ministries, and even at regional/local level. Such differences pre-existed the GFL and continue after the GFL. An important element of MS' adjustment process to implement Article 6 was a certain re-organisation of both the research and policy departments, and the separation of risk assessment from risk management; the actual form of separation varied, with many MS establishing independent scientific bodies (**Table 6**). As it stands today,

[164] This is consistent with the principles of good risk policy set out in the Codex Working Principles for Risk Analysis for Food Safety for Application by Governments (CAC/GL 62-2007).

[165] Nonetheless, in practice, there are cases where EFSA has moved towards more transparency, e.g. in the case of claims for pro-biotics, a dialogue was established with stakeholders to assess the situation, determine the data required for the risk assessment, and there was helpful interaction between scientists and stakeholders.

some MS have a centralised risk assessment body, while others have several scientific organisations covering the different fields which are coordinated in different ways, in some cases in the form of networks (*indicator 20.5a*). The diversity of MS' risk assessment bodies is apparent in the networks of scientific organisations supporting EFSA in the different fields[166].

The challenges faced by MS in implementing each phase of the risk analysis procedures have also been discussed above (*indicator 20.1d*). To some extent they are similar to the challenges that prevail at EU level. These include: in terms of risk managers' requests for scientific data, the need to address the appropriate questions; in terms of risk assessment the complexity of issues under examination and the extensive data gaps that need to be filled, set against time pressures and resource constraints; in terms of risk communication and the interactive exchange of information amongst all interested parties, this is often the weakest/most overlooked element of the risk analysis which results in a certain insufficient transparency and/or misunderstanding of the basis for the final decision, in particular the balance between science and other legitimate factors.

The differences in the organisation of food safety systems between MS, compounded by the challenges posed in implementing risk analysis, and differing socio-economic and political considerations/priorities affecting the final decision-making have led to differences in the implementation/application of Article 6 between MS. According to survey results (Q53), while there are a large number of 'don't know' responses (44% of all respondents), risk analysis is one of the top areas where such differences are identified (albeit to some extent/in some cases) (46% of stakeholders; 11 MS CAs) (*indicator 20.5b and 20.5c)*). This is followed by the application of the precautionary principle (42% of stakeholders; 10 MS CAs).

Examples of such differences have been noted by stakeholders in many of the areas of partly or non-harmonised legislation, including e.g. food contact materials, contaminants etc. This issue is acknowledged at EU level and steps have been taken to address it. Both the networks of scientific organisations supporting EFSA, and the EFSA Advisory Forum[167] play an important role in counteracting the potential differences between MS, by promoting a common view, preventing divergent opinions, and trying to build a European scientific community (training, twinning projects, exchanging information, expertise and best practices). In particular, the scientific network on the harmonisation of risk assessment methodologies (launched in June 2012) aims to build mutual understanding of risk assessment principles and methodologies amongst MS risk assessment bodies and to provide increased transparency in the cooperation between competent risk assessment authorities in the MS and EFSA.

c) Consideration of other legitimate factors

The consultation indicates that other legitimate factors[168] tend to be taken into account in EU/MS risk management process, but the exact range of factors varies on a case by case basis, according to needs (MS CA survey results, Q31a) (*indicators 20.3a and 20.3b*). As in

[166] There are 14 such networks supporting EFSA activities, in the areas of: animal health and welfare; biological hazards; biological monitoring; dietary and chemical monitoring; emerging risks; food ingredients and packaging; GMOs; plant health; pesticides; and the Scientific Committee (network for the harmonisation of risk assessment methodologies). The diversity of the food safety organisation between MS is described further in the EU Food safety Almanac (2014).

[167] EFSA's Advisory Forum connects EFSA with the national food safety authorities of all 28 EU MS, plus Iceland and Norway.

[168] I.e. factors other than scientific opinions assessing the risk to health, such as economic feasibility, societal factors, traditions, environmental impacts, ethical impacts, and feasibility of controls.

the case of the precautionary principle, 'other legitimate factors' tend to be taken into account when there is lack of sufficient scientific basis and/or in view of the technical complexity (which also determines the feasibility of controls), e.g. analytical methods for GMOs or active ingredients in plant-based food supplements. In general, economic factors are often taken into account in the risk management decision process. Other factors come into play where specific national contexts and conditions need to be taken into account (e.g. production methods and consumption patterns in the case of managing the risk from certain contaminants). In some MS, the technical and economic feasibility of controls is a key factor always considered, since this addresses costs of implementation amongst other considerations.

In the GFL, there is no definition of other legitimate factors in relation to its objectives. Guidelines for the application of these factors, including how and when to use them and how to balance them versus science in risk management are also lacking. **The decision making process may thus not always be consistent/transparent across the different sectors, or at least may not appear to be so**. Although some specific legitimate factors are foreseen in some cases in other secondary legislation laying down additional specific procedures for authorisation, including for example on food improvement agents, food contact materials, health claims[169], other factors can still be taken into consideration since the GFL principle on risk analysis applies to all types of measures. Cases of EU measures where 'other legitimate factors' are taken into account are presented in **Table 8** and illustrate the diversity of factors considered and their case-by-case application. The factors may be various and multiple, depending on the case, including: nutritional advantages/ disadvantages, acceptability by the consumer, feasibility of controls, quality, tradition, environmental impact, societal factors, ethical considerations (e.g. cloning), impact on non-communicable diseases (such as obesity, cardiovascular diseases, metabolic diseases), lack of mitigation measures, animal welfare.

Table 8: Consideration of other legitimate factors in various cases of EU measures taken on the basis of other secondary legislation (examples)

EU measure	Factors considered
Food contact materials: ban on Bisphenol A (BPA) in baby bottles (Regulation (EU) 321/2011)	*Risk assessment*: EFSA recommended that the current TDI for BPA remained appropriate to protect all consumers including those potentially most vulnerable to adverse effects; *Decision*: ban of the BPA use in polycarbonate infant feeding bottles (0-1 year); *Other factors*: precautionary approach (uncertainties in EFSA opinion); high public/ media profile; high sensitivity of potential effects on vulnerable groups (infants).
Food improvement agents: list of food flavouring substances (Regulation (EU) 872/2012)	*Risk assessment*: for +/- 500 food flavouring substances, evaluation is not completed or additional scientific data are needed for completion; *Decision*: introduction of these non-evaluated substances in the list of authorised flavouring substances; *Other factors*: economic factors, worldwide history of consumption, avoid legal uncertainties, feasibility of the risk assessment.
Contaminants (Regulation (EC) 1881/2006)	*Risk management:* takes into consideration additional factors, beyond the protection of human health, into establishing maximum levels on various contaminants. Such factors include e.g., climate conditions in the different areas, practical issues regarding consumption (e.g. Baltic region fish species).
Contaminants: review of the maximum levels of cadmium in foodstuffs	*Risk assessment*: EFSA concluded that the mean dietary exposures to cadmium are close to or slightly exceeding the TWI. Exposure to cadmium at the population level should be reduced. For adults, starchy roots and tubers, grains and grain based products and vegetables and vegetable products are major contributors to exposure. *Decision*: the emphasis of the review didn't include the main contributors to the

[169] The Commission's rejection of health claims despite positive assessment by EFSA was done on the basis of other legitimate factors, in the sense that incompliance was identified with one of the general principles and conditions of the claims Regulation (EC) 1924/2006 (e.g. rejection of claim on sodium and maintenance of normal muscle function was considered misleading as it contradicts generally accepted scientific advice, European, national and international authorities informing the consumer to reduce salt intake).

EU measure	Factors considered
(Regulation (EU) 488/2014, amending Regulation (EC) 1881/2006)	exposure, in particular rice, potatoes, cereals, vegetables. Instead of reducing maximum limits, recommendation was given to stimulate mitigation methods and to conduct further research. The situation will be reassessed by 31/12/2018. *Other factors*: economic consequences for primary production of grains and vegetables. *Note: Similar examples with the revision of the maximum limits for lead.*
Health claims (Regulation (EC) 1924/2006) relating to sugars, fat and salt	*Risk assessment*: EFSA has given opinions for several claims relating to sugars, fat and salt. In some cases, these were not fully scientifically substantiated (e.g. in the case of glucose, the conditions of use proposed by EFSA are that a food should be a significant source of glucose based on the reference intakes for sugars). *Decision*: those claims have been rejected by the risk managers. *Other factors:* those claims were considered to be not in line with nutritional recommendations/guidelines/policy, negative impact on non-communicable diseases. *Note: the Regulation sets requirements for establishing health claims that involve both scientific aspects (e.g. that there is a cause and effect relationship in the claimed action of a substance) and practical aspects (e.g. that the claim can be understood by consumers and that clear and feasible instructions are given to achieve the beneficial claimed effect). In addition, the Regulation provides that a decision should be taken based on the opinion from EFSA and "any other legitimate factors"*, including the general principles of the Regulation (see also **Table 4**).
Feed additives (Regulation (EC) 1831/2003)	*Risk assessment*: EFSA requires data regarding efficacy and safety of feed additives (e.g. mycotoxin binders, zootechnical feed additives…); these data requests (particularly on efficacy) are often considered extensive by the industry.
Food additives: enzyme preparation based on thrombin with fibrinogen for reconstituted meat (Regulation (EC) 1333/2008)	*Risk assessment*: EFSA states that there is no safety concern. *Decision*: adoption of a European Parliament resolution (19/05/2010): authorisation of this additive is deemed not compatible with the aim of Regulation (EC) 1333/2008 as it does not meet the principle not to mislead consumers as to the state of the final food. *Other factors*: societal factors, acceptability *Note: the food additives Regulation sets criteria for food additives to be approved: safety positively assessed by EFSA; technological need, and use does not mislead the consumer.*

Source: Agra CEAS Consulting, based on consultation

The impact of the use of other legitimate factors on the objectives of the GFL (*indicator 20.3c*) is identified according to the particular perspectives and viewpoints of the different interest groups. It is generally acknowledged by all consulted parties to have had a substantial positive impact on consumer health and protection. On the hand, operators and some third countries have expressed concerns that it hampers innovation. In particular:

- All consulted parties, including consumer associations and NGOs welcomed the Article 6 principles of conducting risk analysis, including the use of the precautionary principle and the consideration of other legitimate factors than science/safety, which has contributed to a high level of consumer protection in the EU.

- On the other hand operators, while for the most part accepting the arguments in favour of the consideration of other legitimate factors, have also highlighted that, in practice, this is also a major source of uncertainty for businesses, given the lack of precision in the GFL definition and the potentially subjective aspects covered. However, as already noted above, the different interest groups tend to be driven by their specific objectives and have different approaches and expectations on how risk managers should weight the results of risk assessment and other factors. Also, in view of the diversity of sectors/issues, a case by case approach in taking into account other legitimate factors according to actual needs is considered inevitable, although this also needs to be transparent.

Operators indicate that this lack of 'certainty' hampers innovation. For example, in the additives sector, the industry has indicated that consideration of other legitimate factors is largely based on public perception and puts a brake on the development of innovative food ingredients or the re-evaluation of certain existing additives (examples include additives in meat preparations, **Box 3**). The possibility that factors not defined *a priori* could be directly or indirectly invoked at the very last step of the adoption procedure of a regulated

ingredient/product is considered to introduce an arbitrary element in the process. This can undermine the outcome of the authorisation decision, thus prospects for applicants to obtain the expected return on their R&D investments and costs for the application dossiers. The industry indicated that such costs can be very high: in the case of additives, the cost of preparing a new food additive application varies considerably (depending on the nature of the additive), with €10-€20 million indicated by industry as a typical average cost range[170].

Box 3: Cases where 'other legitimate factors' were taken into account (source: food industry)

1. Enzyme preparation based on thrombin with fibrinogen for reconstituted food

In 2010 a Commission Directive was proposed in order to permit "thrombin", a new food additive in pre-packed meat preparations and meat products, whose safety was positively assessed by EFSA. As all other food additives, thrombin would be labelled in the list of food ingredients with a reference to the name of its category followed by a specific name or E number. In addition, the proposed Directive required that the food shall bear the information "combined meat parts" in the proximity of its sales name. Despite these legal conditions being fully met, the co-legislator (European Parliament) blocked the adoption of the proposed Directive as being unsafe and misleading to the consumer. The EP Opinion was based on public perception, as shown by the pejorative "*meat glue*" given to thrombin by the co-legislator in its Motion for a Resolution calling for rejection of the proposed Directive.

2. Additives in meat preparations

A similar issue re-emerged in 2014. When the list of permitted food additives was transferred from the "old" Directives to Regulation (EC) 1333/2008 according to a new food categorisation system, meat preparations were considered as unprocessed meat in which only a restricted number of food additives were authorised. However, different interpretation of the definition of meat preparations led to a situation where the use of certain additives in particular categories of meat differed between MS. Thus, at the request of MS, the European Commission proposed a Regulation that reflects the actual national practices, provided the additives and their uses comply with the criteria required for additives to be permitted, which was eventually adopted (Regulation (EU) 601/2014).

Source: Agra CEAS Consulting, based on consultation with the food industry

III.4.1.3 Impact of measures taken on the basis of risk analysis

Generally, where **national and EU measures on feed/food have been adopted on the basis of a risk analysis, positive outcomes have been achieved** (survey results, Q30) (*indicator 20.2a*). Nonetheless: MS CAs were more positive than stakeholders on the intended/unintended impacts of such measures [171] ; stakeholders provided higher assessments for outcomes achieved by EU measures compared to those achieved by national measures, while MS CAs did the opposite, largely defending national decisions.

In particular, according to stakeholders and MS CAs, measures have been effective, targeted to protect public health, and avoided unjustified barriers to the free movement of feed/food:

- EU/national measures are assessed to be **effective** and **proportionate**, although more so according to MS CAs than to stakeholders, because other factors are taken into consideration and weighted against risk assessment. Insufficient transparency/ communication of these other factors in some cases is one reason why the average

[170] These industry estimates include direct costs (such as R&D and regulatory costs) and indirect costs (such as the time to market delays).
[171] Average ratings for all outcomes were above midpoint (3) for stakeholders, and above 4 for MS CAs, on a scale from 1 to 5.

rating provided by stakeholders on the 'effectiveness' and 'proportionality' aspects of national measures was lower than in the case of EU measures. On the other hand, according to some stakeholders (operators and consumers), in certain cases national measures can be more effective and proportionate than EU measures due to a closer and more detailed consideration by MS risk managers of the national/local context (e.g. FR measures on BSE; DK measures on trans fatty acids). For measures taken at EU level, MS risk managers need to agree on a common denominator, and this may reduce relevance at national level, while the EU is often used as a reason to justify measures that otherwise would meet strong criticism at national level.

- In terms of **protecting health and the protection of consumer interests**, consumers, supply chain stakeholders and MS CAs generally noted that the risk analysis approach introduced by Article 6 has increased the level of protection of the consumers. They stressed that this has contributed to ensure both a harmonised approach and a more global application across the EU; in combination with the increased level of harmonisation (measures taken at EU level) this has led to a more uniform level of consumer protection across the EU. MS CAs generally noted that the development of new more sophisticated/comprehensive risk assessment methodologies (such as measures of effectiveness – MOE, or measures of suitability - MOS) has helped to increase the level of protection of human health. Consumer organisations in particular noted that the consideration of other legitimate factors in the risk analysis process has been a major step towards address the wider interests of the population, including not only health, but also ethical concerns and consumer benefits.

- In terms of **avoiding unjustified barriers to trade**, for the most part, MS CAs indicated that as the food/feed legislation is nearly completely harmonised at EU level and risk analysis is mainly applied at EU level, the incidence of this happening has been reduced compared to the situation before the GFL (e.g. impact on trade of dioxin/PCB incidents). Areas where harmonised risk analysis and/or legislation and/or guidelines are lacking or insufficient at EU level may cause different national legislative approaches or uncertainties leading to barriers to trade and trade disruptions.

- More generally, stakeholders including consumer organisations and MS CAs noted that, in practice, the **adoption of national measures, in the absence of harmonised EU legislation, has an impact on the single market**. Such difficulties arise, for example, where the EU does not (adequately) address food safety issues that some MS are more eager to tackle in order to protect consumers. Such measures taken by MS run the risk of an infringement challenge whenever a measure adopted at national level for health protection reasons is deemed an internal barrier to trade, although the extent to which this can happen depends on the specific discriminatory nature of the measure (e.g. the Danish legal limit on industrially-produced trans fatty acids in food was found by the European Commission to be compliant with EU legislation).

  Some MS CAs specified that any disruptions to intra EU trade caused by national measures can not, *a priori*, be considered as 'unjustified barriers'. Finding the correct balance of factors on which to base a decision relates to the difficulty of interpreting the concept of 'proportionality' and other 'legitimate' factors. It can also be due to a discrepancy between the scientific advice assessment conducted by EFSA and that conducted by national agencies, which might lead to the adoption of safeguard/precautionary measures nationally (e.g., FR BPA decision), although the GFL provides the mechanism for addressing/avoiding the divergence [172] . Consumer

[172] Article 30 provides the mechanism to address diverging scientific opinions. The aim is for the EU and national authorities to work together to prevent the situation from occurring. A review of its application concludes that the

organisations indicated that, where national measures differ from or even contradict EU legislation, it is particularly important to understand the reason why (i.e. whether it results from diverging conclusions at risk assessment level – e.g. FR ANSES vs. EFSA opinions on BPA – or from different political choices in risk management). Consumers need to understand better the political choices and possible trade-offs behind any decision.

- Finally, in terms of the impact on **innovation**, supply chain stakeholders have generally acknowledged the positive impact of harmonised risk analysis procedures in supporting trade and innovation in the single market context. An example of other secondary legislation where this is largely seen to have been achieved is the streamlining of rules and procedures applying to food additives, food enzymes and flavourings with the legislative package on food improvement agents that was adopted in 2008. However, particular concerns were expressed on the difficulties encountered with the specific authorisation/ML setting procedures laid down in certain other secondary legislation (e.g. nutrition and health claims, novel foods, food improvement agents, pesticides, feed additives, food contact materials). These issues are discussed further below. This has restricted innovation in certain areas, especially for SMEs that do not have the capacity/resources to invest in preparing complex authorisation dossiers. The length/speed of the assessment and duplication of authorisation procedures is also seen to have had a negative impact on innovation. Certain MS CAs have acknowledged the potential negative impact of authorisation costs and delays on innovation, but noted that these issues could be magnified in the absence of harmonised EU provisions and differential approaches followed by MS, while the benefits of EU harmonisation would no longer prevail. As already noted, authorisation procedures are laid down in other specific secondary legislation and are only one of the areas where the risk analysis is applied; the main issues pointed out appear to be due to the way the specific procedures of authorisation are designed and/or lack of harmonisation, rather than the risk analysis principle *per se*.

In particular, cases where national/EU measures adopted on the basis of a risk analysis have led to positive and negative impacts were identified (*indicator 20.2b*), as follows:

Positive impacts

Generally, the **implementation of risk analysis principles as laid down in the GFL**[173] is widely acknowledged, both during this consultation and confirmed by literature, to have **improved the scientific basis and transparency of measures adopted both at national and EU level, in all areas of feed/food law**. In particular, together with the creation of EFSA[174], it has acted as a key driving force that led to: major improvements in the collection of data required to carry out risk assessments (particularly, substance occurrence data and consumption data); advancements in the scientific knowledge/understanding of risks linked to food and feed (in particular the concept of cumulative exposure to risk); development of laboratory techniques (also facilitated by expertise exchange through the EU reference laboratories - EURL and national reference

mechanism foreseen by Article 30 in practice addresses/avoids the divergence through the Advisory Forum of EFSA, although there are some particularly sensitive issues where divergence persists (e.g. endocrine disruptors (BPA)). See: Raymond O' Rourke: Scientific Conflict, the EFSA and a Common Risk Assessment, European Journal EFFL - Issue: 04/2007.

[173] Principles defined in Articles 3, 6 and 7. Risk analysis is a methodology incorporating scientific evidence into the decision-making process: risk management is based on risk assessment provided by the experts; where risk assessment is inconclusive, temporary measures may be introduced on the basis of the precautionary principle.

[174] It has been difficult to separate positive impacts due to Article 6 as such, from those due to the establishment of EFSA. Both provisions of the GFL acted in synergy to create combined effects.

laboratories - NRL networks); synergies/pooling of resources/expertise in the use of EU/national research programmes to fill the data and knowledge gaps in many areas; and, development of a culture of information exchange between MS, the Commission and EFSA.

The advancement of knowledge and tools to improve the scientific basis of risk assessment is considered a **key factor for ensuring more proportionate and effective, fit for purpose, risk management measures**. As discussed in the previous sections, based on the feedback received from the consultation, it has also **generated efficiencies**, in terms of[175]: a) cost savings from the central approach followed at EFSA (thus reducing the need for national risk assessments, particularly in smaller MS that cannot afford to invest in the required scientific capacity); and, b) the pooling of scientific resources involved in EU/national assessment bodies. Furthermore, the principle makes the whole process **more transparent**, as risk assessment is public.

Literature[176] indicates that, in the EU, food safety is the only area of risk regulation where a comprehensive risk analysis model has been codified into general principles governing policy that apply both to EU and national measures. This has had an overall positive effect on consumer protection, as EU measures are usually amended in line with the stricter national standard, which becomes a common standard for the whole EU[177].

As already discussed, stakeholders, including operators and consumer organisations, as well as MS CAs indicated that the centralisation of risk assessment at EFSA, as well as risk management measures in the form of EU regulations have contributed to more proportionate, effective measures, both in terms of the protection of human health/life and allowing free moment within the internal market and innovation. Thus **positive examples of a harmonised risk based approach at EU level include all areas where the risk analysis process foreseen in Article 6 has been applied, especially where harmonisation is more complete**. This includes the management of biological, chemical and physical risks, as well as additional procedures for regulated products, such as the authorisation procedures for food improvement agents, the setting of migration limits in food contact material (plastics), the harmonisation of maximum residue levels (MRLs) of pesticides in food/feed across the EU, and the authorisation of nutrition and health claims. Nonetheless, it is noted that in many cases where EU legislation is not yet completely harmonised, although current legislation provides a positive framework, problems remain and this constraints the achievement of the potential positive impacts (examples are discussed further below under 'negative impacts').

Specific examples of EU measures taken on the basis of risk analysis that have led to an **increase in the level of protection of consumer health** were provided by the various consulted parties (operators; MS CAs; consumers). Such examples include the improvement in addressing biological risks, and a higher level of safety requirements for product authorisations or re-assessment of old substances (pesticides) or of substances or claims that were on the market but had never been scientifically assessed – in particular:

- Biological risks: risk analysis has contributed to the improved management of biological risks more generally, which are a major source of food-borne diseases in

[175] Due to lack of data and an appropriate basis of comparison of the costs of risk assessment pre and post GFL, it has not been possible to provide quantitative evidence of the potential savings generated by the central approach followed at EFSA. However, there is largely consensus amongst consulted parties that a central approach and the pooling of scientific resources to apply a common methodology is more cost-effective in comparison to multiple – and potentially diverse - national assessments.

[176] E.g., Szajkowska (2012), Alemanno (2007).

[177] This is not always the case. There are cases where MS measures have set stricter limits than EU measures, e.g. action for annulment launched by France on less restrictive BSE measures at EU level (Case T-257/07 9 September 2011) confirmed by judgment of the Court C-601/11 (11 July 2013).

humans, including notably salmonella in food. This has been a continuously improving field of EU/MS feed/food law. More recently, following the German E.coli case, food safety microbiological criteria for STEC in sprouts and rules for sampling and testing by food producers have been established.

- Food additives: reassessment of food additives, for establishment of positive lists and conditions of use based on risk analysis. E.g. the conditions of use of some food colours have been strengthened (e.g. 3 azo-colours and aluminium). Flavourings: a list of authorised flavourings substances and smoke flavourings, including their conditions of use in food commodities, has been set.
- Contaminants: a new system of markers for the group of polycyclic aromatic hydrocarbons and new maximum levels have been introduced; additional maximum levels for lead in relevant commodities have been recently adopted.
- Novel foods: safety assessment of novel foods prior to their market authorisation; to this end, maximum intake levels (e.g. Glavonoids), maximum limits in food categories (e.g. bovine lactoferrin, dihydrocapsiate, yeast beta-glucans, phytosterols) have been fixed.
- Pesticides: following in-depth assessments (which would not have been possible without the increased risk assessment capacity in the EU), the number of pesticides authorised in the EU fell between 2000 and 2008 from 1,000 to 250.
- Claims: in the past, many not evidence-based nutrition and health claims were used on labels and in marketing. Risk assessment and management in this area has had considerable impact in terns of "cleaning up" previously unjustified claims, thus ensuring consumer protection.

Negative impacts

Despite the overall appreciation of EU measures, some cases of **negative impacts on innovation and/or trade** were indicated by supply chain stakeholders and some MS CAs. However, these were mostly **attributed to the operational challenges of the current set up and workload in relation to the specific procedures** designed in other secondary legislation, and/or incomplete harmonisation, in particular in the case of nutrition/health claims, food improvement agents, enriched food, and feed additives. As such, **these cases are not directly attributable to Article 6**, which lays down the general principles of risk analysis rather than specific procedures of risk assessment, management and communication.

In particular, following Article 6 and the correlated increased scientific capacity created by the creation of EFSA to support the implementation of this Article, other secondary legislation laying down specific procedures built on this increased capacity to establish more modern and complete procedures but also more complex ones. Although this had the intended positive impacts in terms of ensuring public health and consumer protection (described above), it also had the unintended impact of increased complexity. A further operational challenge of the current set up is that these specific procedures are not standardised. Compared to other European Agencies undertaking safety assessments, there is no overall regulatory framework for the risk assessment of regulated products. These problems were already identified in 2005 by the external evaluation of EFSA[178], and further outlined in the latest (2012) external assessment of EFSA, which points out that *"the regulatory processes for the risk assessment of regulated products are defined by a large number of sector specific regulations with different requirements. Regulatory workflows in force in the various areas are diverse and have been established over time as a result of a succession of legislative initiatives developed by the EU in the domain of food and feed*

[178] The 2005 evaluation of EFSA pointed out that the GFL lacks clarity on some issues, such as EFSA's role in communication and its degree of autonomy (self-tasking).

safety". As at 2012, implementation took place on the basis of 34 different EU directives and regulations which *inter alia* defined some 39 different workflows for carrying out risk assessments in the regulated sectors. This is an important source of complexity, compared to other regulated areas of product safety (e.g. medicines; chemicals) where risk assessment processes are based on one or two workflows, applicable universally. Furthermore, as the progress of harmonisation of EU food and feed safety and the onset of emerging issues has deepened, the volume and context of application dossiers to be processed has challenged both EFSA and national risk assessment bodies (EFSA Science Strategy 2012-2016).

In the **food sector**, several examples of areas of other secondary legislation where such specific procedures apply and/or EU legislation is not yet complete were provided by business operators and/or MS CAs, leading to negative (or not yet manifested as positive) impacts. Examples include:

- Enriched food: actual MLs of vitamins, minerals and other substances not yet set[179];
- Health/nutrition claims: absence of nutrient profiles. According to some MS CAs, Regulation (EC) 1924/2006 on health claims has helped considerably intra-EU trade of products bearing nutrition/health claims and has simplified the monitoring of the market by national CAs. However, the full potential positive impact has not yet manifested, as the Regulation has not yet addressed the issue of setting specific nutrient profiles that food products bearing health or nutrition claims should adhere to, thus reducing the effectiveness of the rules. Similarly, the issue of health claims on botanicals has not yet been resolved; as a result, botanical preparations are still free to claim health effects while ordinary food/food ingredients can only use the permitted/authorised health claims on their labelling, presentation or advertising[180].
- GM food: lack of 'technical solution' for food. Defining measures for GM feed/food at EU, rather than at national level has – according to the industry - avoided 'huge' intra-EU trade disruptions. Nonetheless, while the legislation has had a positive impact in the feed sector with the adoption of a technical solution for assessing the negligible presence of GM traces in feed, the absence of a solution for food and delays in authorisation process despite positive EFSA assessments have not allowed the positive impacts of the current EU legislative framework on GM feed/food to fully manifest.
- Food improvement agents: assessment incomplete. The application of the principle of positive lists and common authorisation procedures for food additives, food enzymes and food flavourings (Regulation (EC) 1331/2008) has led to the establishment of lists of these substances on the basis of risk analysis, thus facilitating internal trade. Nonetheless, the assessment is not complete (e.g. for food flavourings, Regulation (EU) 872/2012).

An indicator of the extent of the potential impact is that in some of the regulated sectors a relatively small proportion of substances have been approved, out of a large number of submissions by the industry for authorisation (e.g. health claims (2,500); flavourings (2,500), of which for +/- 500 substances evaluations are still pending) or the total number of substances used by the industry (e.g. non-plastic food contact materials sector >9,000).

[179] Regulation (EC) 1925/2006 (also Directive 2002/46/EC) foresees the setting of MLs of vitamins and minerals in food. Upper levels for vitamins and minerals have been established by the Scientific Committee for Food and EFSA (2004). However, in the discussion that followed with the Commission and the MS no consensus was reached and the process has been put on hold. This case is used to demonstrate the problems that absence of harmonised MLs can cause for trade in the internal market (A.H. Meyer, EFFL, 4, 2008).

[180] Health claims on botanical preparations may still be used on the EU market, under the responsibility of food business operators and subject to the general principles and conditions of the claims Regulation (EC) 1924/2006 and national rules applicable to them. However, this applies to all health claims, not only to botanical claims, which remain 'on hold' pending a final decision by the Commission, i.e. claims on caffeine or on foods with reduced lactose content and very low calorie diets (VLCDs).

In addition to the cost of preparing dossiers/providing data requirements, the length, unpredictability and uncertainty of the authorisation procedures is identified by operators as a key problem with regard to innovation. This causes problems in all areas of other secondary legislation, at varying degrees, but is more important in relatively newer areas, e.g. claims, where it is unclear for applicants how to justify dossiers to EFSA. Furthermore, the food sector has raised the issue of the requirement of multiple parallel or successive authorisation procedures for the same substances (e.g. for substances which are novel food, Regulation (EC) 258/97) three successive authorisations are needed if they are intended for use in general food (Regulation (EC) 1925/2006) and also in food for specific groups (Regulation (EU) 609/2013)[181].

In the **feed sector**, the introduction of the risk analysis principles in EU legislation on feed additives (Regulation (EC) 1831/2003) and the provision that all "existing" (old) feed additives had to be re-evaluated in line with these principles had a big impact on the feed additive sector in the EU. For many substances that were on the market for 30-40 years, a detailed risk assessment for animal feed use never took place at EU level. As a consequence, the sector had to invest in preparing applications and generate scientific data in order to prove the safety of their product for the animal, the consumer and the environment.

EU standards for the risk assessment of feed additives are very high (Regulation (EC) 1831/2003; data requirements laid down in Regulation (EC) 429/2008). Also, for certain types of substances (e.g. technological feed additives, aromas), the scientific data requirements are not always fully clear which leads to further discussions with EFSA. According to the industry, it has become almost impossible (too costly) for SMEs to compile an application for the approval of their product (**Box 4**); this reduces competition and leaves more room for larger companies that are active worldwide and can benefit from economies of scale in preparing authorisation dossiers for feed additives. However, some positive effects of the current centralised EU authorisation process were also noted for several categories of feed additives[182].

A further specific unintended effect raised by the feed industry is that as there are different provisions for the placing on the market of feed additives (which require pre-market approval) versus feed materials (which do not)[183]. However, the classification of products under each category is not always straightforward and many borderline cases exist. Furthermore, for feed additives, health is not the only criterion for authorisation (efficacy is

[181] The authorisation procedure of Regulation (EU) No 609/2013 is not applicable yet (it will apply when the delegated acts become applicable). Today, old rules on dietetic foods (in particular Regulation (EC) 953/2009 on substances that may be added for specific nutritional purposes in foods for particular nutritional uses) are still applicable. Although different authorisation measures need to be adopted under the different pieces of legislation, efforts are being undertaken to at least streamline the process with respect to EFSA assessment, i.e. one single EFSA opinion that assesses a substance from the perspective of different pieces of legislation.

[182] The current centralised EU authorisation procedure (Regulation (EC) 1831/2003) is simplified in comparison with the decentralised system in force under the previous legislation (Directive 70/524/EEC). Furthermore, for several categories of feed additives (including all technological additives, sensory additives such as flavourings and nutritional additives), the EU authorisation granted 'benefits' to all operators, as there is no 'authorisation holder'.

[183] The placing on the market of feed additives requires prior authorisation under Regulation (EC) 1831/2003, unlike the case of feed materials which do not (Regulation (EC) 767/2009). The GFL contains the general principles for feed and secondary legislation for the different types of feed. Both the above Regulations contain provisions allowing clarification between the different types of feed (including the subsequent COM Recommendation 2011/25/EU), in addition to the legal definitions of the products. The legislator considered that the set of feed safety requirements (laid down in the GFL and other secondary legislation) were sufficient for feed materials and compound feed (without prejudice to the approval of 'intended uses of 'dietetic feed' - Art. 9 of Regulation (EC) 767/2009), while a pre-market authorisation should still be required for feed additives in line with the approach historically followed in this sector, also in third countries, but also in the food additives sector.

also assessed)[184]. This leads to a situation where, according to the industry, innovative and safe products may not reach the market or suffer long delays because of their efficacy evaluation process; the focus on efficacy means that scientific trials need a preliminary approval for products not yet approved, which in certain MS takes far too long even when there is no safety concern, thus impairing innovation.

Box 4: Costs of preparing an application dossier (authorisation of feed additives)

Cost of application dossier per product and per major animal species, Regulation 1831/2003 (industry estimates) *(a)*:

Direct costs:

Art. 4 – full dossier / 1 major species: 2 to 5 Mio € depending on the "novelty" and functional group (much higher for zootechnical additives);

Art. 13 dossiers: 0.1 to 2 Mio €: depends widely on the type of modification requested;

Art. 14 dossiers / renewal: difficult to estimate; depends on EFSA demands and if requirements remain consistent over the years (i.e. no predictability/consistency).

Indirect costs:

Besides the above R&D/regulatory costs, there are indirect costs related to the time-to-market when compared to feed materials. We estimate a difference for time to market of +/- 6-7 years, which is due to:

- Scientific content: high requirements linked to the pre-market authorization process, mainly on identity and efficacy, but also potentially on safety;
- Administrative and risk analysis process: this ideally takes +/- 2 years, which is already substantial, but not unlikely to take 3-4 years and more - especially for innovative products. Delays are observed at all stages, especially during risk assessment. This is due to EFSA requests of supplementary information not always clear or/and change of EFSA guidelines during the assessment.
- Risk management process where delays are due to busy agendas, long discussions in the Standing Committee PAFF, micro-management/too detailed annex entries providing little added value in terms of safety.

It is impossible to provide a general figure for indirect costs, as the sales depend on many variables, but 6-7 years of sales represent several 100k € to several millions of €. It is noted that feed additives and feed materials compete on the same market for the same functionality/claim, therefore the costs involved create a non-level playing situation between operators.

(a) Costs according to industry estimates. On the other hand, the positive effects of the current centralised EU authorisation process, when compared to the previous legislation (Directive 70/524/EEC), were also noted for several categories of feed additives.

Source: Agra CEAS Consulting, based on data from the feed industry

It is noted that, although in the above cases business operators have commented that the specific procedures in place have **hindered innovation and/or trade**, this is **not always the case**; for example:

- The removal of pesticides not meeting the safety criteria has also had beneficial effects on innovation (incentive to develop newer, more innovative products that protect better public health and have equivalent or better efficacy);
- The assessment of health claims has improved intra-EU trade of products bearing approved nutrition/health claims (as well as simplifying the monitoring of the market by MS CAs). The harmonised approach of approved/rejected claims facilitates trade and provides legal security to operators as to what claims they or may not use.

In terms of negative impacts on the **protection of consumers' health**, in addition to areas that are not yet harmonised, consumers have raised concerns over cases where they consider that the public health benefits are questionable. This relates in particular to some products which were authorised because the risk management was based on a positive risk assessment, but consumers consider that other legitimate factors, in particular the benefit

[184] The conditions for authorisation of feed additives are laid down in Article 5 of Regulation (EC) 1831/2003. It must be demonstrated that the additive "*satisfies the requirements of paragraph 2 and has at least one of the characteristics set out in paragraph 3*". Therefore, in addition to the basic safety requirements, there is also a condition concerning the intended effect of the additive. In accordance with Article 8(3)(a) of this Regulation, EFSA must assess the additive on the basis of all the conditions laid down in Article 5.

for consumers, should have weighted more (e.g. novel foods, GMOs, health claims, approval of lactic acid rinses on beef etc.).

III.4.2 Application of the precautionary principle (PP) *(EQ21)*

EQ21: To what extent have the public authorities implemented the precautionary principle (Article 7)? How has the precautionary principle been used and interpreted? What was its impact on innovation and consumer protection?

Key findings (EQ21):

The analysis of the available evidence highlights a considerable level of misperception both over the use of the PP and its potential impacts on innovation and trade. Provisional risk management measures were indicated to have been taken on the basis of Article 7 at national level in most MS, although there is lack of clarity amongst consulted parties on the actual basis of the measures, in particular the overlap/interface between the consideration of 'other legitimate factors' of Article 6 and the application of the PP in line with Article 7.

Bearing in mind those caveats, the findings of the consultation indicate that the PP is, for the most part, considered to have been applied correctly both at EU and national level. Nonetheless, when assessed on the basis of objective criteria (duration of measures; whether reviewed; basis/trigger for adoption), most of the examples provided by MS CAs, are not strictly speaking fulfilling all three criteria. Also, the identified difficulties in understanding/interpretation of Article 7 explain to some extent the differences in the implementation of the PP by MS. At EU level, there is more limited use of the PP on the basis of Article 7 as such; where it has been used, measures have been reviewed in most cases. A key continuing concern for failure/gap in the application of the PP is the scope for potential misunderstanding, in particular for wider interpretation of 'scientific uncertainty' than originally intended, e.g. presumption of risk or uncertainty about the facts rather than the science, within a context where it is challenging to cover all areas of food safety and science. Although this is an inherent challenge of the PP across EU policies, literature suggests that there is no single area in EU policy, including in food law, where the precautionary principle has been misused.

Despite the challenges, all consulted parties have largely asserted that public health and consumer protection has gained in that the application of the PP in food law has allowed a certain prevention/earlier intervention. Consumer organisations stress that the inclusion of other legitimate factors in the risk management process, including in the application of the PP, has protected consumers' health and interests; successful examples of the use of PP, as provided by consumers, include growth promoting hormones ractopamine and other beta-agonists (pre-GFL and post GFL), as well as GMOs.

No evidence was provided during the consultation on adverse impacts on innovation and trade, when the PP is correctly applied (as also supported by literature, e.g. EEA report, 2013). The trigger/basis and duration of the measures are important, as impacts are expected to be minimised when the PP is applied correctly (i.e. has a temporary duration). The fact that the PP is an option, not a mandatory obligation, is meant to ensure proportionality in its use, taking into account a science-based prioritisation of the various risks for human health. In this context, it is noted that a key constraint for the correct application of the PP, both at EU and at MS level, is that the reasonable time by which PP-based decisions should be reviewed - a key factor for the potential impact of PP measures on trade/innovation - depends on the availability of new scientific studies.

III.4.2.1 Incidence and approach of use

The precautionary principle (PP) is a general principle of EU law arising from different Articles of the EU Treaties[185]. The PP definition in Art 7 of the GFL has been the first legal definition of the principle laid down in EU food law.

Prior to the GFL, in the food safety field, there was no legal basis or definition of the precautionary principle (PP) in EU law or at international level (Codex, SPS), although some general guidelines of the PP in Community policies existed and were used as the basis in some European Court decisions on food safety measures[186]. It was in particular recognised as a principle to be applied in the area of food law by the Court of Justice at the beginning of the BSE crisis[187].

At MS level, there is some evidence that national legislation in some cases contained some kind of precautionary approach which was applied at national level (*indicator 21.1a*). For example, in BE the almost complete ban of chicken meat, eggs, etc. during the first weeks of the Belgian dioxin crisis in 1999 was taken on the basis of a precautionary approach[188]; the use of antimicrobial animal feed was banned in Finland on the basis of the PP prior to the GFL (ten years earlier than their ban in EU-legislation)[189].

Following the introduction of the GFL, **provisional risk management measures are indicated to have been taken on the basis of Article 7 at national level in most MS** (survey results, Q32: such measures have been taken in 15 of the 25 responding MS CAs, while 4 MS CAs indicated that provisional measures have not been taken and 6 MS CAs did not know) (*indicator 21.1b)*.

It is important to point out that the PP is not disconnected from the risk analysis principle of Article 6, since it is required to try to perform a comprehensive risk assessment and to have its results before triggering the PP. In practical terms, **two conditions may trigger the use of the PP**: following an assessment of available information, the possibility of harmful effects on health has been identified; **and**, following an assessment of available information, scientific uncertainty persists. Even when both conditions are met, the PP provides also for the possibility that the risk managers decide not to take legal measures but use other tools (e.g. launch a campaign of public information etc.). In the case where risk managers decide to take risk management measures, these have to follow the general principles required for the adoption of EU law (consultation, transparency of the motivation, taking into account

[185] At EU level, the precautionary principle (PP) was first acknowledged in environmental policy by the 1992 Maastricht Treaty (Article 174) and later by the 2007 Lisbon Treaty (Article 191(2)). Guidelines provided by the Commission on 17/10/1998 on the application of the principle gave a first definition and criteria for its implementation. The Commission adopted a communication on the precautionary principle on 02/02/2000 (COM(2000)1). In its resolution of 05/12/2000, the Council recommended the application of the EC guidelines.

[186] Before 2000, the European Court of Justice referred to the PP in several decisions related to food products: case 53/80, 1981 E.C.R. 409 (use of nisin in cheese production); case 174/82, 1983 E.C.R. 2445 (fortification of food); case T-13/99, 2002 E.C.R. II-3305 (use of virginiamycin as growth promoter).

[187] On the application of an annulment of a Commission decision on EU emergency measures to protect against BSE, the European Court of Justice considered that *"at the time when the contested decision was adopted, there was great uncertainty as to the risks posed by live animals, bovine meat and derived products" and "where there is uncertainty as to the existence or extent of risks to human health, the institutions may take protective measures without having to wait until the reality and seriousness of those risks become fully apparent".* Judgments of the Court in Cases C-157/96 and C-180/96, May 1998.

[188] In BE, a kind of precautionary approach was laid down in the Royal Decree of 03/01/1975 concerning foods that are considered unsafe. According to the provisions of this national legislation, food had to be withdrawn from the market if it contained undesirable or harmful substances. This Royal Decree remains applicable.

[189] The precautionary principle was laid down in the previous Finnish Food Act which was adopted in 1995, although it was rarely used.

other legitimate factors, proportionality, no more restrictive of trade than required), and to be provisional (have to be reviewed within a reasonable period of time)

A key finding of the consultation is that there is **some lack of clarity amongst consulted parties** on **the overlap/interface between the consideration of 'other legitimate factors' of Article 6 and the application of the PP along the lines of Article 7**. This is especially the case for areas that are not fully harmonised at EU level, such as contaminants and food contact materials. This partly explains the large number of 'don't know' responses and comments received during the consultation in relation to the PP. Furthermore, it has been difficult for most MS/stakeholders to isolate cases of EU/national measures explicitly based on the provisions of Article 7. More generally there is a tendency to understand 'precautionary' in the wider/colloquial sense of the term. Finally, several consulted parties indicated that the term 'precautionary', translated in the various language versions of the GFL, can be understood differently and this has a bearing on how it can be interpreted by the authorities.

This lack of clarity reflects to some extent in the examples of measures provided by MS, with considerable overlap between cases where national risk management decisions are reached on the basis of national risk assessments (Article 6) and those indicated to be based on the PP (Article 7). Examples are national measures on food contact materials (e.g. BPA), and measures taken on various contaminants (chemical and microbiological contamination, such as salmonella in feed). Several MS indicated that there is no national basis/guidance on the use of the PP, and Article 6 constitutes the main legal basis, with Article 7 less well understood.

Bearing in mind those caveats, the findings of the consultation indicate that the **PP is, for the most part, considered to have been applied correctly both at EU and national level** (*indicators 21.1c to 21.1f*). Generally, stakeholders considered the principle to have been applied correctly mostly for measures taken at EU level and to a lesser extent for measures taken at national level, while MS CAs considered this to be the case mostly for measures taken at national level and to a lesser extent for measures taken at EU level (survey results , Q34)[190].

The identified difficulties in understanding/interpretation of Article 7 (as well as interface with Article 6) explain to some extent the differences in the implementation of the PP by MS. The online survey provides an indication of the extent to which there have been differences in the implementation/application of the relevant Articles of the GFL. Survey results (Q53) indicate that, while there are a large number of 'don't know' responses to this question (44% of all respondents), the areas where differences are mostly identified (albeit to some extent/in some cases) are risk analysis (46% of stakeholders; 11 MS CAs) and the application of the precautionary principle (42% of stakeholders; 10 MS CAs).

Three **criteria** can provide more objective indicators of the extent to which the PP has been applied correctly: the **duration of the measures**; whether they have been **reviewed**; and, the **basis/trigger** for their adoption (as described above).

At MS level, out of the 23 examples of national measures which were indicated by MS CAs to have been taken on the basis of the PP (survey results, Q33b), the majority (61%) have had a duration of more than 1 year, while one third of these measures have lasted over 5

[190] Average ratings in all cases were above midpoint (3), on a scale from 1 to 5. The high number of "don't know" responses for MS CAs is noted (8 of 25 MS CAs for EU level measures and 10 of 25 MS CAs for national level measures).

years. This calls into question the intended provisional or temporary character of the measures[191]. It is noted that some of the measures that were indicated to have a more limited duration (<1 year) were adopted recently, therefore their final duration is not yet definite. Only about half of these measures have been reviewed. The main trigger for the adoption of the measures was the identification of potential harmful effects on health (15 measures, or 65% of all examples provided), with persisting scientific uncertainly raised only for few (3) measures; other factors were raised for few (5) measures e.g. environmental reasons for the trade restrictions on transgenic maize adopted in two MS.

At EU level, there is more limited evidence of the use of the PP on the basis of Article 7 as such (**Table 9**). Where the PP has been used, measures have largely been reviewed, depending on the availability of further scientific evidence. As already noted, the reasonable time by which PP decisions should be reviewed depends on the availability of new scientific studies. For example, Commission Decisions on non-authorised GMOs were based on the PP and were later amended taking into account newer scientific evidence. EU measures banning the use of growth promoting hormones pre-dating the GFL were later reviewed based on the PP[192]. Measures relating to BSE were also reviewed based on the PP[193]. The ban since 2002 of the use of azodicarbonamide in the manufacture of food contact materials was also reviewed twice (in 2004 and in 2007, when the latest Commission Directive was adopted, confirming the ban). The PP is used as the legal basis for measures restricting use of certain substances on products destined to infants and young children, at both EU and MS level, due to the high sensitivity/vulnerability of this particular group of the population.

Table 9: Use of the precautionary principle (GFL Article 7) in EU food law *(a)*

Area	Measure
Food contact materials	Restriction of use of Bisphenol A in plastic infant feeding bottles (Commission Directive 2011/8/EU of 28 January 2011, amending Directive 2002/72/EC).
Food contact materials	Suspension of use of Azodicarbonamide (blowing agent in PVC gaskets in lids) since 2002; this was subsequently reviewed and the ban confirmed, latest in 2007 (Commission Directive 2007/19/EC of 2 April 2007 amending Directive 2002/72/EC).
GMOs	A number of Commission Decisions (2005/317, 2006/601, 2008/289) on non-authorised GMOs, which were later reviewed to take into account newer data.
Products destined to infants/young children	Restrictions on the use of food additives (general ban in food supplements for infants and young children); systematic decision to apply the lowest level of contaminants and pesticides; EU provisions to restrict flavourings (which are not evaluated for infants under 14 months) used only as nutritionally necessary ingredients; and, Directive 2011/8/EU above.
Growth promoters (feed)	Prohibition on the use in livestock farming of certain substances having a hormonal or thyrostatic action and of beta-agonists (including Ractopamine) (Directive 2003/74/EC of the European Parliament and of the Council) of 22 September 2003, amending Council Directive 96/22/EC). The ban (including Ractopamine, a drug belonging to the 'β-agonist' category)

[191] The review of measures depends on the availability of new scientific studies, as laid down in Article 7. The term 'provisional' is used in Article 7 to reflect the term used in the WTO SPS agreement for similar measures. Both Article 7 and the WTO SPS agreement make no reference to a defined period, but a limited duration is generally accepted to refer to <1 year.

[192] On the application of the PP in relation to growth promoting hormones, their ban in the EU was first enacted in 1981 (Council Directive 81/602/EEC). In 1999, the EC Scientific Committee on Veterinary Measures relating to Public Health (SCVPH) re-evaluated the risks to human health from hormone residues in bovine meat treated with six hormones for growth promotion. It concluded that no acceptable daily intake (ADI) could be established for any of these hormones and that adverse effects on health could be envisaged. Consequently, in 2003, Directive 2003/74/EC was adopted, which permanently banned one hormone (oestradiol-17β), while provisionally banning the use of the five other hormones pending the availability of new science, in application of the precautionary principle.

[193] Commission Regulation (EC) No 746/2008 of 17 June 2008 amending Annex VII to Regulation (EC) No 999/2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies. Although the revision of the rules was contested/appealed by FR, on the grounds that the PP was not taken into consideration, the ECoJ upheld its earlier judgment, in support of the Commission's decision, ruling that the Commission had not breached the PP or the obligation to maintain a high level of protection of human health (Case C-601/11 Judgment of the Court (Fourth Chamber), 11 July 2013).

Area	Measure
	from use in food producing animals in the EU was first introduced by EC Directive 96/22/EC, with some exceptions for therapeutic purposes; it was amended in 2003 on the basis of the PP (Article 7). EFSA has evaluated in 2009 the safety of Ractopamine in feed, on the basis of newer data (risk assessment carried out by the Joint FAO/WHO Expert Committee on Food Additives (JECFA)) and found weaknesses in the data underlying the JECFA assessment which would undermine any proposal for a maximum residue level for ractopamine.

(b) Lists only measures taken after the GFL.

(c) Excludes the use of the PP on the basis of other specific legislation, e.g. pesticides. The pesticides sector does not refer to the PP as defined in the GFL since the scope of Article 7 is limited to cases where "the possibility of harmful effects on health" exists. The pesticides sector having significant impacts on the environment, the use of the PP also covers the case of unacceptable effects on the environment. Thus, Regulation 1107/2009 refers to the application of the PP in Recital 8 and Article 1(4). In practice, the PP is rarely used in this sector as the decisions are in the large majority based on a fully completed risk assessment. Nonetheless it has happened, notably in 3 instances, that Commission Directives approving active substances under Directive 91/414 referred explicitly to the implementation of the PP (cases where the risk assessment was performed but showed scientific uncertainty): Directive 2006/132 (inclusion de procymidone); Directive 2006/133 (inclusion de flusilazole); Directive 2006/134 (inclusion de fenarimol).

Source: Agra CEAS Consulting, based on consultation

III.4.2.2 Impact of measures taken on the basis of the PP

The impacts (positive/negative, or intended/unintended) of the measures taken on the basis of Article 7, including on consumer protection and innovation, and cases of continuing failures/gaps in the application of the precautionary principle have been further investigated during our consultation (*indicators 21.2a and 21.2b*).

Both consumer organisations and MS CAs have highlighted that, as the key rationale for the majority of measures taken has been to address the possibility of harmful effects on health (survey results, Q33b), this should contribute to an **increase or at least the maintenance of a high level of protection of human health**. Articles 6 and 7 are seen as two fundamental principles of the GFL that serve this objective. Consumer organisations stress that they have allowed the protection of consumers' interests as foreseen in the GFL objectives: the inclusion of other legitimate factors in the risk management tool, in combination with the PP, has protected consumers' health and interests. Successful examples of the use of PP, according to consumers, include: growth promoting hormones ractopamine and other beta-agonists (pre-GFL and post GFL), as well as GMOs.

By their nature, measures taken on the basis of the PP, especially when taken at national level and in the absence of harmonised legislation, are feared to lead to some negative impacts on trade and innovation. As already discussed, these measures are also prone to misinterpretation of the basis for their justification (in particular with reference to scientific uncertainty and the consideration of other legitimate factors), and differences in implementation between MS and across sectors/ issues[194]. All this adds to a general perception, amongst stakeholders representing the supply chain, that they constitute 'unjustified barriers' and can 'stifle innovation'.

The key continuing concern for failure/gap in the application of the PP is the **scope for potential misunderstanding**. Literature[195] indicates that the PP more generally is

[194] For national measures indicated by MS CAs to have been taken on the basis of the PP, we note again the caveats of distinguishing between measures taken on the basis of Article 7 and those taken on the basis of Article 6 (consideration of other legitimate factors) (see section III.4.2.1).

[195] There is extensive academic literature on the challenges of the application of the precautionary principle, both specifically in food law and more generally. For example:

controversial because it is an abstract idea that can be interpreted in different ways, hence leading to differential implementation and potential misuse. The PP is a risk management tool in the sense that the decision whether scientific evidence is conclusive or not is left to the risk managers (to this end, the risk assessors are required to clearly indicate the level of uncertainty in their opinions). This leads to a situation where uncertainly becomes politicised and public risk perception comes into the risk analysis. For this reason, it also requires more prudence and transparency in its use by policy makers. The literature and expert interviews indicate that these **problems are by no means specific to the application of the principle in food safety matters but are more generally due to the inherent challenges of applying the PP across EU policies**.

The challenges of balancing scientific uncertainty against the need to act to prevent potential adverse effects, in a context of rapidly evolving technological innovations, are illustrated in a review by the European Environment Agency of the application of the PP across different sectors (EEA report on late lessons from early warnings, 2013[196]). Despite the challenges, the EEA report concludes that there **is no single area in EU policy, including in food law, where the precautionary principle has been misused**. The report demonstrates that precautionary measures do not lead to excessive false alarms: of 88 cases of claimed 'false positives', where hazards were wrongly regulated as potential risks, only four were genuine false alarms[197]. On the contrary, most of the cases examined are 'false negatives' — instances where early warnings existed but no preventive actions were taken. Overall, the analysis shows that *"fear of false positives is misplaced and should not be a rationale for avoiding precautionary actions where warranted"*. Furthermore, according to the report findings, there is growing evidence that precautionary measures do not stifle innovation, but instead can encourage it, in particular when supported by public consultation, identification of the actual needs of society and smart regulation.

When the PP is applied correctly, especially when measures are provisional and of limited duration, **negative impacts should be minimised**. While very few of the examples provided by MS CAs were measures triggered by persisting scientific uncertainly (which is one of the two necessary conditions for the application of the PP, as laid down in Article 7), only half of these measures were applied on a temporary basis (survey results, Q33; see also section III.4.2.1). In the case of EU measures, very few measures were identified to have been taken on the basis of Article 7 and these have been reviewed (**Table 9**). No evidence was provided during the consultation on concrete adverse impacts of any of these measures on innovation and trade. With regards to impacts on international trade, many existing EU regulations and decisions regarding the importation of food, feed and animals from third countries aim to address problems with contaminants, microbiological criteria, additives, animal health, and plant health; however, it is not always clear if these measures have been taken on the basis of the PP (within the meaning of Article 7) or risk assessment (within the meaning of Article 6).

- Dangerous interpretation of the precautionary principle and the foundational values of European Union food law: risk versus risk. M.A. Recuerda, Journal of Food Law &Policy, 2008, vol. 4:1.
- Barbara Berthoud (2014): The Precautionary Principle in EU Risk Regulation: A Matter of Priorities. Hamburg, Anchor Academic Publishing 2014.
- Jale Tosun (2013): Risk Regulation in Europe: Assessing the Application of the Precautionary Principle. Springer.
- Anna Szajkowska (2012) Regulating Food Law: Risk Analysis and the Precautionary Principle. Wageningen Academic Publishers.

[196] The EEA review draws on lessons learnt from the application of the precautionary principle. The analysis draws on findings from several case studies where the PP was applied, across sectors and countries, including in the GFL context e.g., on BPA.

[197] The cases examined in this report cover all sectors and both EU and non EU measures. The four real false positives identified were US measures.

Article 7 constitutes the only detailed legal reference to what the PP is in EU law and, as it stands, has the merits of a general wording that allows implementation in differing contexts particularly in such a highly complex technical area as food safety. The Commission has provided guidelines on the use of the PP more generally (European Commission, 2000b). However, in the absence of further specific guidelines on Article 7[198], whether at EU or at national level, the inherent challenges of applying the PP across EU policies are also evident in its application in the food safety policy area.

Literature on the application of the PP in the context of food law (e.g. Szajkowska (2012)) indicates that Article 7 has in practice acquired a wider interpretation of 'scientific uncertainty' than its original scope, i.e. also encompasses presumption of risk or uncertainty about the facts rather than the science, within a context where it is challenging to cover all areas of food safety and science. Examples include: EU prior authorisation schemes (GMOs, novel foods), where the presumption of risk from unknown products cannot substitute for scientific uncertainly in view of the incompleteness of existing scientific evidence; national prior authorisation schemes, e.g. ECoJ Case C-333/08 EC vs FR which concluded that prior authorisation schemes on food processing aids introduced without scientific reasons do not correspond to the requirements of Articles 6 and 7 of the GFL that food safety measures should be underpinned by an assessment of risks posed by a product or group of products.

An international round table, organised under the Belgian EU Presidency in 2010 on the role of science in food policy, has addressed the extent to which the PP is the right approach in the process of decision making in light of the inevitable uncertainties involved in science. Roundtable participants (internationally recognised scientific experts) concluded that it all depends on its use. Although defending the rationale for the principle, there was some concern that it has become a pretext for certain inertia, "*do nothing in case of doubt*" and that this principle is used more than originally intended to handle scientific uncertainty surrounding potential unknown risks. This is considered to be counterproductive as it reflects an intellectually open ended attitude to opposing scientific progress. The identification of potential harmful effects on health was the main driver in two thirds (65%) of all examples of national measures taken on the basis of the PP which were provided by MS CAS, while scientific uncertainty as such was the justification in only few measures (survey results, Q33).

Nonetheless, EFSA opinions are increasingly becoming the point of reference for the European Courts, which rely on scientific evidence form EFSA. In November 2014, EFSA took steps, in the framework of the "Open EFSA" project to improve the reliability and the transparency of risk evaluations. One of the projects focussed on drafting a guidance document to improve and harmonise the analysis of the level of uncertainty in EFSA's scientific opinions.

In conclusion, both the literature review and the results of the consultation highlight a **considerable level of misperception both over the use of the PP and its potential impacts on innovation and trade**. In a context where the PP is often confused with a precautionary approach or even misused (e.g. ECoJ case EC vs FR quoted above), there is a relatively limited number of cases of use of the PP, in application of Article 7 as such. This is partly explained by the inherent challenges underpinning the application of the PP, in particular how to address scientific uncertainty. Despite the challenges, all consulted parties have largely asserted that public health and consumer protection have gained in that the application of the PP in food law has allowed a certain prevention/earlier intervention to

[198] No guidelines were produced with regard to the use of the PP in the context of Article 7, because general Commission guidelines already existed, had been discussed inter-institutionally and were referred to in several EU Court cases.

address potential risks. No evidence was provided during the consultation on adverse impacts on innovation and trade, when the PP is correctly applied (as also supported by literature, e.g. EEA report, 2013). The fact that the PP is an option, not a mandatory obligation, is meant to ensure proportionality in its use. As the objective remains the protection of public health, proportionality needs to take into account a science-based risk prioritisation. Enhancing scientific understanding and public awareness of exposure to a particular risk versus other, potentially more important risks, as well as the cumulative exposure to substances is important. For example, the microbiological risks of poor hygiene can be higher impact short term than toxicological risk of exposure to residues of plant protection products.

III.5 Transparency

Transparency is a fundamental principle of the GFL. In particular:

- Article 9 (public consultation) pertains to the application of transparency during the legislative and decision-making process in peace time;
- Article 10 (public information) pertains to transparency during times of important risks.

Both of these provisions aim to ensure consumer confidence and the confidence of stakeholders and trading partners through: the open and transparent development of food law (Article 9); public authorities taking the appropriate steps to inform the public where there are reasonable grounds to suspect that a food may present a risk to health (Article 10). This is necessary in view of the growing interest in food safety issues and the protection of consumer's health and interests, of the general public, non-governmental organisations, professional associations, international trading partners and trade organisations.

The purpose of the study with regard to the transparency principle has been to analyse the impacts (positive and negative) of these provisions, including their implementation in other secondary legislation, the extent to which they have been of added value/benefit, whether or not positive impacts outweigh negative impacts, and the overall sufficiency and effectiveness of the provisions for ensuring the open, balanced and transparent development of food law as well as in crisis situations, and ultimately, ensuring consumer trust and confidence of all interested parties.

EQ22: To what extent has the gradual adoption of the GFL harmonised framework in the Member States ensured transparency through public consultation of stakeholders during the preparation, evaluation and revision of food law (Article 9)? With what impacts?

EQ23: To what extent have the provisions of the GFL and its implementation ensured adequate /appropriate information to the public in case of a significant risk (information on measures by public authorities to prevent, reduce or eliminate risks) (Article 10)? With what impacts?

Key findings (EQ22/EQ23):

Considerable progress towards greater transparency, both in terms of public consultation and public information, was noted by all consulted parties following the GFL, both at EU and at MS levels. As in the case of other adjustments introduced by MS following the GFL, those made to apply Articles 9 and 10 in practice run concurrent to parallel developments at national level, in particular the considerable reorganisation of MS CA competences on food safety, and were accelerated by developments in the communications/media sector. In this sense, it is difficult to attribute particular adjustments introduced at national level, hence impacts, to the GFL as such, although the GFL was one of the contributing factors for more harmonisation. Despite persisting national differences, our findings indicate that these are progressively narrowing down, leading to an overall higher standard of transparency throughout the EU. Thus, overall, the level of transparency as a whole has improved both at EU and national level, when compared to the situation prior to the GFL.

In terms of **public consultation**, the most important improvements include a more systematic application, the involvement of the wider spectrum of stakeholders/interest groups across the various legislative fields and, the increase in general public consultation (facilitated also by the development of online consultation/survey tools and access to online information). The impact of these improvements is that they contribute to: an increase in stakeholder confidence in the consultation process and the authorities, as documented by the results of public satisfaction surveys in MS where these exist; and, improving the evidence-base underpinning legislation and the feasibility of application/implementation. Nonetheless there is scope for further improvement, in particular in narrowing down persisting differences between MS approaches, as certain MS remain more advanced than others, with cultural differences persisting as an important underlying factor.

Similarly, the process of **informing the public** that a food/feed may present a risk has improved over time, in particular taking into account lessons learnt from poor communication and its impact during previous crises (e.g. dioxin, E.coli, etc.). The findings indicate that authorities tend to inform the general public in an order of priority that is generally defined and is proportionate to the level of the potential food/feed safety risk, and the type of information provided (in the case of recalls) is generally adequate/appropriate. Although this is considered to have had a positive impact in more effectively/efficiently managing food and feed emergencies, stakeholders (i.e. consumers; operators) tend to have different viewpoints regarding the actual impact of the current implementation on consumer confidence/trust and trade/business disruptions. Stakeholder feedback depends also on national differences, which both consumers and operators identify to be considerable and persisting, despite progress. Authorities highlight that there are no fixed rules on the best approach to take, particularly in balancing the need to provide additional information versus confidentiality requirements, which also depends on the circumstances and the case (i.e. trigger point; food safety issue). As also highlighted in the context of the RASFF study, there are several areas where shortcomings or gaps remain, including different understanding and implementation of the rules by MS CAs on what type of information should be provided and how to address professional secrecy, particularly when additional information may play an important role to address public health risks. Such differences/shortcomings surrounding communication towards the public can have considerable impact on the effectiveness and efficiency of addressing an incident, which is one lesson drawn from the communication errors/lack of consistency during the 2011 E.coli outbreak. Nonetheless, there is commitment to the process of developing public information mechanisms, which remains dynamic, both at EU and MS level (e.g.: EU – establishment of RASFF Consumer Portal, 2014 and the pending proposal for a new Official Controls regulation; MS – ongoing development in some MS of mechanisms to inform the public of the results of official controls).

III.5.1 Public consultation *(EQ22)*

EQ22: To what extent has the gradual adoption of the GFL harmonised framework in the Member States ensured transparency through public consultation of stakeholders during the preparation, evaluation and revision of food law (Article 9)? With what impacts?

The extent and manner in which MS applied public consultation prior to the introduction of the GFL has been quite variable and highly dependent on national traditions and cultures (*indicator 22.1a*)[199]. While in some MS there has been a long standing tradition of dialogue and cooperation between authorities and operators, in other MS (particularly on some of the new MS) this culture did not exist and had to be progressively introduced in the national legislative development process. These, to some extent 'cultural', differences between MS are also discussed in the context of risk analysis and the organisation of competences at national level on food safety and consumer interest matters, the withdrawals and recalls system, the allocation of responsibilities and public information. According to the feedback received from MS CAs, where consultation was practiced:

- It ranged from: usually, ad hoc (non-systematic) informal feedback of some interest groups on certain pieces of legislation; to, more rarely, systematic formal involvement of the more complete spectrum of interest groups and for nearly all/all legislation.
- It involved, to a variable extent any combination of the following interest groups: consumer organisations; food producers' organisations; SMES; distribution/retail associations; farmers; and, other ministries. In most cases, consultation of NGOs and/or of the general public as such was fairly limited.

As in the case of other adjustments introduced by MS following the GFL, discussed elsewhere in this Report, the adjustments to apply public consultation as laid down in Article 9 (*indicator 22.1b*)[200] in practice run concurrent to developments that took place, in parallel, at national level. In this sense, it is **difficult to attribute particular adjustments introduced at national level, hence impacts, to the GFL as such**, although the GFL was one of the contributing factors.

The developments that contributed to changes in relation to transparency are to some extent linked to the **considerable reorganisation of MS CA competences on food safety** (see section III.4.1.2). In many cases, this was driven at national level by the same underlying causes that led to the introduction of the GFL: notably the various feed/food safety crises that occurred in the EU in the 1990s. The required adjustments were **compounded by developments in the communications/ media sector**, in particular the increase in speed and access (online) to information which fed back into stimulating public reaction. It was therefore essential for public administrations to adjust to keep up to speed with these developments. The main difficulties encountered by national authorities during this process were the cost and the workload resulting from the effort to develop systems enabling an enhanced transparency: the extent of the difficulty depended on the level of transparency prior to the GFL (which, as discussed, was highly variable between MS). In many of the consulted MS, particularly in those that acceded to the EU since 2004, the adjustments in transparency over the last 15 years have been so extensive that they were described by MS CAs as a rapid evolution, even a '*revolution'*. In other MS, it has been more of a continuum, building on an already strong base.

[199] Similar conclusions on the situation prior to the GFL are drawn in the case of public information (Article 10).
[200] Similar conclusions on the adjustments made, following the GFL, are drawn in the case of public information (Article 10).

Considerable progress towards an improved public consultation was noted by all consulted parties following the GFL, both at EU and at MS levels. Nonetheless, according to stakeholders, **the level/frequency of public consultation is generally higher in the case of EU legislation than in the case of national legislation**, although this view is not shared by MS CAs. In particular:

- Over two thirds of stakeholders and an even larger majority of MS CAs (20-22 of 25 MS) indicated that there has been an open and transparent public consultation for EU feed/food legislation, during the three phases of its development (preparation, evaluation and revision) (survey results, Q35) (*indicator 22.1c*)[201].
- On the other hand, stakeholders had mixed views on whether there has been an open and transparent public consultation for national feed/food legislation, while nearly 40% replied 'don't know' for all three phases of legislative development. Of those that replied, roughly two thirds indicated that there has been an open and transparent public consultation. However, nearly all MS CAs (22-24 of the 25 MS CAs) indicated that there has been an open and transparent public consultation during all phases of the development of national feed/food legislation (survey results, Q36) (*indicator 22.1d*) [202].

Furthermore, there is some discrepancy of views, between MS CAs and stakeholders, on the **comprehensiveness and depth of the national consultation process**:

- According to MS CAs, national consultation involves the systematic and comprehensive coverage of all major groups of stakeholders during the preparation, evaluation and revision of national food law: a majority of MS CAs indicated that the groups they tend to always consult are farmers, food processors, distribution/retail, SMEs, consumers, importers and exporters (survey results, Q37) (*indicator 22.1e*) [203]. In terms of the manner in which the consultation process is conducted, MS CAs indicated that they most typically apply the following tools: invitations for comments/positions (21 of the 25 responding MS CAs 'always'; 4 MS CAs 'sometimes'); consultation groups composed of associations representing the different stakeholders of the food chain (17 MS CAs: 'always'; 7 MS CAs: 'sometimes'); internet consultations (13 MS CAs: 'always'; 5 MS CAs: 'sometimes'); cost/benefit analysis and feasibility/impact/evaluation studies (11 MS CAs: 'always'; 9 MS CAs: 'sometimes') (survey results, Q38) (*indicator 22.1f*).
- Stakeholders indicated they have not always been sufficiently[204] consulted by the national CAs during the preparation, evaluation and revision of food/feed legislation at EU or national level, although nearly a third of stakeholders replied 'don't know' to this question (survey results, Q39) (*indicator 22.1g*)[205].

Cases of **continuing gaps/failures in public consultation at MS level** (*indicator 21.2b*), as noted by stakeholders including consumers, include the following main issues:

- Impact assessments, to support the preparation/revision of legal provisions, are not systematically carried out;
- Not all relevant stakeholders are consulted, and/or given access to relevant information, and/or – even when they are – there is limited follow up and it is not clear how the balance between interests and objectives was weighted in the final

[201]For both stakeholders and MS CAs: sum of replies: 'yes, always/in most cases' and 'yes but not systematically'. Nearly a fifth of stakeholders did not provide an answer, i.e. replied 'don't know'.
[202] For both stakeholders and MS CAs: sum of replies: 'yes, always/in most cases' and 'yes but not systematically'. Nearly 40% of stakeholders did not provide an answer, i.e. replied 'don't know'.
[203] MS CAs indicated that these stakeholders are involved in the consultation 'always' or 'sometimes'.
[204] Sufficiently = input has been sought in a structured manner and has been taken into account by the CAs in a balanced way.
[205] On a scale from 1 to 5, the average rating was around midpoint (3.00). Nearly 40% of stakeholders did not provide an answer, i.e. replied 'don't know'.

management decision. This issue was also highlighted in the context of the consideration of other legitimate factors and transparency in final decision-making in the risk analysis process (section III.4);
- The impact on SMEs, particularly micro and small enterprises, is not systematically investigated, neither in the evaluation nor in the preparation/revision of law;
- There is significant variation in the level of public consultation between MS.

Some stakeholders reported **certain gaps/failures**, but **to a much lesser extent**, also in the consultation process **at EU level** for EU food/feed law. A key criticism was that consultation of the general public should be the norm rather than the exception, as is currently the case, in contrast with many other Commission policy areas where it is already systematically applied. Other issues reported include: access to documents (e.g. background to decisions by the Standing Committee); and insufficient time available to consult internally within organisations (particularly for some of the larger and more complex umbrella organisations) and to provide comprehensive feedback. Finally, it was noted that emphasis tends to be placed on the costs of legislation, and less on the benefits (or the costs of non-regulation) for the broader society, which are inevitably more difficult to demonstrate[206].

The main reason accounting for the discrepancy between stakeholders and MS CAs is that, despite progress, there remain considerable differences in the consultation process, and transparency more generally, between MS: certain MS remain more advanced than others, with cultural differences persisting as an important underlying factor (*indicator 22.1h*).

Despite persisting national differences, our findings indicate that these are progressively narrowing down, leading to an overall higher standard of transparency throughout the EU. Overall, **the level of public consultation as a whole has improved both at EU and national level**, when compared to the situation prior to the GFL. The most important improvements are: a more systematic application of public consultation, involving the more complete spectrum of stakeholders/interest groups across the various legislative fields; and, the increase in the consultation of the general public (facilitated also by the development of online consultation/survey tools and access to online information). Although these improvements cannot be attributed exclusively to the transparency principles of the GFL (and may have occurred in any case in some MS), having these provisions embedded in EU legislation ensures that the principles apply whatever the political developments at national level. Furthermore, even in MS with a strong and long-standing tradition in stakeholder consultation, the CAs indicated that Article 9 of the GFL have complimented and strengthened the authorities' own statutory duties and core principles, while it has ensured consistency of approach with other MS.

Several MS CAs have indicated that these improvements have contributed to an **increase in stakeholders' confidence in the consultation process and the authorities**, as documented by the results of public satisfaction surveys where these exist[207] (*indicators 22.2a and 23.2b*). Although, even in best practice cases, there are continuous stakeholder requests for more information dissemination and more direct involvement, to some extent this also reflects the increase in the volume and complexity of food safety related

[206] BEUC response to Commission public consultations on impact assessment guidelines and stakeholder consultation, 26 September 2014.
[207] For example, in BE, during the latest public satisfaction survey, globally, 85% of participants have evaluated favourably the activities and services provided by the national agency AFSCA including on transparency and communication aspects. Nonetheless, 44% would like more information to be provided and 86% would like the individual results of inspections to be published. In the UK, results of consumer omnibus surveys carried out for the FSA on a biannual basis indicate an increased trust in the activities of the Agency, with the most recent wave indicating trust by 65% of respondents.

legislation. Most of the consulted MS CAs have indicated that stakeholder involvement remains an important commitment, both to ensure business and consumer trust, and when it comes to supporting the development of legislation, particularly with a view to administrative simplification. In particular, views of stakeholders contribute to improve the evidence-base underpinning legislation and to ensure that legislation is feasible, more realistic, and proportionate. Furthermore, through the consultation process stakeholders improve their awareness and level of understanding on the various issues, particularly when these are complex. More generally, the participation of stakeholders from an early stage in the policy development process contributes to enhanced implementation of legislation when this eventually comes into force. It was nonetheless noted, by all consulted parties, that the right balance needs to be reached between under-consultation and over-consultation, as the latter can also be counter-productive.

III.5.2 Public information *(EQ23)*

EQ23: To what extent have the provisions of the GFL and its implementation ensured adequate /appropriate information to the public in case of a significant risk (information on measures by public authorities to prevent, reduce or eliminate risks) (Article 10) ? With what impacts?

Prior to the GFL, both the extent to which MS provided information to the public on food safety matters and the circumstances under which this was occurring were variable and piecemeal (*indicator 23.1a*). The trigger points for informing the general public were any reasonable grounds for authorities to suspect that public health was severely at risk; usually this occurred during the more severe instances of food poisoning and/or in reaction to press reports, followed by specific complaints, notifications through RASFF[208] (involving cross-border trade) or directly from other national administrations. In practice, even in cases where there was a good level of exchange and collaboration between the services involved, there were no formal or systematic procedures in place on the communication to the general public. Overall, collaboration between services to this end was rather limited, which more generally reflects the shortcomings of the administrative structures in place and division of responsibilities prior to the GFL (as analysed in the context of risk analysis, section III.4.1.2b).

As in the case of Article 9, the adjustments by MS CAs to apply Article 10 in practice (*indicator 23.1b*) **formed part of the broader adjustments of administrative structures** to apply the wider framework of risk analysis and transparency. Thus, the constraints and difficulties encountered echo the broader adjustment process. MS CAs have indicated that the main difficulties were in terms of **keeping in pace with the parallel development of the media** which was also a driver accelerating the required adjustments. In particular, it required an adjustment of the communication strategy from the authorities, to enable high responsiveness in case of feed/food safety incidents; this involved considerable costs and workload for MS CAs. Another major driver in the case of public information was the need to **adequately respond to the major crises** that undermined public trust and confidence in food safety over the last two decades. For example in BE, following the dioxin crisis of the late 1990s considerable work has been carried out at constitutional and legislative level, aiming at enhancing the transparency of public administration. Nonetheless, as in the case of Article 9, having the principle of public information laid down in the GFL ensures that there is a level playing field for all MS across the EU in terms of the obligation to inform consumers in crisis situations.

[208] The RASFF was created in 1979 and is therefore one of the few elements of the European food safety framework Pre-dating the White Paper on Food Safety in 2000.

The findings of the consultation indicate that the **process of risk information has improved over time, in particular taking into account lessons learnt from previous crises** (e.g. dioxin, E.coli, etc.). The 2011 DE E.coli outbreak in particular involved a series of communication errors, starting from the erroneous identification of cucumbers as the source of the outbreak, while the problem originated in sprouts, thereby causing considerable financial damage (as discussed further below). Over three quarters of stakeholders have indicated that public information has improved, either 'considerably' (28%) or 'to some extent' (48%), while nearly all MS CAs that provided an assessment indicated it has improved, either 'considerably' (11 of the 25 responding MS CAs) or 'to some extent' (13 MS CAs) (survey results, Q41) (*indicator 23.1e*).

As it stands today, MS CAs **inform the general public in an order of priority that is generally defined and is proportionate to the level of the potential food/feed safety risk**. In particular, MS CAs communicate to the general public **mostly in the event of recalls** of specific feed/food, followed by: in response to press reports; as soon as there are reasonable grounds to suspect risk; where relevant, only after confirmatory testing; and, in the event of withdrawals of specific feed/food (survey results, Q40) (*indicator 23.1c*). In all cases (for all trigger points), the communication tends to occur the most in situations of high risk and the least in situations of low risk. There are also indications that the **type of information is generally adequate/appropriate**. In the case of **recalls** that have occurred in the last five years, all of the 25 responding MS CAs have indicated that they have typically communicated to the general public the following information: product details, producer, lot numbers (survey results, Q43) (*indicator 23.1d*). Compared to the situation prevailing prior to the GFL, the provision of information to the general public has become more systematic and harmonised across the EU, both in terms of the trigger points and the type of information provided.

Indeed the findings of the consultation generally indicate that, in the case of recalls that have occurred in the last five years, the **impacts** of communicating to the public that a food/feed may present a risk for human or animal health **have generally been positive**, although more so according to MS CAs than stakeholders. In particular, both MS CAs and stakeholders for the most part agree that informing the public has had a positive impact in preventing/managing food and feed crises (survey results, Q42) (*indicators 23.2b and 23.2c*)[209]. However, while MS CAs for the most part indicate that it has limited unnecessary disruption of trade/financial damage and sustained consumer confidence/trust, stakeholders are more divided on whether the impact has been positive or negative. All consulted parties agree that if communication towards the public is coordinated, balanced, targeted, science based and timely, it should help in more effectively managing food and feed safety emergencies and preventing fully blown crises from occurring, thereby limiting loss of consumer confidence/trust, unnecessary disruption of trade as well as financial damage.

The results from the evaluation of the RASFF and emergency procedures provide some further insight on the evolution and impact of public information following the GFL, since typically in these circumstances authorities also have to provide urgent information to the public[210]. Overall, the study has found that the provision of information to the public has

[209] Most of the examined aspects have received an average rating above midpoint (3), on a scale from 1 to 5; the only exception was 'limiting financial damage' which received an average rating below 3 (2.79). For all aspects, it is noted that over a quarter of stakeholders responded 'don't know'.

[210] It is noted that the RASFF is designed under Regulation 178/2002 (Articles 50-52) to ensure information exchange amongst its members (i.e. MS CAs) and not to operators or consumers. The provision of information to the public is based on the principles of Article 10, subject to the confidentiality rules of RASFF which are laid down in Article 52. The latter provide that *"in general, the public shall have access to information on product identification, the nature of the risk and the measure taken"*. Furthermore, in case of emergencies, in accordance with Article 57, the Commission's crisis unit has the role to communicate to the public on the risks involved and the measures taken. In practice, the Commission has gone beyond the requirements of RASFF and emergency

improved, including through initiatives taken at EU level (through RASFF tools) that go beyond the provisions of the GFL as such. Nonetheless, there are several areas where shortcomings or gaps remain, including different understanding and implementation of the rules by MS CAs on what type of information should be provided and how to address professional secrecy, particularly when additional information may play an important role to address public health risks.

These issues can have **considerable impact on the effectiveness and efficiency of addressing an incident, which is one lesson drawn from the 2011 E.coli outbreak**. During the outbreak, the lack of an effective communication strategy compounded with the difficulties in finding the source of the outbreak (which was largely due to the complexity of the case) and ensuring the cooperation between authorities, with extensive media coverage of the events contributing to the pressure by raising alarm among the public about possible affected products. Based on the available literature on the lessons drawn and further examination of this case, the RASFF study notes that there was an apparent lack of a coordinated and effective strategy for communication to the public, which could have allowed the effects of this pressure to be mitigated and ensured the transmission of coherent messages to consumers by the different authorities involved across the affected MS and EU institutions [211]. The avoidance of communication errors and a clearer and coordinated strategy for communication to the public is a key area identified by the consultation during the RASFF study, where costs related to the E.coli incident could have been minimised[212]. Similar cases have been experienced elsewhere in the world[213].

In analysing these findings it is important to bear in mind, once more, the **different viewpoints of the stakeholders**, with different expectations, in particular on the detail of the information to be provided and the circumstances under which further information should be provided, pointing also to **considerable and persisting national differences:**

- For business operators, informing the public, while providing beneficial reassurance in the short term, also carries the risk of lasting adverse impacts on business reputation and consumer trust. An important observation made by operators in this respect is that it takes years to build up reputation in the food business and only one poorly managed/communicated incident to completely destroy it. Continuing shortcomings are identified by stakeholders in the balance of information provided to the public and the timeliness and coordination of the communication between the different authorities involved (within MS and between MS).

- On the other hand, according to consumers, although the level and type (adequacy/ appropriateness) of the information provided to the general public has considerably

management (Articles 50-57) by providing tools (i.e. RASFF Portal; and, more recently (since 2014), the RASFF Consumers Portal) to inform non-members, i.e. professional operators and consumers, taking into account the legal limitations of the GFL, without this being an objective of the RASFF as such. Both portals are publicly available internet platforms. The RASFF Portal is accessible at https://webgate.ec.europa.eu/rasff-window/portal/. The RASFF Consumers Portal (accessible at https://webgate.ec.europa.eu/rasff-window/consumers/) provides on a temporary basis (notifications are removed after a four-week period) information on food recall notices and public health warnings issued by food safety authorities and food business operators.

[211] The lessons learnt from the E-coli outbreak were analysed further by the ECDC (2011) and the European Commission (2011a). In a recent overview report on emergency preparedness (European Commission, FVO, 2014g), the FVO has focused on the need to ensure better communication, *inter alia* by enhancing the combination of technical/scientific and communication skills for staff assuming these roles within the CAs).

[212] Apart from the human deaths, the losses for fruit and vegetable growers alone were estimated to have exceeded €800 million in the first two weeks, in addition to other costs (European Commission, 2011a).

[213] E.g. the 2008 salmonella case in the US, the source of which was first identified to be US tomatoes, but a month later was correctly identified as cucumbers from Mexico, resulted in considerable damages for tomato growers as the authorities advised the public against the consumption of tomatoes. The cost to tomato growers in Florida alone was estimated at about US$100 million (Charlebois et al (2014)).

improved overtime, it remains variable amongst MS and case by case. Consumers indicate that: information is not always provided (e.g. not generally provided in case of product withdrawals in some MS but provided in some cases in others); and/or it is not always precise enough to allow consumers to be sufficiently informed (e.g. on affected product name, brand etc.). While some national consumer organisations noted good progress in some MS, they stressed the need for more regular and improved communication in other MS. As discussed further below, similar complaints are raised with regards to the information provided through the RASFF Consumers Portal.

MS CAs have indeed indicated that there are **no fixed rules on the best approach to take, which also depends on the circumstances and the case (i.e. trigger point; food safety issue)**. For example, several MS CAs have commented that, as the recall is usually carried out by operators it is up to them to also take care of the communication aspects, except in circumstances where the CA is involved because operators fail to take action to communicate to the general public or the action is not sufficient (e.g. internet sales). Additionally MS CAs tend to communicate, e.g. via the press, in **high profile cases**, even when these are of low food safety risk as such (e.g. there was wide communication from MS CAs during the horse meat scandal), and/or when the food safety risk is high but does not affect directly their citizens (e.g. at the time of the E.coli incident in DE, other non-affected MS CAs provided communication to the general public). The continuing variable level of the information communicated to the general public can been identified by the information available on the relevant MS CA websites[214].

It is noted that the provision of public information in the case of food that is 'unfit for human consumption' (Article 14.2b) has been an area of considerable variable implementation between MS (which is more generally associated with the differences surrounding the implementation of this provision by authorities, as discussed under section III.3.3). In 2013, the European Court of Justice ruled that the GFL (Articles 10 and 17) allows national authorities to provide the public with information identifying food which is not prejudicial to health, but which is unfit for human consumption, in accordance with the requirements of professional and business secrecy[215]. In consultation with MS CAs, there were continuing differences in the provision of public information in such cases; one MS CA noted that, despite having in place national legislation on this, *"public information would depend on the decision by the local authority"*.

The process of developing public information mechanisms is still dynamic, **both at EU and MS level**. Many MS CAs are currently considering further initiatives to enhance transparency, such as for example the publication (available to consumers) of the results of official controls carried out by public authorities at the level of operators, including food manufacturers, retailers and catering[216]. At EU level, the information provided via the RASFF Consumers' portal (opened in 2014) is also considered, both by consumer groups and MS CAs, as a positive step to improved transparency as well as having the potential to enhance harmonisation on these aspects between MS, as it provides a standardised way to present information on incidents and actions taken. Nonetheless, there is scope to make the information more meaningful and standardised, subject to the constraints of ensuring

[214] Accessible directly at the various national authority websites, or indirectly via the RASFF Portal.
[215] Court of Justice of the European Union (2013): Judgment in Case C-636/11, Karl Berger v Freistaat Bayern. May 2013. In its judgment, the Court considered that EU law does not preclude national legislation, in accordance with the requirements of professional and business secrecy, information issued to the public relating to food not injurious to health, but which is unfit for human consumption, to mention the name of the food or the name or trade name of the food manufacturer, processor or distributor.
[216] It is noted that transparency requirements are already in place in the context of Regulation (EC) 882/2004. MS CAs are required to publish information on official controls that are carried out and on their effectiveness. However, in doing so, authorities should not disclose information that is covered by professional secrecy.

professional secrecy in duly justified cases when the provision of the information is not required in order to protect public health. The confidentiality requirement poses particular challenges, both in terms of the potential for variable MS understanding/interpretation, which can create confusion and be time-consuming to clarify in the case of an emergency (as noted for example, in the case of the 2011 E.coli outbreak)[217]. The potential impact of the pending proposal for a new Official Controls regulation on transparency is also noted.

III.6 Trade and international aspects

Several GFL provisions deal with trade with third countries and international aspects:

- **Imports**: Article 11 of the GFL requires food and feed imported into the EU to comply with the EU requirements (including those more specifically found in sectoral legislation), or to provisions considered equivalent to the EU requirements, or to requirements contained in specific agreements.
- **Exports**: Article 12 of the GFL requires food/feed exported/re-exported from the EU to a third country to comply with EU requirements or with the requirements of the third country. In other circumstances, except in the case of food injurious to health or unsafe feed, food/feed can only be exported/re-exported if the CAs of the third country of destination have expressly agreed.
- **International standards**: Article 5.3 that international standards (whether existing or under development) should be taken into consideration in the development/adaptation of EU feed/food law, except where inappropriate/ineffective for the fulfilment of the objectives.

EQ16: To what extent has the GFL influenced the quality and quantity of trade?

EQ17: To what extent have the public authorities implemented restrictions of the export of unsafe food/feed (Article 12)? With what impact on achieving the objectives?

EQ18: To what extent have international standards been used in the development or adaptation of EU food law and national legislative acts?

[217] The challenges of balancing the provision of sufficient information to the public to make an informed decision versus the need to respect the requirements of Article 52 on professional secrecy are explored further in the RASFF evaluation study, including in the context of the information provided in the RASFF Consumer Portal. Although the survey respondents overall thought that this Portal is accessible and transparent to the general public, almost half indicated that it does not address the needs of the general public for information on unsafe food. Respondents' suggestions for potential improvements largely focused on the provision of additional information, such as the name of the product and business operator. Although for the most part the RASFF is assessed to have achieved an adequate balance between ensuring confidentiality and providing information to consumers, nearly a third of respondents disagreed with most requiring additional information to be provided.

Key findings (EQ16/EQ17/EQ18):

The consultation, including with selected third country authorities, has found that the GFL has overall facilitated feed/food trade with third countries, as determined by several positive outcomes. In particular, it has influenced rather positively both imports of feed/food into the EU from third countries and EU exports to third countries. Nonetheless, the impacts that can be attributed to the GFL are mostly in qualitative terms, including enhanced business/ consumer trust and confidence and quality/safety aspects. When it comes to the potential impact on the volume and pattern of trade, the consulted parties have indicated that these are influenced mostly by market/economic factors, rather than the GFL *per se*, although harmonisation more generally both across the EU and in alignment to international standards exerts a positive role on international trade.

The positive impact of the GFL lies particularly in setting the same requirements for both imported and EU food products, which has led to harmonisation and setting a level playing field. The EU and MS have made considerable efforts to ensure alignment of EU food law and national legislative acts with international standards adopted at the level of Codex Alimentarius, and the GFL has largely been based on international standards, or, when this is not the case, it is transparent towards third country partners through the process of making reservations on some Codex standards. Articles 11 and 12 provide for MS to implement restrictions on trade, when deemed necessary. Although the available evidence does not allow systematic analysis in the context of this study, it indicates that for the most part such restrictions are applied when justified and that the application of restrictions is generally transparent. In the case of exports (Article 12), restrictions are usually implemented with measures taken under Articles 19-21 of Regulation (EC) 882/2004 and/or the non-issuance of health certificates for export, taking into account the specific rules applying in export destinations, rather than an export prohibition. This has achieved the intended objectives of the GFL, in terms of avoiding the export to third countries of feed/food potentially injurious to health and no such incidents were reported by the consulted third countries

Despite the overall positive impact of the GFL on trade, certain problems persist, although these also highlight the divergence amongst stakeholder interests and viewpoints. Importers highlighted the uncertainty of regulatory compliance stemming from EU standards that are in some cases more stringent than international standards (e.g. GMOs); however, all the cases provided do not point to systemic failures of the GFL principles as such while the EU standards also apply to EU products. Consumers and NGOs are concerned over the extent to which imported feed/food is in compliance with EU standards (e.g. animal welfare standards, restrictions on the use of antibiotics in animal farming). EU producers highlighted that the high standards set at the EU, both on safety and quality aspects, have resulted in higher costs for EU operators in some cases, thus affecting their competitiveness in international markets; however this view was not supported by evidence or the available literature. On the other hand, EU food standards are recognised as among the highest in the world, including by consumers in third countries, and, in certain respects, the beneficial impact of higher EU standards was also noted by some of the consulted third countries.

Regarding EU exports to third countries of feed/food more generally, MS CAs and stakeholders indicated that these are frequently hampered by the divergence of the GFL from third country food law systems and/or the non respect of international standards by some third countries. Concerns were expressed by both EU operators and MS CAs over the lack of balance between the principles that the EU applies on its imports of feed and food from third countries (where the EU is considered to apply generally a high level of openness and transparency, including at Codex level) and those applied by some third countries on their imports of feed and food from the EU (e.g. with regards to the pre-listing of establishments and the application of the regionalisation principle in trade restrictions).

III.6.1 Imports and exports *(EQ16/EQ17)*

EQ16: To what extent has the GFL influenced the quality and quantity of trade?

EQ17: To what extent have the public authorities implemented restrictions of the export of unsafe food/feed (Article 12)? With what impact on achieving the objectives?

Based on the findings of the consultation, including of the selected third countries[218], the **GFL has overall facilitated feed/food trade with third countries**, as determined by several positive outcomes. Despite the overall positive impact of the GFL on trade, certain problems persist, although these also highlight the divergence amongst stakeholder interests and viewpoints.

In particular, according to stakeholders:

- The **GFL has influenced rather positively imports** of feed/food into the EU from third countries. This has been the case, for most of the aspects considered, including: quality/safety of imports; business trust and confidence in imported feed/food; avoiding/limiting the impact of a feed/food crisis in the EU; the acceptance/use of EU standards in international trade; and, consumer trust and confidence in imported feed/food (survey results, Q24)[219] (*indicators 16.1a and 16.1b*). The only aspect in which the GFL has played a rather neutral role[220] is the quantity of imports, which, as stakeholders confirmed, cannot be attributed to the GFL as such.
- The **GFL has also influenced rather positively EU exports** of feed/food to third countries. This has been the case, for most of the aspects considered, including: including business trust and confidence in exported feed/food; quality/safety of exports; consumer trust and confidence in exported feed/food; quantity of exports; acceptance/use of EU standards in international trade; avoiding/limiting the impact of a feed/food crisis on international trade; and, competitiveness of EU exports in international markets (survey results, Q25)[221] (*indicators 16.2a and 16.2b*).

The positive impact of the GFL lies particularly in setting the **same requirements for both imported and EU food products**, which has led to harmonisation and setting a level playing field. This has **largely** been **based on international standards** (as discussed further in section III.6.2), although in certain areas EU objectives have been set a higher level, not only on safety but also on quality aspects (including e.g. environmental impacts, animal welfare etc.). There is also evidence that the GFL has worked in synergy and/or has stimulated a parallel development of private standards, particularly in areas where there are a limited number of international standards: e.g. in the feed sector (Codex Code of Practice for Animal Feeding), where the industry has developed feed safety assurance schemes to ensure feed safety of imported feed ingredients. Furthermore, the consulted third countries generally appreciate the EU harmonisation process, allowing access to a more uniform set of rules across the enlarged EU market, and the conclusion of bilateral trade agreements with

[218] Five third countries were selected for this in-depth consultation. The selection includes some of the most significant trading partners, based on the value of feed/food trade with the EU, as follows: USA, Chile, Brazil, Canada and China. Complete feedback was received from the following countries: USA, Chile and Canada.

[219] Average ratings higher than midpoint (3), on a scale from 1 to 5, on all aspects considered, with the exception of 'quantity of imports' (stakeholders). The relatively large number of 'don't know' responses is noted (13-30 of 67 stakeholders, depending on the aspect considered).

[220] Average rating just under midpoint (3), on a scale from 1 to 5, on this aspect. Nearly half of the responses provided a neutral rating to this question (3).

[221] Average ratings higher than midpoint (3), on a scale from 1 to 5, on all aspects considered (stakeholders). The relatively large number of 'don't know' responses is noted (15-30 of 67 stakeholders, depending on the aspect considered). Also, there was a high number of "don't know" responses on the impact of the GFL on the quantity of exports and that many stakeholders commented that the quantity of trade is influenced mostly by market/economic factors rather than food safety policy or the GFL as such.

the EU enhancing further trade[222]. However, they also noted that, in practice, MS continue to some extent to have varying interpretations of EU food law, leading to different commercial requirements for their exports across the EU.

Nonetheless, it is **not possible to substantiate to what extent the GFL has, overall, affected the quantity or patterns of trade** by reviewing trends in the aggregate volume/value of EU agri-food imports from and exports to third countries. Such trends are influenced by the more complex interaction of a range of market/economic as well as broader trade policy factors, as confirmed by stakeholders and the consulted third countries. However, harmonisation more generally both across the EU and in alignment to international standards exerts a positive role on facilitating international trade.

Despite the positive feedback, the following **aspects of international trade** were highlighted by certain stakeholders (business operators, mainly importers; some third countries) as the **least positively or even negatively affected**:

- **Quantity of feed/food imports from third countries**: Importers in particular highlighted the uncertainty of regulatory compliance, due to what they perceive as an *'increasing deviation of EU requirements from international standards'*, with EU standards in some cases more stringent than international standards, resulting in '*disproportionate'* costs and risks for imports into the EU. One such example provided was the case of GMOs, in particular the current "de-facto" moratorium on GMO import authorisations and zero tolerance for non-EU authorized GMOs, in combination with the lack of a pragmatic solution for implementing 'zero tolerance' in the sampling and analysis of food imports[223]. Other examples noted by the consulted third countries include the use of antimicrobial rinses on meat, and the use of novel ingredients in food supplements. It was also noted by one third country that the requirement for animal health certificates may act as a barrier to trade; for certain products there may be no designated CA which can issue the certificate in question. Nonetheless, **all the cases provided do not point to systemic failures of the GFL principles as such**, while it is noted that the EU standards also apply to EU products. Moreover, EU operators have also stressed that high requirements are set not only by EU regulation (the GFL/ other secondary legislation), but also by private standards set by EU retailers in response to consumer demand.
- **Ensuring consumer trust and confidence in imported feed/food**: Consumers and NGOs in particular noted that, while the GFL requirements have proven relatively

[222] This position is not necessarily representative of other third countries. In particular, the conclusion of bilateral trade agreements with some third countries/regions tends to be seen by other third countries/regions as having the potential to erode existing preferences and competitive advantages, where these exist, thus potentially diverting trade from their markets and adversely affecting the prospects of their market access to the EU.

[223] Business operators reported that this has implications on restrictions to import consignments of food, if traces (low level presence (LLP)) of one of the 13 "blocked" GM material are detected in food, when technically unavoidable, for example due to cross contamination during processing/transport/storage. These problems have been addressed in the feed sector with the so-called technical solution [defined in Regulation 619/2011: this introduces harmonized rules for testing with the definition of methods for sampling and for analysis and sets the "technical zero" at 0.1% (mass fraction of GM material in the tested material) at which results can be interpreted robustly]. At the same time, the EU imports significant quantities of commodities (raw material and processed products) produced in third countries where GMO cultivation is widespread, the final destination of which (feed or food) is not always predetermined (at the point of entry of a commodity shipment into the EU); thus, the food sector is extensively affected by LLP due to the multiplier effect which cascades the impact along the food chain. Similar problems (presence of traces of undesirable substances due to cross-contamination) were highlighted with the setting of import tolerances for pesticide residues (for certain pesticides legally authorised in third countries), despite the fact that a clear process is set in the relevant secondary legislation (Regulation 396/2005 foresees that MRLs for imported products should be set at levels that do not impair the current level of consumer health protection, while minimising the negative impact on trade and avoiding trade disruptions). According to data provided by EU operators, the rejection at EU borders of a 25,000-50,000 tonnes cargo can cost USD 20-80 million. The implications of the current implementation of EU legislation on GM/PPPs is that less quantities are ultimately imported into the EU, because there is increasingly a risk that the entire cargo is blocked at EU borders.

effective in ensuring the safety of imported feed/food, this is perhaps less true when it comes to certain quality aspects. Various such aspects were highlighted, including animal welfare standards, restrictions on the use of antibiotics in animal farming (e.g. ban on use of growth promoters), methods of production, and origin labelling. EU requirements regarding these aspects either do not have to be met for food that is imported into the EU, or, when they do, reliance on controls by the exporting country's CAs is not considered sufficient to ensure a high level of consumer confidence (this issue was raised not only with regards to quality aspects, but also safety issues e.g. ensuring the traceability of imported food from farm to fork). In a context of increasingly globalised food supply chains, they are concerned that this not only creates a non-even playing field for EU producers but also results in a situation that is potentially misleading for consumers. On the other hand, supply chain stakeholders noted that generally consumers are not aware of the legal provisions, and their confidence or trust in food is often affected by the media or certain incidents, despite the safety assurance provided by the actual legal framework.

- **Competitiveness of EU feed/food exporters in international markets**: some EU-based product sectors have indicated that the high standards set at the EU, both on safety and quality aspects, often result in higher costs for EU operators thus affecting their competitiveness in international markets (particularly in sectors where the market is increasingly globalised and prices are set at global level). No specific examples/data were provided to substantiate the negative impact of EU standards on EU feed/food production costs and competitiveness[224]. Nonetheless, the need to ensure a level playing field by promoting standards both in the EU and in third countries in compliance with international standards, as a means of ensuring that market access and the competitive position of EU producers is not eroded in third country markets, was frequently raised in the consultation with EU stakeholders[225]. Although EU exports have to comply with standards set in the destination third country, operators note that it is not always predetermined at production stage where products will be finally destined; therefore all products have to comply with the (generally higher) EU standards. While this ensures the quality/safety of EU exports, and business/consumer trust/confidence in EU products exported to third country destinations where EU standards are used/recognised (in national food law and/or demanded by consumers), EU products are simply higher cost in third country destinations where this is not the case. This was confirmed by the consulted third countries.

Another aspect raised by certain stakeholders (in particular consumer groups and NGOs) relates to the notion of "*equivalence*" referred to in the GFL (Article 11) and trade agreements in general. According to these stakeholders, compliance with EU requirements is not the same as equivalence, while equivalence determination and other specific agreements negotiated with EU trading partners are seen as suffering from a lack of transparency, which may give rise to concerns among the public that imported food in effect does not fully comply with EU requirements. Past and ongoing trade negotiations have shown that SPS-related issues remain a sensitive area between the EU and some of its trading partners.

[224] Some evidence on this is provided by a study for the European Commission (CRPA, 2011) examining the impact of EU legislation (including food safety, animal welfare and environmental standards) on production costs at farm level. The study concludes that impacts depend on the sector. Although in some sectors (e.g., dairy, beef) the costs of compliance to EU legislation for EU farmers fall within a slightly higher range than costs of some major third country producers this does not undermine the EU competitive position on the world market, which tends to be affected by other factors determining production costs such as access to raw material, input prices, labour costs and productivity differences.

[225] This is generally in line with the overall FDE position on promoting EU food industry competitiveness, e.g. FoodDrink Europe: Priorities for the development of an EU industrial policy for food: Competitiveness Report 2012.

Nonetheless, **EU food standards are recognised as among the highest in the world**. An example of this is the 2013 TACD resolution on food issues in TTIP, which was jointly drafted by US and EU consumer groups, and indicates that in most food law areas, EU standards are demanded by consumer groups on both sides of the Atlantic[226]. **In certain respects, the beneficial impact of higher EU standards was also noted by some of the consulted third countries**. Third countries noted that certain provisions in bilateral agreements such as the equivalence of veterinary checks, and certain equivalence provisions in other secondary legislation, as well as the management committees set up in the context of association agreements which facilitate the discussion of food law issues, may have had positive impacts on the quantity of trade. Another Third Country reported that, following a large number of rejections of imports of a certain product due to the presence of a certain toxin, the third country in question implemented a robust control system for the toxin, hence contributing to an increase in the quality of the exported product. Similarly, the demand for private standards by EU importers was identified by another third country as having had positive impacts on food safety in a specific case.

Articles 11 and 12 provide for MS to implement restrictions on trade, when deemed necessary. The available evidence[227] indicates that **for the most part such restrictions are applied when justified and that the application of restrictions is generally transparent**. In particular, MS CAs indicated that:

- They have implemented **restrictions on imports** of unsafe feed/food. In particular, 20 of 25 responding MS CAs indicated that they have always/in most cases implemented restrictions while a further 3 MS CAs have implemented restrictions but not systematically (survey results, Q26) (*indicators 16.3a to 16.3c*). In particular, key reasons for which restrictions on imports are implemented are for non-compliance issues identified during controls at border inspection posts: for food of animal origin, issues arising during veterinary checks carried out on the basis of Directive 97/78[228], including particularly parasites and microbiological contamination (all cases are recorded in TRACES); for food of non-animal origin, issues arising during the controls carried out on the basis of Regulation (EC) 669/2009[229], including particularly pesticide residues and contaminants (e.g. mycotoxins). In the event of non-compliance with legislation, the measures provided for by Regulation (EC) No 882/2004 apply, particularly the possibility to destroy or return the products in question, or to subject them to any other appropriate treatment. Nonetheless, as noted above, EU operators raised concerns on differing approaches taken by MS in terms of accepting/restricting imports into the EU, in particular in non-harmonised areas where MS can fix different MRLs/tolerance levels (as discussed elsewhere in the report, such non harmonised areas include: contaminants[230]; salmonella in feed; certain pesticides; GM food etc.). It was also noted that, in some cases of restrictions on imports, the precautionary principle (Article 7) is applied rather than the case of a reasonable suspicion of the food to be unsafe, as foreseen on the basis of Articles 14.6 and 14.8 of the GFL.

[226] Transatlantic Consumer Dialogue (TACD): Resolution on the approach to food and nutrition related issues in the Transatlantic Trade and Investment Partnership (TTIP). DOC No: FOOD 34/13. October 2013. http://tacd.org/wp-content/uploads/2013/09/TACD-FOOD-Resolution-on-the-approach-to-food-and-nutrition-related-issues-in-the-TTIP.pdf

[227] It is not possible on the basis of the available data to carry out systematic analysis to draw conclusions on the trend of these restrictions (*indicator 16.4a*). Imports: data exist at EU level on restrictions imposed following border inspection controls (TRACES) and MS notifications (RASFF); in other cases, data are not systematically collected. Exports: data not systematically collected. For caveats on data analysis, see section II.3.2.

[228] Council Directive 97/78/EC of 18 December 1997 laying down the principles governing the organisation of veterinary checks on products (entering the Community from third countries.

[229] Commission Regulation (EC) No 669/2009 of 24 July 2009 implementing Regulation (EC) No 882/2004 as regards the increased level of official controls on imports of certain feed and food of non-animal origin.

[230] Other than those contaminants indicated in **Table 1**, for which EU measures (establishment of maximum levels) have been taken.

- They have taken **measures to ban the export to third countries** of unsafe/injurious to health feed/food under Article 12. In particular, 16 of 25 responding MS CAs indicated that they have always/in most cases taken measures while a further 2 MS CAs have taken measures but not systematically (survey results, Q27) (*indicators 17.1a to 17.1c).* MS CAs indicated that, as foreseen by Article 12, their national food authorities in most cases do not allow food that is injurious to health/unsafe to be exported/re-exported to third countries, unless in specific cases if bilaterally agreed with the importing country. This is usually implemented with measures taken under Articles 19 to 21 of Regulation (EC) 882/2004 and / or the non-issuance of health certificates for export, taking into account the specific rules applying in export destinations[231], rather than an export prohibition as such. As such, **these restrictions have achieved the intended objectives of the GFL**, in terms of avoiding the export to third countries of feed/food potentially injurious to health and no such incidents were reported by the consulted third countries (*indicator 17.2a*).

It was also noted by one third country that the GFL provided the opportunity for Memoranda of Understanding to be signed with third countries relating to the exchange of information (including confidential) for RASFF purposes; hence enabling the sharing of sensitive information which may, for example, ensure trade can be effectively and efficiently re-established following an alert.

Regarding **EU exports to third countries of feed/food**, MS CAs and stakeholders indicated that these are **frequently hampered by the divergence of the GFL from third country food law systems and/or the non respect of international standards by some third countries**; this is also confirmed by reviews of non-tariff barriers faced by EU companies in key third country markets[232] (*indicators 16.5a and 16.6a*). At the same time, Article 12 does not generally foresee the principle of reciprocity in international trade relations but only in the context of bilateral agreements concluded with third countries. This creates considerable barriers to EU exports more generally, given the divergence of standards applied between the various third country trading partners, and vis a vis the EU. Although it is not possible in the context of this study to systematically review all areas where EU standards diverge from those applied by third countries, a number of issues were indicated in relation to fundamental differences in principles. Concerns were highlighted by EU operators and MS CAs over the **lack of balance between the principles that the EU applies** on the import of feed and food from third countries (where the EU is considered to apply generally a high level of openness and transparency, including at Codex level) **and**

[231] For example, the US requires that a specific sampling program for *Listeria Monocytogenes* is applied in EU exporting establishments as well as an inspection monitoring program. Russia applies specific measures for certain products/sectors (e.g. veterinary and phytosanitary standards for animal/plant products); it requires MS CA inspections in EU establishments to cover these rules and/or carries out its own inspections, with further measures taken including restrictions to exports to Russia, in case non-compliance is detected.

[232] The non-tariff barriers for EU exports to key third country markets have been highlighted by the Commission in systematic annual reviews. The latest (2015), Trade and Investment Barriers Report, covers a selection of key barriers faced by EU companies on the markets of the EU's strategic partners, i.e. China, India, Japan, Brazil, Argentina, Russia and the US, and indicates that food products are one of the sectors frequently facing regulatory barriers (European Commission, 2015a). Furthermore, studies conducted by the Commission in the context of the TTIP negotiations on regulatory barriers for EU exporters to the US (European Commission, 2015b) highlight that SMEs are particularly affected by such barriers. Another recent study on the EU-US trade relations and TTIP (European Parliament (2015) highlights several barriers for EU operators, including in areas where the US has been critical of the EU approach, such as Articles 6 and 7 (risk analysis; precautionary principle) where US courts are applying similar concepts. According to this study: *"The US scientific approach to regulation is supported by the central role of the White House's Office of Information and Regulatory Affairs (OIRA) and the "Regulatory Impact Assessments" (RIAs) that agencies are required to produce. Both are based on science-based cost-benefit analysis. (Alemanno and Parker, 2014). In place of the precautionary principle, the US has a stringent civil liability system that acts as a means of ensuring that health and safety regulations and product standards are not lax (Bergkamp and Kogan, 2013). In multiple cases the US Supreme Court has ruled that the US's Office of Safety and Health Administration must have demonstrated "significant risk" prior to regulation (Wiener and Rogers, 2002)."*

those applied by some third countries on the import of feed and food from the EU. Hence the level playing field that the GFL and EU law more generally aims to ensure for third country suppliers to the EU market may not be ensured in third country markets (this is not directly attributable to the GFL). Such examples include:

- The **pre-listing of establishments** (approval by the importing country of the establishments guaranteed by the exporting country without carrying out on-site inspections for verification): this principle is applied by the EU on all third countries approved for export to its territory even when the latter do not apply the same principle and require on-site inspections, which are sometimes carried out years after the request was made. China, Russia, and South Korea were indicated as some of the numerous countries that do not apply the pre-listing approach.
- The **regionalisation principle** applied in trade restrictions raised by veterinary matters (in case of a grave disease affecting cattle, restrictive measures should be implemented just on the region or province involved and not on the entire country or sometimes the entire Union): the EU applies this principle if the exporting country provides it with all the required animal health guarantees but some third countries apply this principle towards the EU just in a few cases. The US, China, Russia, Korea, Japan and Australia are some of the many countries that do not apply regionalization.

III.6.2 International standards *(EQ18)*

EQ18: To what extent have international standards been used in the development or adaptation of EU food law and national legislative acts?

The consultation has found that **the EU and MS have made considerable efforts to ensure alignment of EU food law and national legislative acts with international standards adopted at the level of Codex Alimentarius** (Codex). At the same time the EU and MS have played a key role, as also recognised by their international partners, in the development of international standards consistently with the broader Codex objectives[233] and this is generally acknowledged both during our consultation and in literature[234], to have played a positive role in international food safety governance.

Over time, depending on the area, the **trend can be towards an alignment of EU standards to international standards, or the other way round**. It is not possible to measure this with a quantitative indicator as such, for example, by drawing any conclusions from observing the trend of reservations put forward by the EU in Codex decisions[235], since these are on specific matters and constantly evolve. On the other hand, the fact that the EU makes reservations on some Codex standards is an indicator of **transparency towards third country trading partners**, as the EU makes clear to its trading partners that it deviates from the Codex, by adopting what is usually a stricter standard, thus allowing potential exporters to the EU to prepare accordingly to meet the EU standards.

All consulted parties generally agree that the robust food safety framework set up by the GFL is internationally recognised and, in some cases, a source of inspiration for third countries developing their national legislation, or even at Codex level, thus influencing the quality of agri-food trade not only within the EU (as outlined above), but also globally.

[233] A general principle in Codex is to review existing guidelines/standards developed by other international organisations before developing new standards.
[234] Alemanno A. (2007): Trade in Food: Regulatory and judicial approaches in the EC and WTO.
[235] Where the EU legislation is not in line with the Codex, the EU delegate flags it up, by indicating a **reservation** in the specific committee and then at the Codex Commission (CAC). In this way, the EU is transparent in its position vis-a-this other Codex members, and also provides a solution to avoid blocking the adoption of international standards if there is support otherwise.

Examples that were provided during the consultation include: the modernisation of feed legislation in some countries (e.g. Japan, Canada) on the basis of the EU model; the modernisation of food legislation in some countries (e.g. US[236], Canada) (see EQ14/15, III.3.1). The US representatives indicated that existing trade between the US and the EU is possible because both have in place legislation that is largely science based and they both recognize international bodies such as the OIE; because of this it was also possible to conclude a Veterinary Equivalence Agreement and to engage in the current TTIP talks.

The European Commission and MS authorities actively participate in the development of Codex standards and this is considered beneficial both for the development of international standards and for improving the international acceptance of EU standards. EU legislation tends to follow updates adopted by Codex, and the other way round. For instance:

- The drafting of the Regulation on claims was based on Codex, but certain areas went beyond Codex requirements and this has been subsequently updated in Codex (in line with EU legislation);
- The Codex Committee on fresh fruit and vegetables set standards based on existing UNECE standards for different commodities;
- In the context of the revision of the current hygiene rules, Codex has been revised on the basis of EU regulation, which is considered globally to be more advanced.

It is EU membership of Codex since 2003 (in addition to individual MS membership), rather than the introduction of the GFL as such, that has resulted in an improved representation of EU legislation at Codex. The cooperation/coordination between the Commission and MS in Codex meetings is considered sufficient and the division of competence between MS and COM works well. Within the EU, EU membership of Codex has resulted growing discipline and acceptance across MS to follow a common approach in international standard setting fora. MS have the possibility to provide additional comments in case of specific expertise on specific issues, and MS generally intervene when there are no EU harmonised rules.

Both EU operators and the consulted third countries, confirmed that the principle of "equivalence" of sanitary and phytosanitary requirements between the EU and its trading partners is of upmost importance for facilitating trade in agri-food products. Essential to achieve this are regulatory cooperation with governments of third countries and recognition of international standards, both by the EU and its trading partners. However, concerns remain over an apparently persisting lack of cooperation with governments of third countries in certain areas, leading to unnecessary food and feed trade disputes (e.g. with the USA and Canada in order to establish common mycotoxin limits (OTA for food - Afla B1 for feed)).

At the same time, in certain areas where there is persisting divergence between EU and third country standards, the private sector has taken the initiative to prepare global standards and benchmarks, for example: the GFSI (Global Food Safety Initiative) has been developed as the overarching benchmark for globally recognised food safety standards (see EQ12/13, III.3.2.1); the feed additives sector has engaged in a convergence project globally in order to harmonise the requirements world-wide.

III.7 Coherence and complementarity

This section presents the findings of the evaluation regarding coherence and complementarity.

[236] The latest US Food Safety Modernization Act includes several provisions which go in the direction of the GFL e.g. import controls, more enforcement power to food safety authority (FDA), and traceability.

Coherence covers both aspects of internal and external coherence, as follows:

- **Internal coherence**: The extent to which the GFL has contributed to the internal coherence of EU food law.
- **External coherence**: The extent to which the EU food safety regulatory framework established by the GFL and its implementation works together with other MS interventions which have similar objectives.

Complementarity covers the extent to which the EU food safety policy framework established by the GFL proved complementary to other EU interventions/initiatives in the field of food policy such as the Common Agricultural Policy (CAP).

Key findings (EQ32/EQ33/EQ34):

Key findings on coherence/complementarity are summarised under the evaluation theme of coherence in section IV.4.

III.7.1 Internal coherence *(EQ32)*

EQ32: To what extent has the GFL contributed to internal coherence of the EU food law?

Overall the legislative framework introduced by the GFL has largely contributed to improving the internal coherence of food safety rules across MS, as well as between the key areas of other secondary legislation, compared to the baseline. These two aspects are found to be some of the most important benefits of the GFL, compared to what could have been achieved in the absence of a common framework by MS at national and/or regional levels or at international level (Codex, OIE) (survey results, Q50) [237]. In particular, nearly all stakeholders and MS CAs indicated that the GFL has provided the basis for a single, uniform framework and principles to develop EU rules in other secondary legislation on food/feed safety, and this has improved coherence of food safety rules across the EU and between sectors.

One of the benefits (added value) of the GFL has been that it established the streamlining of comitology procedures through the replacement of all previous standing committees with a single Standing Committee on the Food Chain and Animal Health [238]. This aspect is considered to have contributed to improve the link between the objectives, issues and principles transcending policy implementation on food and feed safety, animal health and welfare and plant health, thereby also improving coherence between the various relevant policy areas.

The contribution of the GFL in improving internal coherence is also highlighted throughout the findings regarding the main provisions in the scope of this study. The **GFL has created a common framework for addressing food safety and has formalised the various concepts, provisions and procedures that existed in individual MS and/or sectors/fields of food law**. Furthermore, it has instituted a chain approach, thus contributing to address/remove the shortcomings of previous fragmented, piecemeal approaches. Creating this common ground has been an important contribution of the GFL, from providing common definitions (as outlined in III.2), to defining common objectives, to laying down base principles and general requirements (risk analysis; precautionary principle; transparency; allocation of responsibilities to operators and authorities for ensuring food safety; traceability; and withdrawals/recalls). An essential part of this is the scientific underpinning, in application of Article 6, notably with EU-level risk assessments

[237] Both stakeholders and MS CAs provided average ratings on these aspects above 4, on a scale from 1 to 5.
[238] Now called Standing Committee on Plants, Animals, Food and Feed (PAFF).

provided by EFSA[239], and an increased convergence of food safety organisation and risk analysis approaches between MS (discussed below). The contribution of the GFL in importing coherence is also evidenced by the lack of coherence (and implications) in cases where there is lack of harmonisation or the harmonisation process is not complete (examples include: food contact materials other than plastics; contaminants; salmonella in feed; lack of technical solution for GM food).

III.7.2 External coherence *(EQ33)*

EQ33: To what extent has the EU food safety regulatory framework established by the GFL worked together with other MS interventions which have similar objectives?

The main MS intervention of relevance to the GFL objectives which was identified in the context of this evaluation relates to the **creation of independent scientific bodies at MS level for risk assessment**[240]. This issue has been analysed further in the context of the risk analysis case study, including interviews with the selected MS CAs covered by the case studies.

As outlined in section III.4.1, the GFL - in conjunction with related parallel developments that occurred at the time of its introduction, all of which were motivated by the need to respond to the safety crises of the late 1990s - has been a driving force for a major re-organisation of the food safety structures in the MS. This led in the establishment of independent risk assessment bodies in some MS, and in any case the separation of the risk assessment and the risk management functions (**Table 6**). The consultation has found that **such national interventions have been coherent with the GFL objectives**, i.e. they aimed to improve the governance structures in place to deliver food safety objectives. These **national structures have largely worked in synergy, i.e. have been complementary, to the EU food safety structures established by the GFL (EFSA).** The establishment of national risk assessment bodies, in parallel to EFSA, has responded to the continuing need for national risk assessments to: a) provide the scientific basis for MS measures in non-harmonized areas (e.g. processing aids) or partially harmonised areas (food contact materials, contaminants in food, food supplements); and, b) to determine at national level factors of exposure to risk (e.g. from contaminants) which *inter alia* depend on national consumption levels/patterns and production systems. Furthermore, this has generated

[239] EFSA has a wider scope than the food/feed safety since it also covers all scientific issues linked to plant health, animal health, animal welfare, nutrition issues not impacting directly or indirectly food and feed safety (Article 22 of the GFL). The aim is to provide a global scientific view on all aspects of the food chain.

[240] Other interventions of relevance relate to the application of the principle of mutual recognition (Regulation (EC) No 764/2008). This principle defines the rights and obligations for public authorities and enterprises that wish to market their products in another MS. The Regulation also defines how MS can deny mutual recognition of a product but need to notify this to the Commission. The first report on the application of Regulation (EC) No 764/2008 (COM(2012) 292 final), identified certain shortcomings in the application of the principle by MS (including that MS do not notify all decisions falling under Articles 6(2) and 7 of the above Regulation) and concluded on the need to continue monitoring during the period 2012-2017 within the relevant Consultative Committee its application with the objective of analysing the functioning of the existing EU legal framework for mutual recognition. As concerns food, notably food additives and food supplements, this is one of the main areas in which notifications are received, and for which a specific guidance document has been issued; the COM report concludes: *"in light of the* partial harmonisation within this *area, there might be differences in national legislation (e.g. the classification of some products as medicinal products or foodstuffs, in various MS, the use of substances other than vitamins or minerals in the manufacture of food supplements, etc.) which may be factors affecting the free movement of those products."* During the consultation for the present study, supply chain stakeholders commented that, as public health reasons can be an exception to the mutual recognition principle, MS sometimes invoke such reasons in the case of vitamins/minerals and in such cases it is sometimes necessary that operators take legal actions to contest the application of the mutual recognition principle. **An external evaluation of this principle is currently on-going for the European Commission.**

efficiency gains from access to a larger, complementary pool of EU and national scientific expertise.

III.7.3 Complementarity *(EQ34)*

EQ34: To what extent has the EU food safety policy framework established by the GFL proved complementary to other Union interventions/initiatives in the field of food policy such as the Common Agriculture Policy (CAP)?

The focus in the context of complementarity aspects has been on the **extent to which the EU food safety policy framework established by the GFL and the Common Agricultural Policy (CAP) are complementary to one another**. Other areas of complementarity and consideration of other Union interventions/initiatives that touch on the field of food policy, including environmental, trade, and growth and competitiveness objectives are discussed in the context of other EQs (see sections III.8.3 and IV.1).

The current objectives of the CAP, set out in Article 39 of the Treaty on the Functioning of the European Union, in line with the original objectives of the CAP set out in the agricultural legal basis of the Treaty of Rome (ex Article 37 EC Treaty), are as follows[241]:

- to increase agricultural productivity by promoting technical progress and by ensuring the rational development of agricultural production and the optimum utilisation of the factors of production, in particular labour;
- thus to ensure a fair standard of living for the agricultural community, in particular by increasing the individual earnings of persons engaged in agriculture;
- to stabilise markets;
- to assure the availability of supplies;
- to ensure that supplies reach consumers at reasonable prices.

The GFL is based on ex Article 37 EC Treaty but also Article 152(4)(b) EC Treaty: *"by way of derogation from Article 37, measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health".*

The consultation has found that food safety is considered to be fully complementary to the CAP. In particular, food safety principles reinforce the CAP objective to support agricultural production by ensuring a safe and therefore viable supply of raw materials and food products. They also act to stabilise markets by reducing the likelihood of volatility in demand arising from food safety scares. In turn, this avoids excessive volatility in supply in response to fluctuating demand. Finally, by setting out common definitions, principles and requirements which facilitate the smooth functioning of the single market in the area of food/feed law, the GFL helps to ensure that supplies reach consumers at reasonable prices. Although not mentioned explicitly in the CAP objectives, food safety is an essential attribute expected of food produced in the EU. The **food safety objectives of the GFL underpin the CAP objectives**; the production of unsafe food would clearly not be compatible with the objectives of the CAP. By definition therefore there is complementarity between the CAP and food safety policy objectives. The GFL objectives to ensure safe food are essential to meeting the objectives of agricultural policy not only in the EU but also more globally (e.g., in the context of the FAO definition of food security[242]).

[241] Under the CAP Strategy to 2020 (European Commission, 2010e), the three main objectives for the future CAP will be to ensure: viable food production; sustainable management of natural resources and climate action; and, balanced territorial development. The objectives correspond to three broader strategic aims: to guarantee long term food security; to support farming communities that provide the European citizens with quality, value and diversity of food produced sustainably; and, to maintain viable rural communities.

[242] The FAO definition that has acquired the broadest acceptance is that of the World Food Summit (WFS) in November 1996: "*Food security exists when all people, at all times, have physical, social and economic access to*

More generally, the system of inter-services consultation has worked well over the years for the effective screening of any contradictions in policy design and in reviewing/evaluating measures. When the GFL was drafted, there was extensive inter-services consultation within the Commission and the draft reflected all views of the various policy departments. The complementarity of the sectors is institutionalised further in the DG AGRI – DG SANTE relations; following the transfer of the food safety dossier from AGRI to SANTE after 1999, the two DGs have introduced an effective procedure to ensure regular cooperation. However, there are some concerns at the level of MS implementation over a lack of coherence/complementarity between policies. A relevant question here for MS has been how inter-departmental consultation between relevant national CAs is ensured; the consultation has found considerable variations in the level and quality of consultation between the relevant CAs at MS level.

The CAP has evolved considerably over the last two decades. Since 1992 and the McSharry reform, EU agricultural production has progressively and increasingly adapted to market demand as a result of the shift from market support to direct payments. The market orientation of the CAP has increased further with the decoupling of direct payments. This policy evolution will further progress with the phasing-out of milk and sugar quotas.

It is important to note that food safety scares generated significant market disturbances (some over a long period such as the BSE) which required financial intervention from the CAP. Due to the increased market orientation of the CAP, most of the traditional legal instruments available for intervention to stabilise prices are no longer available and as regards, for instance, support to recover consumer confidence following food safety and non-safety related scares, are all subject to financial discipline within the CAP budget.
The underlying link to food safety has become an important dimension of the evolved CAP. In particular, under a major reform of the CAP in 2003, which removed the link between subsidies and production, farmers receive an income support payment on condition that they comply with strict standards relating to food safety, environmental protection and animal health and welfare standards ('cross-compliance' rules[243]). The link to food safety is reinforced in further reforms of the CAP, including the CAP Health Check of 2008 and the Europe 2020 strategy offers a new perspective.

In particular, three strategic aims were articulated in the Commission's 2010 Communication on "The CAP towards 2020: Meeting the food, natural resources and territorial challenges of the future" (European Commission, 2010e). Food safety is implicit in all three of these aims, but is more explicit in the second one: "*to support farming communities that provide the European citizens with quality, value and diversity of food produced sustainably, in line with our environmental, water, animal health and welfare, plant health and public health requirements*". Food safety is an essential component of public health. In addition, Regulation (EU) No 1306/2013 on the financing, management and monitoring of the CAP explicitly refers to the GFL under Statutory Management Requirement (SMR) number 4 in relation to cross-compliance rules (Article 93 and Annex II), and strict penalties in the case of non-compliance are also foreseen (Art. 97). The GFL provisions specifically mentioned in SMR4 include Articles 14 and 15, which do not permit the placing on the market of unsafe food or feed, and Articles 17, 18, 19 and 20 on

*sufficient, **safe** and nutritious food which meets their dietary needs and food preferences for an active and healthy life.*"

[243] Direct payments to farmers under the CAP are linked to the fulfilment of certain basic standards concerning the environment, food safety, animal and plant health and animal welfare, as well as the requirement of maintaining land in good agricultural and environmental conditions. Since 2005, all farmers receiving direct payments are subject to compulsory cross-compliance. The mechanism of cross-compliance creates synergies between CAP payments and the need to ensure compliance with basic mandatory standards.

responsibilities of operators and traceability requirements. Essentially the evolution of the CAP, which has continued since the adoption of the GFL, has increased the interconnection of the EU agricultural policy and food safety goals. **Rather than being implied, food safety is now mentioned more explicitly in the guiding principles of the CAP and the GFL is specifically referenced.**

Despite the complementarity in objectives, the tools available in the context of the different policies serve the objectives of the policy for which they have been developed and are not necessarily designed or appropriate for addressing fully other policy objectives. For example, the cross-compliance requirements laid down in the CAP, although establishing a link between food safety and CAP objectives, apply only to primary producers that receive direct payments. Nonetheless, cross-compliance remains a useful instrument to increase awareness of the broader issues affecting EU farmers and compliance with EU standards, including on food safety. As such, it therefore establishes a principle which can be built on and further developed, as envisaged in the strategic aims of the CAP to 2020.

III.8 Achievement of objectives

The analysis presented in this section covers both the achievement of the current core objectives of the GFL (protection of consumer health and interests; ensuring the effective functioning of the internal market) and the extent to which other objectives, interests/needs and current trends are being addressed. With regards to the protection of consumers, the analysis covers both aspects of ensuring food safety and the protection of consumer health, as well as consumer interests in the broader sense, thus including the prevention of fraud.

Key findings (EQ3/EQ4/EQ5/EQ7):
Key findings on the achievement of objectives are summarised under the evaluation themes of effectiveness, as well as relevance, in sections IV.1 and IV.2 respectively.

III.8.1 Protection of consumers' health and interests *(EQ3)*

III.8.1.1 Overall assessment

EQ3: To what extent has the GFL and its implementation contributed to achieving the objective of protection of consumers' health and interests including fair practices in food trade (Article 5.1)?

The general horizontal framework introduced by **the GFL and its implementation/application at EU/national level have largely contributed to achieve the protection of human life and health**: this objective received the highest average rating amongst all core objectives of the GFL, according both to stakeholders and MS CAs (survey results, Q1)[244] (*indicators 3.1a and 3.1b*). Generally, the contribution of the current provisions of the GFL and MS implementation in this respect is considered satisfactory by all consulted parties, including consumer organisations.

A key point raised by operators was that the outcome of the core GFL requirements should be better defined as consumer safety rather than consumer health. On the other hand, consumer organisations have stressed that the GFL is very much focused on safety aspects. While the GFL has adequately drawn the lessons learnt from the feed/food safety scares of the 1990s and laid down the right foundations in this regard, consumer organisations indicated that the GFL does not very well reflect the broader concept of consumer health which includes nutrition. They note that consumer needs have changed since the 1990s,

[244] Average ratings higher than 4, on a scale from 1 to 5, both for stakeholders and MS CAs.

with a rising obesity trend which makes pertinent the consideration of nutrition issues. These issues are examined under the relevance of the GFL in section IV.1.

Set against the context that led to the establishment of the GFL, namely the BSE crisis and its severe impact on consumer confidence in the food chain, the GFL has aimed to re-build trust. Even though some incidents have shaken consumer confidence over the years, overall this goal has been achieved. The **GFL has been successful in achieving a minimum, high-standard harmonisation** across the EU in order to ensure the safety of food and feed placed on the market and to protect consumers' health and interests, while facilitating the free movement of goods. Positive feedback to this effect was received by all consulted parties, including organisations representing consumers, food business operators, SMEs and the environmental NGOs.

In particular, the EU consumers organisation (BEUC) and environmental NGOs noted that *"Generally speaking and especially when comparing the EU food regulatory framework with that of third countries, the GFL established fundamental principles that have contributed to ensuring Europeans have access to food that is safe".* Furthermore, they noted that the implementation of the GFL through other secondary legislation has, over the years, contributed to the **effective harmonisation of consumer protection across the EU**. In particular, the **explicit inclusion of the "*protection of consumers' interests*" under the general objectives of the GFL in Article 5.1 is considered to have brought a change in approach in EU food law**. An example demonstrating this change is food labelling legislation (Regulation 1169/2011 on Food Information to Consumers – the **FIC Regulation**), which puts consumer interest at the heart of the legislation: the scope of the FIC Regulation allows consumers to make informed choice according to interest.

All the core requirements for operators, as laid down in Articles 14, 15, 17, 18, 19 and 20 of the GFL, **have largely ensured a high level of protection of consumer health** (*indicator 3.1e*). According to a large majority of stakeholders and nearly all MS CAs, the protection of consumer health has been achieved by all core GFL requirements, as follows: to place safe food/feed on the market and verify that food/feed is compliant with food law; to establish one step back - one step forward traceability; to perform withdrawals/recalls of food/feed at risk; to notify public authorities in case food/feed considered at risk; and, to collaborate with public authorities on actions taken to avoid or reduce risk (survey results, Q4) [245]. Furthermore, the positive contribution of the GFL was noted in terms of the development of an advanced system of **traceability** (Article 18), the **allocation of responsibilities** (Article 17), and the formalisation and systematic application of **risk analysis** as well as the precautionary principle (Articles 6 and 7). The consultation with food/feed supply chain representatives has found that, fundamentally, operators accept the **need to take responsibility for food/feed safety as the backbone of sustaining consumer trust and confidence** in their sector. The contribution of these provisions in harmonising and raising food safety standards across the EU is outlined extensively in the relevant sections of this Report.

In particular, **each of the requirements has played a positive role in this respect**. The allocation of responsibilities along the food chain as laid down in Article 17 overall contributed to high level of protection of human health and consumers' interests as regards feed/food products placed on the market, making this one of the highest achievements of Article 17, according both to stakeholders and MS CAs (survey results, Q8) [246] (*indicator*

[245] On a scale from 1 to 5, average ratings provided by both stakeholders and MS CAs were above or nearly 4 for all requirements (slightly lower average ratings were recorded in the case of stakeholders). The number of negative responses was marginal: depending on the requirement, 1-4 of 67 stakeholders, and 0-1 of 25 MS CAs.
[246] On a scale from 1 to 5, average ratings provided by both stakeholders and MS CAs were above (4).

3.1h); although concerns were expressed on the allocation of liability which remains defined on a legal basis found in the national legal order (as foreseen in Article 21) and in the specific infringed legislation. The traceability requirement of Article 18 of GFL ("one step back – one step forward" approach) for the most part assisted in containing a food/feed safety problem, and contributed to maintain consumer trust and confidence to the safety of a food/feed (survey results, Q13) [247] (*indicator 3.1i)*. The combined application of the provisions on determining the safety of feed/food, both in terms of traceability (Article 18) and withdrawals/recalls (food: Article 19; feed: Article 20), for the most part have ensured a high level of protection of consumer health and restored consumer confidence/trust in food (survey results, Q19)[248] (*indicator 3.1j).*

Bearing in mind the caveats in the analysis of certain quantitative indicators of food safety (see section II.3.2), the **improvement in food safety trends is generally supported by the trend in the number of food safety incidents** (such as: RASFF notifications on food safety incidents e.g. cases of food poisoning 2008-2013; ECDC/EFSA annual report on zoonoses and food-borne outbreaks (Salmonella, Lysteria, Campylobacter)).

Despite the overall positive findings on the contribution of all relevant provisions of the GFL in improving food safety and the protection of consumers' health, some weaknesses persist as outlined below.

The achievements of the GFL in ensuring a high level of protection of consumer health do not appear to be fully reflected in consumers' trust and confidence in food safety and public authorities more generally (*indicator 3.1c*). It is indicative that, despite the very high positive feedback of the both MS CAs and stakeholders on the contribution of the GFL in ensuring food safety and the protection of consumers' health, the **feedback in terms of ensuring consumer trust and confidence, although positive, is not equally high**. Although all of the key GFL requirements for operators (as laid down in Articles 14, 15, 17, 18, 19 and 20) have largely ensured consumer confidence/trust in food/feed, the achievement of this objective has not scored as high in the consultation (by stakeholders in particular), as the achievement of a high level of protection of consumer health (survey results, Q4)[249]. Despite an average positive feedback, stakeholders in particular provided a relatively high number of negative responses, with regards to the requirement for operators to place safe food/feed on the market and verify that food/feed is compliant with food law, i.e. that this requirement has not fully ensured consumer confidence/trust in food/feed. These stakeholders come from a mix of sectors, other than food or feed as such, including some citizen movements and animal welfare NGOs, although other organisations/ counterparts representing these sectors provided positive scorings. In most cases these stakeholders did not justify their scoring. Overall, the main issue that was raised by stakeholders more generally was that consumers are not aware of the legal provisions therefore their **confidence or trust in food is often affected by the media or specific food incidents** despite the legal framework (this observation was also raised in the context of traceability, as discussed further in III.3.1 and elsewhere in this report).

According to a 2010 Special Eurobarometer (No 354) report (European Commission, 2010c) on perceptions of food-related risks, EU citizens broadly agree that public authorities do a

[247] On a scale from 1 to 5, average ratings for both objectives above (4), by both stakeholders and MS CAs.
[248] On a scale from 1 to 5, average ratings by both stakeholders and MS CAs: for ensuring a high level of protection of consumer health above (4); for restoring consumer confidence/trust in food above (3).
[249] On a scale from 1 to 5, average ratings provided by MS CAs on the contribution of the core GFL requirements in ensuring consumer trust and confidence were above or nearly (4) for all requirements, while for stakeholders they were under (4). The number of negative responses was small in most cases (depending on the requirement, 3-6 of 67 stakeholders, and 0-1 of 25 MS CAs); except in the case of the requirement for operators to place safe food/feed on the market and verify that food/feed is compliant with food law (10 stakeholders).

lot to ensure that food is safe in Europe, that they are quick to act, base their decisions on scientific evidence and do a good job in informing people about food-related risks. The level of agreement in the 2010 Eurobarometer report is higher than that in a similar survey carried out in 2005 (European Commission, 2006b), although some results pointed to areas where trust can be further improved. It would have been useful to analyse any more recent trends in consumer trust following some major issues that have emerged in the EU since then, in particular the E.coli outbreak (June 2011) and the horsemeat fraudulent labelling scandal, but EU-level data are not available, while available data at MS level do not allow a systematic analysis[250]. Where data exists, it shows that **certain incidents can have lasting effects on consumer trust and confidence**. In the UK, a September 2014 survey on consumer confidence showed that over a quarter of consumers indicated that the horsemeat scandal had resulted in changing their meat purchasing habits, over a year after the scandal unfolded. It is noted that consumer trust in food safety authorities and perceptions of food-related risks remains a partial only indicator of the effectiveness of the GFL in meeting a high level of consumer protection, while the interpretation and comparison of these data over time poses certain limitations/caveats (see section II.3.2).

Despite the overall positive feedback on the contribution of the GFL to increase the protection of consumers' interests (e.g. as demonstrated by the objectives of the FIC Regulation), consumer organisations and some MS CAs have nonetheless expressed some concern that, in practice, this objective is less well achieved than the protection of consumer safety as such[251]. This was justified on the basis of the **persisting potential for fraud and misleading practices** (these aspects are analysed further in section III.8.1.2.).

III.8.1.2 Prevention of fraud and misleading practices (EQ6)

EQ6: To what extent were the provisions of Article 8 of Regulation (EC) No 178/2002 and their implementation instrumental and successful in achieving a higher level of protection of consumers' interests, in particular through the prevention of fraud and of misleading practices?

Survey results (Q22) indicate that **MS have for the most part taken measures at national level to implement the provisions of Article 8** in order to address: a) fraudulent/deceptive practices; b) food adulteration; c) any other misleading practices (*indicator 6.1a*). In particular 19 of the 25 responding MS CAs have taken measures for the prevention of fraudulent/deceptive practices and the prevention of food adulteration, while 5 MS CAs have not taken any measures and 1 MS CA did not provide an answer. 11 MS CAs have also taken measures for the prevention of any other practices which may mislead the consumer, while 7 MS CAs have not and 7 MS CAs did not provide an answer. Amongst the MS that have not taken any measures, 2 MS indicated that measures addressing the issues raised by Article 8 were already in place prior to the GFL.

Amongst those MS that indicated they have measures in place addressing the provisions of Article 8, further explanation of these measures highlights the **diversity of provisions that currently apply across the EU, both in coverage** (i.e. whether specific to food or general provisions; whether covering all cases of Article 8, a to c, or some of them) **and in severity of penalties** (i.e. whether administrative or criminal or both). In particular:

[250] In the course of our consultation (in particular with consumer organisations and MS CAs), we have tried to establish the availability of consumer confidence surveys at MS level. Where data have been made available, these do not allow systematic analysis across the EU.

[251] MS CAs consider the protection of consumer interests to have been achieved less than stakeholders: amongst all GFL objectives, this objective received the lowest average rating by MS CAs (3.80) and the second highest by stakeholders (4) (survey results, Q1).

- At least 2 MS indicated that no specific legislation has been adopted as regards food, but other general provisions apply: e.g. in one of these MS various types of fraudulent food related activities can be crimes against the general criminal law and there are also a number of consumer protection laws that are applicable to fraudulent sale of food; in another MS relevant provisions are included in the Consumer Protection Act. Several MS also specified that these issues are routinely covered by their food/feed inspection control programme.
- Definitions may differ considerably between MS or may not exist in all cases. 1 MS specified that, as a result of Art.8, the definitions of unfair commercial practises and of food fraud were introduced in the national legislation. Some MS indicated that the development of a common/uniform definition for food fraud is an issue that should be addressed at EU level.

Examples of measures were provided by some MS CAs, although the available information does not allow a systematic presentation of the measures currently in force in application of Article 8 (**Table 10**).

Table 10: National measures in place, consistent with the provisions of Article 8

	Examples of national measures in place, consistent with the provisions of Article 8
EE *(a)*	The Consumer Protection Act contains provisions on unfair commercial practices. It does not refer explicitly to food, but these provisions are applicable also to FBOs. Consumer Protection Act: § 12-2. Unfair commercial practices. (Commercial practices are unfair if they mislead consumers or are aggressive with respect to consumers.) § 12-3. Misleading commercial practices. § 47-1. Violation of prohibition to use unfair commercial practices (1) Violation by a trader of the prohibition to use unfair commercial practices is punishable by a fine of up to 300 fine units. (2) The same act, if committed by a legal person, is punishable by a fine of up to €10,000. Food Act § 20. (1) It is prohibited to counterfeit food and handle counterfeit food. (2) The following is deemed to be counterfeiting: 1) alteration of the composition of food without alteration of the labelling; 2) alteration of labelling without alteration of the actual composition; 3) addition of other substances in any manner to food or processing food with such substances in order to conceal the lower value of the food or non-compliance of the food with the requirements; 3-1) non-compliant use of a health mark or identification mark on the labelling; 4) handling during which the business name or trade mark of another undertaking is used without the permission of the undertaking. § 20 was in force before the GFL, except 3-1 (entry into force 01.07.2006)
CY	Prevention of fraudulent/deceptive practices and of food adulteration: Art.7 of the national Food (control and sale) Law of 1996 to 2014 prohibits the sale of any food stuff that is not of the nature and quality required by the consumer. Art. 22 of the national Food (control and sale) Law of 1996 to 2014 provides that the food stuffs produced by GMOs or containing GMOs should be placed on separate shelves at the point of sale. Furthermore, according to Art. 16A of the same Law, announcement to the media can be issued in cases of food fraud or food adulteration.
HU *(a)*	Act XLVI of 2008 on the Food Supply Chain and on the Control and Supervision of the Food Supply Chain; Act XLVII of 2008 on the Prohibition of Unfair Business-to-Consumer Commercial Practices; Article 14/A.§ is specifically about food fraud. Ministry of Rural Development Decree no. 74/2012 (VII. 25.) on the obligation of voluntary use of certain distinctive signs in foods administrative penalty: Section 47(1) of Act CLV of 1997 on Consumer Protection states that the consumer protection authority, if it finds in its proceedings any infringement of the consumer protection regulations prescribed in Subsections (1)-(3) of Section 45/A, may impose the following sanctions taking into consideration material circumstances, in particular, the sphere and gravity of the infringement, the duration of the illegal conduct and any recidivism where applicable, and also the gain achieved by the infringement, and in accordance with the principle of proportionality: a) order the state of infringement to be terminated; b) prohibit continuation of the illegal conduct; c) order the business entity in question to terminate within the prescribed time limit the deficiencies and disparities exposed; d) ban, restrict or impose conditions regarding the supply and offering of goods until the infringement is eliminated; e)-f) g) order for the period until the infringement is eliminated the temporary closure of the commercial establishment affected, where deemed necessary for the protection of human lives, health, physical integrity, or for the prevention of dangers posing significant threats to a broad range of consumers; h) ban the sale of alcoholic beverages, tobacco products and sex products in connection with any infringement of the provisions under Subsections (1)-(3) of Section 16/A for a maximum period of one year from the effective date of the infringement, and in the event of any repeated offense, may order the temporary closure of the establishment affected for a maximum period of thirty days; i) impose a consumer protection fine (hereinafter referred to as "fine").
SK	Covered by national Act N.152/1995 as amended and by executive legislation to this act. Provisions regarding adulteration and fraudulent activities are also under Section 163, 164, 168, 169 of the Slovak

	Examples of national measures in place, consistent with the provisions of Article 8
	Criminal Code, law number 200/2005.
DE	Section 11 and Section 12 of the Food and Feed Code regulate the protection from deception and the ban on health-related claims made on foods. The DE CA has also indicated that measures have been taken at national level for the prevention of food adulteration.

(a) Unfair practices are more generally regulated by EU law on the basis of the Directive 2005/29/EC on unfair commercial practices. One of the objectives of this legislation is to boost consumer confidence by identifying unfair business practices, such as providing untruthful information to consumers or using aggressive marketing techniques. This Directive does not address the specific issues linked to food fraud, in particular adulteration. In practice, it has been not been possible during the consultation to separate implementation of Article 8 of the GFL, in particular with regard to adulteration, from transposition of the Directive 2005/29/EC on unfair commercial practices.

Source: Agra CEAS, based on FCEC survey (2015), Q22 (MS CA survey)

The extent to which MS have in place sanctions/penalties to address infringements of food/feed law (Art. 17.2), the nature of MS sanctions/penalties (criminal/administrative), and the extent to which these have been an effective deterrent (*indicator 6.2a*) are covered by EQ13. The findings (section III.3.2.2) indicate that MSs largely have measures and penalties in place in their legal systems against infringements relating to the core GFL obligations[252] imposed on food/feed business operators, although for the most part rules pre-existed the GFL and changes only partly occurred on the basis of Art. 17.2[253]. As is the case with the implementation of Article 8, the specificity and severity of the measures/penalties foreseen under Article 17.2 tend to vary considerably between MS, both in terms of the provisions of the GFL to which they apply, and whether they involve administrative measures and/or penalties and/or criminal prosecution/ imprisonment, which *inter alia* is due to legal/constitutional reasons. Nonetheless, both penalties and measures (other than remedial measures) are considered by MS CAs to have been an effective method to deter feed/food business operators from committing further infringements. For example, one MS indicated that penalties were effective and in some cases have discouraged some fraudulent practices, such as the penalties in case of illegal slaughter (IT, art. 6 national decree 193/2007). Another MS indicated that penalties for infringement are easier to apply than other corrective actions/measures aiming to improve business practices that would have entail higher costs for authorities to pursue and control.

Thus although MS CAs indicate that for the most part they have put in place measures and penalties, in application of Article 17.2 and Article 8, in practice there is considerable variation in the form and severity of the measures/penalties foreseen. This appears to have implications in terms of potential application and effectiveness to address the objectives of Article 8, in particular relating to the prevention of fraud.

Hence, there is some concern that the current regulatory framework and control system, extending beyond the GFL as such, is not sufficiently equipped to prevent, detect and sanction fraud in the food chain (*indicators 6.3a and 6.3b*). In this context, it is noted that in order to be able to prosecute the natural or legal person liable for intentional violation of regulations (fraudulent practices), aspects of criminal law need to be in place, and this can only be done at national level. As discussed above and in the context of national penalties and measures foreseen under Article 17.2, the dimension of applying criminal law has not always been taken into consideration in some of the national food safety systems despite Article 8.

[252] Placing only safe food/feed on the market (compliant with food/feed safety legislation); Establishing one step back – one step forward traceability at all stages of production, processing and distribution; Notifying public authorities in case of food/feed at risk; Collaborating with public authorities on actions taken to avoid or reduce risk in food/feed; Verification that the relevant requirements of food/feed law are met (Article 17(1) of GFL).

[253] It is noted that in some cases the national measures indicated by MS CAs as being currently in force are taken on the basis of Article 54 of Regulation (EC) 882/2004, rather than Article 17.2 of the GFL.

Furthermore, several MS were more sceptical about the ease of application of the fuller range of measures/penalties – even when this is laid down in legislation. Even where fines are laid down by law, several MS indicated that the current maximum fine is in some cases not sufficiently high to deter infringements, particularly in case of fraudulent practices when the potential economic gain is very high. At least one of these MS is currently working on the adjustment of national legislation to review penalty levels.

More generally, MS CAs commented that food fraud and other violations, especially those related to e-commerce, are difficult, time-consuming and resource-intensive to investigate, as they typically involve complex transactions, often spanning across different countries. Apart from the availability of a clear legal framework, such investigations require sufficient and specialist resources, as well as cooperation between different authorities both within and between MS. This has been evident in the management of the 2013 horse-meat scandal which involved complex transactions in multiple countries.

It is noted that the effectiveness of the national judicial system in terms of the time required for a final judgment is another factor that undermines the dissuasive effect of the penalties, particularly when prosecuting complex cases of fraud.

Beyond the legislation as such, these are also indications that the recent concerns on food fraud have had an impact on MS CA approaches to addressing fraudulent or deceptive activities, with actions taken at different levels linked to control. For example, one MS commented that as a follow up to the recent incidents of food fraud, several initiatives for improvement at the level of the CA have been initiated, including: better chain control in quality systems, higher fines, and more attention in inspections into misleading labelling. Another MS indicated that in 2014, the relevant competent authority conducted a Fish Speciation Survey using genetic (DNA) analysis (all samples were compliant). Another MS indicated that further types of measures, such as different projects on unfair practices[254], and work related to food fraud are being undertaken.

Finally, some representatives of the supply chain have indicated that they are considering various concepts to integrate food fraud related issues in existing private standards. For example, retailer schemes (including e.g. BRC / IFS) have integrated requirements such as unannounced controls to address fraud issues. The recently published BRC version 7 standard has introduced a requirement for demonstration of a fraud vulnerability assessment to ensure that manufacturers demonstrate awareness of their supply chains and identify potential weaknesses. Fraud vulnerability is more generally considered as an extension to existing HACCP systems for the identification and assessment of critical points that may be conducive to potential malpractices. Although these initiatives are a positive indicator that the industry is taking its responsibilities to address malpractices, it is noted that they do not have the power of investigation and corrective action that are needed for fully addressing fraudulent activity.

In relation to protecting 'consumers' interests' against misleading practices, consumer organisations have noted as a positive indicator that the principles of Article 8 have been applied in other secondary legislation, in particular Regulation (EU) 1169/2011 on Food Information to Consumers and Regulation (EU) 1333/2008 on Food Additives. These regulations have reached further than the GFL or been more explicit in defining what the

[254] Unfair practices are more generally regulated by EU law on the basis of the Directive 2005/29/EC on unfair commercial practices. One of the objectives is to boost consumer confidence by identifying unfair business practices, such as providing untruthful information to consumers or using aggressive marketing techniques. This Directive does not address the specific issues linked to food fraud, in particular adulteration.

term 'consumers' interests' encompasses, including health, economic, environmental, social and ethical considerations as well as the notion of consumer benefits. Nonetheless, to ensure consistency with all potential fields of application in other secondary legislation, it is considered important to define 'consumers' interests' further also in the GFL (as also discussed in section III.2). The concept of 'food integrity'[255] is also raised, in line with the objectives of the FIC Regulation; it is noted that in the new Official Controls legislation, the European Parliament has proposed to establish a new Reference Centre on the Authenticity and Integrity of the Food, while a major EU-funded research programme is currently under way on this issue.

III.8.2 Internal Market *(EQ5)*

EQ5: To what extent has the GFL and its implementation contributed to achieving the objective of the internal market (Article 5.2)?

The general horizontal framework introduced by **the GFL and its implementation/application at EU/national level have largely contributed to achieve the objective of free movement of food and feed in the internal market** (survey results, Q1)[256] (*indicator 5.1a*). This is confirmed by the results of the consultation on several aspects of the GFL and with all parties, including supply chain stakeholders and MS CAs, although it is noted that, generally, the various aspects considered were assessed more positively by authorities than by operators.

The contribution of the GFL and its implementation is overall positive in terms of all the relevant GFL provisions pertaining to facilitating trade within the internal market. In particular:

- The **considerations set out in Articles 14 and 15** to determine whether food/feed is safe overall have contributed to the effective functioning of the internal market (survey results (Q5c.i[257] and Q5c.ii[258]) (*indicator 5.1b*).
- The **allocation of responsibilities** along the food chain as laid down in Article 17 overall achieved the internal market objective. In particular, it facilitated the placing on the market of feed/food products; contributed to the effective functioning of the EU internal market; and, created a level playing field for all feed/food operators in the EU (survey results, Q8)[259] (*indicator 5.1c*). Nonetheless, some questions were raised on the consistency of national liability systems in place (see section III.3.2.1).
- The **traceability** requirement of Article 18, in combination with own systems/ procedures in place to provide relevant information to the CAs, for the most part have

[255] Food Integrity is defined by an EU funded research programme (foodintergrity.EU) as: 'the state of being whole, entire, or undiminished or in perfect condition'. Providing assurance to consumers and other stakeholders about the safety, authenticity and quality of European food (integrity) is of prime importance in adding value to the European Agri-food economy.

[256] On a scale from 1 to 5, average rating provided: MS CAs above (4); stakeholders above midpoint (3).

[257] On a scale from 1 to 5, the average ratings provided by stakeholders and MS CAs on the four considerations to take into account to determine whether food is safe (Article 14: the short- and long-term effects of consuming a specific food; the probable cumulative toxic effect; the particular health sensitivities of a specific category of consumers when the food is intended for that category of consumers; and, the unacceptability of a food for human consumption) are higher than midpoint (3.00). However, about a quarter of the 67 responding stakeholders did not provide an assessment on this aspect.

[258] On a scale from 1 to 5, the average ratings provided by stakeholders and MS CAs on the two considerations to take into account to determine whether feed is safe (Article 15: the adverse effect of a feed on human or animal health; and feed is unsafe if it makes the food derived from food-producing animals unsafe for human consumption) are higher than midpoint (3.00). However, 42% of he 67 responding stakeholders did not provide an assessment on this aspect.

[259] On a scale from 1 to 5, average ratings on all these aspects were: for MS CAs above (4); for stakeholders above midpoint (3.00).

contributed to ensure fair trading amongst FBOs, and to avoid/limit unnecessary disruption of trade (survey results, Q13)[260] (*indicator 5.1d*).
- The combined application of the provisions on determining the safety of feed/food, both in terms of traceability and **withdrawals/recalls** (food: Article 19; feed: Article 20), for the most part have contributed to avoid/limit disruption of trade, although again this was more appreciated amongst MS CAs than amongst stakeholders (survey results, Q19) [261] (*indicator 5.1e*) .

The extent to which there have been **differences in the implementation/application of the various Articles of the GFL** provisions by MS is already outlined in section III.1 (EQ24). According to the consultation, there have been differences, although overall the differences identified are **for the most part not systematic, i.e. they occur mostly to some extent/in some cases** (survey results, Q53). Despite the identified differences, the consultation has found that, **for the most part**, these are **not due to the GFL as such**, and they **do not hinder the achievement of the GFL core objectives, i.e. public health protection and the internal market** (survey results, Q1).

Notwithstanding the overall strong positive contribution of the GFL in enhancing harmonisation in the area of feed/food law, in some cases certain issues hinder the full achievement of the internal market objective, as it emerges from the preceding analysis of the core GFL requirements. The **GFL has not been able to prevent certain disruptions in the functioning of the internal market** due to national regulations at MS level or differing interpretation of EU law in the MS. As a result, certain barriers to the free movement of food/feed are persisting, as well as more generally some uncertainty for operators. It is important to bear in mind that the achievement of the internal market remains also a key relevant objective also for consumers; the EU consumers' organisation (BEUC) noted that *"from a consumer viewpoint, the EU internal market for food and feed is functioning well, although there remain areas where full harmonisation is yet to be completed"*.

As also highlighted in section III.1, it is important to distinguish between harmonised rules and areas where harmonisation is not complete or there is no harmonisation. In particular:
- **Variable application of harmonised rules**: Such differences were identified to lie mostly – but not exclusively - in other secondary legislation, and in areas where harmonisation is not complete. When it comes to the GFL as such, the scope of variable application tended to be highlighted in cases of a more general wording of certain terms and where there are no EC guidelines or existing guidelines are not considered to be sufficient - such as:
  - '*Consumer interest'*: in particular, where provisions both in the GFL and in other secondary legislation aim to the protection of consumers interests rather than food safety and *vice versa*. It was also highlighted, as also explained in section III.8.1, that the focus of the GFL appears to be food safety, creating some uncertainty of how the GFL provisions apply in other secondary legislation where the main focus in consumer interests, such as the FIC Regulation, addition of vitamins/minerals and other substances to food, *etc.*.
  - '*Unfit for human consumption'*: although criteria are laid down in Article 14 and in the existing Commission guidelines (2010), the appreciation of these criteria varies. As explained further in section III.3.3, this is due to the difficulty of establishing objective criteria that can be applied by authorities in a uniform

[260] On a scale from 1 to 5, average ratings provided by both MS CAs and stakeholders on all these aspects were above midpoint (3.00).
[261] On a scale from 1 to 5, average ratings on all these aspects were: for MS CAs above (4); for stakeholders above midpoint (3.00).

manner to each and every case to determine 'unacceptability' for human consumption.
    - *'Risk analysis'* and the *'precautionary principle'*: examples of issues that are handled differently across the EU were provided, including e.g. salmonella in feed; food contact materials; contaminants etc.. As explained in section III.4, this is largely due to the complexity both of the subject matter and of the risk analysis process, as well as the diversity of interests and viewpoints that enter into play in the final risk management decision; all of these factors result in a situation where it is difficult in practice to apply Articles 6 and 7 in a uniform manner in all situations.
- **Areas where harmonisation is not complete or there is no harmonisation**: in such areas the link is made to the application of the mutual recognition principle in the MS (Regulation 764/2008). Examples of other secondary legislation where, according to the food/feed sector, the lack of common provisions hinders the free movement of food/feed in the internal market, include:

  Food:
    - Food contact materials: legislation is not harmonised, except for plastic materials. Consequently, MS initiate actions and regulate food contact materials at national level. The differing national approaches towards bisphenol A is a case in point, where the risk assessment by EFSA is not consistently used as the basis for EU-wide legislation.
    - Addition of vitamins/minerals and other substances to food: the setting of minimum and maximum levels of vitamins/minerals added in food (Regulation 1925/2006) and in food supplements (Directive 2002/46/EC) is still outstanding, although consultation on this issue took place back in 2006. This was because the consultation highlighted divergent MS approaches and provisions. Nonetheless, there has been a call, by both consumers and industry, for the setting of harmonised minimum and maximum levels across the EU[262].

  Feed
    - Medicated feed legislation: Directive 90/167/EEC on medicated feed, which sets out the conditions under which medicated feed is manufactured, placed on the market and used within the EU, gives no specific indications on what standards to apply in approving plants, or on the acceptable techniques to produce medicated feed. For example, there is lack of harmonised rules for "carry-over" of veterinary drugs from medicated to non-medicated feed. As a result, the transposition of the Directive in MS has led to differences in national regimes and the conditions stipulated therein for manufacturers and farmers (FCEC, 2010)[263], further leading to the quasi-absence of intra-EU trade. However, in September 2014 the Commission tabled a proposal for a new Regulation to replace Directive 90/167/EEC, which aims to address these issues.
    - Feed materials versus feed additives: there are different regulatory criteria in the current authorisation procedure laid down in the legislation, with feed additives

[262] Another case provided by supply chain stakeholders relates to the **mandatory** addition of iodine and/or fluoride to food grade salt, which remains variable across the EU in line with recital (3) of Regulation 1925/2006. In particular, different national rules apply on the levels of mandatory addition of this mineral to food in the MS, although uniform WHO recommendations exist to this effect (WHO. Guideline: fortification of food-grade salt with iodine for the prevention and control of iodine deficiency disorders. Geneva: World Health Organization; 2014). As stated in recital (3) of Regulation 1925/2006, *"some Member States require the mandatory addition of some vitamins and minerals to certain ordinary foods, for reasons dictated by public health considerations. These reasons may be pertinent at national or even regional level, but would not currently justify harmonisation of the mandatory addition of nutrients across the Community. However, if and when this became appropriate, such provisions could be adopted at Community level. Meanwhile, it would be useful for information on such national measures to be compiled*". To address this, the Community Register published in DG SANTE's website contains a list of all national provisions with the mandatory addition of *inter alia* foods with iodised salt.

[263] FCEC: Evaluation of the EU Legislative Framework in the Field of Medicated Feed. February 2010.

requiring a pre-market safety assessment whereas this is not required for feed materials. As explained in section III.4, while rules regarding safety aspects for each category are laid down in the legislation in force, the classification of products under each category is not always straightforward and many borderline cases exist.

- The boundaries between the feed and food and the waste legislation are not harmonised across the EU, with certain products like former foodstuffs qualifying as waste in certain countries, and food, or feed, in others. It is noted that the Commission has just adopted a proposal to amend Directive 2008/98/EC on waste, which *inter alia* clarifies this issue[264].

III.8.3 Other objectives, interests and needs *(EQ4/EQ7)*

EQ4: To what extent have the provisions in food law taken into account the protection of animal health and welfare, plant health and the environment and been efficient and effective in producing the desired results (Article 5.1)?

EQ7: To what extent have the provisions of the GFL and their implementation contributed to or hindered the achievement of other interests or needs in particular competitiveness of the food supply chain, innovation, sustainability/food waste, e-commerce, global trade?

The majority of the consulted parties stressed that **the core GFL objective is to address food safety and the protection of human health**, whilst ensuring the effective functioning of the internal market. It cannot aim to address a range of diverse objectives, although **coherence with other EU and MS policy objectives** should be maintained. The latter is ensured during the full policy cycle, through: regular dialogue with all relevant stakeholders including public consultation; as well as inter-services consultation of the relevant CAs. Both of these aspects, as discussed in sections III.5.1 and III.7 respectively, have **improved over the evaluation period** at both EU and MS level, and the **GFL has partly contributed to this improvement**. However, at MS level, there remain considerable differences in approaches and cultures amongst MS.

It is noted that, in the context of this evaluation, the approach for determining whether the current provisions of food law have been efficient and effective in producing the desired results in relation to the above objectives has been to establish the extent to which these aspects are sufficiently taken into account where appropriate in the general framework of the GFL (*indicator 4.1a*) and gaps/failures identified in other secondary legislation which are due to the GFL (*indicator 4.1b*).

The consulted parties provided **mixed feedback on the extent to which the general framework introduced by the GFL has sufficiently taken into account**, where appropriate, **animal welfare, animal health, plant health and the environment** (*indicator 4.1a*). For stakeholders, the GFL has sufficiently taken these aspects into account, although as expected there are differences in views between groups of stakeholders. On the other hand, MS CAs largely considered that these aspects have not been sufficiently taken

[264] in the context of the Communication on the Circular Economy: A zero waste programme for Europe (COM/2014/0398 final), the Commission has just adopted a proposal for amendment to Directive 2008/98/EC on waste, in order to exclude feed materials (including former foodstuffs) from the scope of the Directive (COM(2015)595. As noted in recital 11 of the Proposal, plant based substances from the agri-food industry and food of non-animal origin no longer intended for human consumption, which are destined to be used as feed are subject to Regulation (EC) 767/2009 and are not regarded as waste for the purposes of that Regulation. Directive 2008/98/EC should therefore not apply to those products and substances when used for feed.

into account (survey results, Q54)[265]. However, it is noted that **negative feedback** (both of stakeholders and of MS CAs) **relates to the extent that it is appropriate/relevant for the GFL to take into account these aspects**, rather than the extent to which they have been taken into account where it has been appropriate.

NGOs active in the areas of animal welfare and food labelling in particular have provided extensive feedback on specific aspects of other secondary legislation that, in their view, do not sufficiently (therefore, efficiently/effectively) take into account **animal health and animal welfare** objectives. In nearly all cases, these relate to the implementation of specific secondary legislation and no clear link to the GFL provisions as such can be established[266] (*indicator 4.1b*). The only cases where some link to the GFL is made are in relation to expressed concerns over the following aspects:

- Scope and definitions. The general wording of Article 5(1) may result in differences of interpretation regarding the scope, including those aspects related to animal health and animal welfare. Considering the very wide breadth of scope of certain definitions (Articles 2 and 3), such as 'primary production' and 'stages of production' which could relate to all food products, this fails to distinguish between 'methods of production' (different types of livestock farming, for example intensive indoor vs. extensive vs. free range vs. organic), which may pose varying food safety/public health risks.
- Protecting consumer interests. In conjunction with the previous point, the general principles of Article 8 and 16, and other secondary legislation on labelling including the FIC Regulation and specific labelling rules (e.g. for egg products), are not considered sufficient to address the ability of consumers to make informed choices between different production methods, and to raise awareness more generally of the animal health and animal welfare, as well as potential food safety and environmental implications, of the different production systems.

Nonetheless, **all consulted parties agree that the EU has some of the highest animal health, animal welfare, as well as plant health and environmental standards worldwide.** Furthermore, in some cases national legislation and/or private standards are established to set even higher standards, thus responding effectively and efficiently to specific consumer demand. For example, in some MS, credible, higher animal welfare farm assurance schemes have been developed that exceed the minimum EU legal standards.

In terms of the extent to which the general horizontal framework introduced by the GFL is adequate to address **other objectives/needs and current trends**, the consultation has found that this is generally considered only partly adequate (survey results, Q2a and Q2b)[267] (*indicator 7.1a*). Generally, the **GFL is considered more adequate to address other objectives/needs**, such as consuming healthier foods and the competiveness of the supply chain, **than current trends** such as distance selling or sustainability/food waste. In terms of other objectives/needs, MS CAs tend to consider the current framework more adequate to address innovation and competitiveness than stakeholders; on the other hand, stakeholders consider it more adequate to address the objective of consuming healthier food/nutrition needs of the general population and food quality than MS CAs. In terms in particular of addressing current trends, the GFL is largely not considered adequate to

[265] On a scale from 1 to 5, average ratings on all of these aspects were: for stakeholders above midpoint (3); for MS CAs below (3).
[266] For example, concerns were expressed on whether MS authorities are sufficiently verifying compliance of operators, and how this may evolve in the revision of Regulation 882/2004 on official controls. If controls are not sufficient, in combination with the concept of operators' primary responsibility of Article 17.1, this may lead to a situation that allows too much flexibility on some parts of the chain that are considered particularly vulnerable to non-compliance with animal health and animal welfare, as well as hygiene standards, such as slaughterhouses.
[267] On a scale from 1 to 5, the average ratings provided by MS CAs and stakeholders vary by aspect, and are in some cases above midpoint (3) and in others below (3).

address sustainability/food waste, food availability and distance selling/e-commerce, neither by MS CAs and for stakeholders[268]; on the other hand, both MS CAs and stakeholders consider the current framework at least partly adequate to address food quality and globalisation of trade. The issues underlying negative feedback are discussed further below.

The marked differences between the assessments provided by MS CAs and stakeholders, as well as amongst groups of stakeholders, indicate the **divergence of viewpoints and interest groups that are affected by the GFL**, which is a common theme running throughout the analysis of key findings in this Report. Unlike the case of the GFL core objectives (survey results, Q1), there are a relatively high number of negative responses, both by MS CAs and stakeholders, on the adequacy of the GFL to address other objectives/needs and current trends (survey results, Q4a and Q4b)[269]. This reflects to some extent the observation made in the context of EQ4, i.e. that **negative feedback relates to the extent that it is appropriate/relevant for the GFL to take into account these aspects**, rather than the extent to which they have been taken into account where it has been appropriate. Both stakeholders (including operators and NGOs) and MS CAs commented that **certain objectives/needs and current trends**, such as consuming healthier food/nutritional needs, innovation and competitiveness of the supply chain, sustainability/food waste and food availability, **fall outside the scope of the GFL** and should best be addressed by dedicated policies and/or legislation. It is noted that, in the context of this evaluation, the approach has been to focus on specific cases where Union objectives have been facilitated or hindered by the GFL provisions *(indicators 7.1c and 7.2a*).

In assessing the **impact of the GFL on innovation and competitiveness**, most stakeholders and MS CAs noted that **by improving harmonisation in EU food law, the GFL has enhanced predictability and ease of implementation and has reduced the overall burden** on companies selling products in various MS that would have resulted from adapting to each MS's legislative requirements, thus contributing to create a more level playing field across the EU. This is also a conclusion reached from the analysis of findings on costs and burden (section III.9). It is noted that one of the three dimensions of the competitiveness proofing of EU policy as applied in the food chain is the 'capacity to innovate'[270].

It is noted that the potential **synergies between some of the above objectives/needs and current trends** were also highlighted, in particular food/feed availability and food waste, food quality and sustainability, as well as **areas of potential conflict** for example food quality and globalisation versus food availability. These **issues are generally complex and multi-faceted and require combined policy approaches**. Consideration of impacts cannot be made in isolation of the interplay between the objectives pursued and the various EU policies that pursue them.

[268] On a scale from 1 to 5, in all of these cases, the average ratings provided both by stakeholders and MS CAs was below midpoint (3).

[269] Negative responses (i.e. scoring '1' or '2'): depending on the aspect, from 3 to 12 out of 25 responding MS CAs; and, from 8 to 31 out of 67 responding stakeholders. For both stakeholders and MS CAs, the highest number of negative responses was in relation to sustainability/food waste (31 stakeholders; 12 MS CAs), and food availability (25 stakeholders; 12 MS CAs).

[270] *Capacity to innovate: the capacity of the business to produce more and/or higher-quality products and services that better meet customers' preferences (innovative competitiveness) including the cost of bringing new products to market (authorisation)*. The other two dimensions are cost competitiveness (including compliance costs) and international competitiveness (including the impact of policies). Source: European Commission, 2013c (CSW(2013)516 on the Fitness Check of the Food Chain). These competiveness criteria are based on the objectives pursued by the Europe 2020 Flagship initiative 'industrial policy for the globalisation era' (European Commission, 2010d).

Overall, the following key points emerge from the analysis of the more **negative feedback** received:

- Generally, once more, **shortcomings** are identified with **other secondary legislation**, **rather than the GFL as such**, where there are concerns that current implementation and lack of harmonisation in some areas can hamper the achievement of other objectives/needs.
- In particular, in relation to **consuming healthier food/addressing the nutritional needs** of the general population:
  - Consumer organisations noted that this aspect is currently embedded in the GFL, although not explicitly stated as such: *"The GFL pursues the objective of a high level of human health, which in our view provides the legal basis for policy measures aimed at making the healthy option the easy one for all consumers"*. Furthermore, EFSA's mission includes the provision of scientific opinions on nutrition issues (Article 22.5(a) of the GFL). However, in practice, failure to achieve further progress in the area of healthy diets and nutrition partly stems from a lack of implementation/enforcement in other secondary legislation. For example, in Regulation (EC) 1924/2006 on nutrition and health claims, the nutrient profiles – legally due by January 2009 – are yet to be established; according to consumer groups, without these profiles, the announced goal *"to avoid a situation where nutrition or health claims mask the overall nutritional status of a food"* cannot be achieved. Nonetheless, this does not in practice impede the achievement of the broader objectives of this Regulation[271]. Furthermore, consumer organisations have noted that consumer needs have evolved since the 1990s, with a rising obesity trend which has increased the importance of nutrition issues. In their view, this requires a more comprehensive EU approach to health that not only looks at specific health issues, but also targets wider health interests of the population such as overall nutritional needs, addressing nutrient deficiencies, fighting obesity and reducing the risk of cardio-vascular diseases, in line with the EU ambition to promote a balanced approach to food and healthy lifestyles. In this context, consumer organisations indicated some missed opportunities for action at EU level (e.g. no EU compulsory front-of-pack nutrition labelling to facilitate healthier food choices; no legal restriction at EU level on the use of trans fat to date[272]), and the need to strengthen rules in the areas of food formulation, labelling/nutrition profiles to help consumers evaluate the nutritional composition of food and consideration of the marketing of food to children. Consumer organisations find that soft measures in this area, such as the voluntary initiatives taken in the context of the EU platform for diet, physical activity and health, do not work well. They note that although some progress has been achieved e.g. on direct marketing to children, progress has since stalled. Thus, they see an opportunity for the GFL more generally to make a link to nutrition objectives (i.e. the 'wholesomeness of food').
  - Food industry organisations noted generally that the aim of the GFL is to achieve a high level of food safety, while it is the purpose of other secondary legislation to achieve further objectives. Article 8 of the GFL states that food law shall provide a basis for consumers to make informed choices; other secondary legislation

[271] Regulation (EC) 1924/2006 aims to ensure that health claims made on foods are truthful and substantiated on science in order to ensure that consumers are not misled when trying to achieve a balanced and varied diet in their food choices. The objective of nutrient profiles is to prevent foods with a relatively unhealthy profile bearing claims which could mislead consumers, as to the overall nutritional status of a food product, in their effort to pursue a healthy diet by choosing foods bearing claims. Consumers are not directly exposed to nutrient profiles (i.e. these do not appear on labels and are not communicated to the consumer), so they are not immediately affected by them. The analysis of the implementation to date of procedures to authorise claims indicates that the above objective of the Regulation on claims is being achieved (e.g. see Table 4).

[272] It is noted that the Commission is about to adopt a report on trans fats pursuant to Article 30(7) of the Regulation (EU) 1169/2011 (the FIC Regulation).

extensively relies on information to consumers so as to raise consumer awareness and empower consumers to meet their nutritional needs. This requires educating and providing the right information to consumers; however, concerns were expressed on the extent to which this objective is met in other secondary legislation, such as for example the FIC Regulation and nutrition labelling.

- In relation to the **innovation potential**:
  - Supply chain stakeholders, both from the food and feed sector, noted that innovation is not hampered by the GFL as such but by certain secondary legislation establishing authorisation procedures, such as: novel foods (Regulation 258/97); claims (Regulation 1924/2006); the approach for placing on the market feed additives (with pre-market approval) which differs from feed materials (not requiring pre-market approval). More generally, there were concerns that authorisation procedures are cumbersome and time-to-market delays take too long compared to other parts of the world, while the final outcome is uncertain in view of the consideration of other legitimate factors, thus creating uncertainty and acting as a disincentive for innovation (e.g. according to the industry, the consideration of legitimate factors in the case of additives in meat preparations is based on public perception and hampers innovation). For smaller businesses, in particular, authorisation procedures as those required for health claims or novel foods are considered too costly and unattainable. Nonetheless, supply chain organisations also acknowledged that, despite continuing shortcomings, overall progress has been made in some of the above secondary legislation in facilitating innovation, such as with the legislative package on food improvement agents adopted in 2008, while more generally the GFL principles applying harmonised risk analysis procedures are acknowledged to have had a positive impact in supporting innovation in the single market context. The positive and negative impacts of authorisation procedures have been analysed in detail in section III.4.1.3.
  - Consumer organisations noted that innovation should not only be safe but shall also be acceptable to consumers while delivering benefits, and that the benefits of innovation for consumers should be demonstrated. While the GFL is not explicit on this, the 'other legitimate factors' to be taken into account in risk management to some extent address acceptability (including ethical concerns) and consumer benefits. However, the lack of explicit reference to the consumer acceptability/benefit aspects in the GFL may mean that these are not consistently reflected in secondary food legislation.
- In relation to **competitiveness of the food supply chain**:
  - As in the case of innovation, supply chain organisations noted again that competitiveness is not hampered by the GFL as such but by lack of harmonisation in the implementation of certain secondary legislation; as a result, a level playing field has not been fully achieved.
  - At the same time, several supply chain stakeholders, particularly from the retail sector, noted that the competitiveness potential is ensured by the GFL in providing principles rather than prescriptive provisions, which can be tailor made to fit the operational context of individual businesses (these issues are analysed in sections III.3.2.1 and III.9.2).
- In relation to **sustainability**/**food waste**:
  - Supply chain stakeholders noted the potential unintended effect, in particular where there are unjustified differences between MS CAs in implementation of certain provisions of EU food law, resulting in unnecessary waste in the case of withdrawals/recalls. For example, several national food industry associations indicated that the interpretation of Article 14.2b ('unfit for human consumption'), in conjunction with the presumption of Article 14.6 of the GFL, differs considerably across the EU and is sometimes used '*excessively*', and that this often leads to unnecessary cases of food waste.

  - The feed sector noted the merits of the current approach of EU legislation to consider waste as such by default, until the moment it is demonstrated it is not waste, to avoid that discarded products get into the feed and food chain. Nonetheless, strict implementation discarding valuable products of the food chain from use in feed in certain countries, although traceability and safety can be ensured, may be conflicting with feed availability which remains a challenge.
  - Consumer organisations and NGOs noted that waste can also be reduced by changing consumption patterns, while sustainability can also be pursued by more actively promoting sustainable food production and consumption.
- In relation to **food availability**, there was again some difference in perspectives between stakeholders:
  - Consumer organisations noted that food security is a multifaceted issue and there are conflicting views on how this can best be achieved in the future, including on the very need to increase food production as opposed to wasting less and changing food consumption patterns and on where in the world food production should increase. In this context, the arguments put forward by opponents to stricter EU rules on e.g. the impact of pesticides and biotechnology policies on food productivity are considered biased, because they focus on a partial aspect of this issue. Against this background, consumer organisations believe the GFL framework remains adequate.
  - Supply chain stakeholders focus on the link between food waste and food/feed availability in the sense of the above highlighted unintended negative impacts which are due to inadequate implementation rather than the GFL as such, and tended therefore to consider the GFL not relevant.
- In relation to **distance selling/e-commerce:**
  - All stakeholders (supply chain operators, consumers, NGOs) and MS CAs noted that this has emerged as an important distribution channel for food/feed after the GFL and has therefore subsequently only been dealt with in other secondary legislation. However, the key issue is primarily the enforcement of existing provisions, both in the GFL and in other secondary legislation, i.e. making sure that food/feed sold via the internet complies with EU requirements. Consumer organisations noted that distance selling/e-commerce poses some specific challenges (e.g. in terms of providing food information), which are not necessarily addressed in relevant secondary legislation.
  - The feed sector noted that distance selling has been taken up to a certain extent in the labelling provisions of Regulation (EC) 767/2009 (Article 11.3), although labelling should allow to take into account the specific needs of today.
- In relation to **food quality**, on balance most stakeholders agree that the GFL framework is currently adequate:
  - In assessing the impact of the GFL on food quality, most stakeholders noted that safe food ultimately leads to higher quality therefore, by improving food safety, the GFL has enhanced the quality of EU food and the reputation/recognition/trust in EU food as safe, quality food, both within the Union and in third countries.
  - Consumer organisations tend to expand the concept of food quality to include a number of factors, such as addressing fraud and nutrition/diet-related issues, and the provision of adequate information to consumers, for example to easily identify the farm system used to produce their food.
- Finally, in relation to **globalisation,** both MS CAs and stakeholders (including consumers, FBOs, and NGOs) generally consider the GFL framework is adequate, The challenges of globalisation are adequately addressed with the key requirement of Article 11 that any food/feed that is imported into the EU shall comply with EU rules. With this general provision on imports, the GFL is largely considered to contribute to ensure consumer trust in food safety in an increasingly global market (see also section III.6). Nonetheless, once more the differences in perspectives and interests are noted:

- Consumer organisations and NGOs noted that while the EU is party to a number of international agreements such as the WTO SPS agreement and as such must abide to its principles, it is vital that it remains free to set the level of protection it deems appropriate for its citizens and that this is respected by third countries exporting food/feed to the EU. Although the impact on trade is one of the many different aspects that need to be considered in EU food policy making, it should not be an objective *per se*.
- Several issues were highlighted with regard to the extent to which importers/traders are sufficiently covered by the GFL provisions. This ranges from whether importers/traders are explicitly covered by the definition of 'food business' and 'food business operator' (Articles 3.2 and 3.3), and therefore are fully covered by the primary responsibility obligations of Article 17.1, to whether the official controls to verify compliance performed by national authorities sufficiently covers this part of the chain. Furthermore, the feed sector expressed some concerns in terms of the persisting lack of a list of third country suppliers approved for imports.
- According to importer organisations, the implications of globalisation may be conflicting with the objectives of ensuring high quality standards at the same time as food availability within the EU. This is particularly in sectors where the EU is not self-sufficient and therefore dependant on imports within an increasingly globalised market, such as fruit and vegetables and cereals/oilseeds. For example, in the fruit and vegetable sector, for African exporting countries the emerging markets of China and Brazil are growing while the EU is decreasing in volume terms. This is partly a consequence of the high standards demanded by EU retailers, and not only linked to high food safety standards as such. This might lead to problems with the availability or food for the EU market, especially in the lower price segment of this market.

III.9 Cost and burden of core GFL requirements

The analysis below covers specific concerns and burdens associated with the implementation of the GFL, the extent to which certain aspects of the GFL implementation have acted as mitigating factors, and potential for simplification, including potential for cost and burden reduction. The reduction of regulatory burden is addressed in the context of the wider objective of the GFL to ensure a high level of consumer protection. The challenges and caveats for conducting a full analysis of costs and burden of EU food law (i.e. the GFL and secondary legislation based on the GFL) in the context of the present study are outlined in section II.2.2.

Key findings (EQ25 to EQ31):
Key findings on the costs and burden of the GFL are summarised under the evaluation theme of efficiency in section IV.3.

III.9.1 Specific concerns on costs and burden *(EQ25/EQ29)*

EQ25: To what extent have the obligations of safety, verification withdrawal/recall, notification (Articles 14, 17, 19, 20) and their operationalization entailed a fair and proportionate burden on food/feed business operators?

EQ29: Which specific concerns and burdens for business (particularly SMEs) and public authorities have been identified in the implementation of the GFL (including in the application of its fundamental definitions, principles and requirements in related specific pieces of food law)?

Although a full analysis of costs and burden of EU food law (i.e. the GFL and secondary legislation based on the GFL) has not been possible in the context of the present study[273], the analysis has nonetheless highlighted certain key findings regarding these aspects.

All of the key GFL requirements have entailed a fair and proportionate burden on business operators, according to a large majority of stakeholders and MS CAs (survey results, Q4) (*indicator 25.1e*). **Nonetheless, some areas of concern are identified**.

In particular:

The requirement **to place safe food/feed on the market (Articles 14/15) and to verify that food/feed is compliant with food law (Article 17.1)** has largely entailed a fair and proportionate burden on business operators (survey results, Q4a)[274]. Despite on average a positive feedback, stakeholders have also expressed several concerns[275]. More generally, operators noted that the burden associated with the primary responsibility obligation (Article 17.1) and placing safe feed/food on the market (Articles 14/15) is distorted by the impact of additional requirements posed by secondary legislation and differential implementation by MS CAs; private standards also distort the calculation of regulatory costs and burden, and the distinction between regulatory and non-regulatory is not straightforward, since these are often intertwined with regulatory requirements [276]. More specifically, the following concerns were raised by organisations representing the sectors of SMEs, retailers, hotels/catering, and feed:

- SME organisations: ensuring compliance with these intertwined regulatory and non-regulatory requirements continues to pose disproportionate burden for small and micro-enterprises, particularly for those that produce a large and frequently changing range of products; in this sense, their ability to 'innovate' in terms of new products and consumer demand is stifled by the need to ensure compliance with requirements posed by secondary legislation, but also by private standards. More specific findings for SMEs are provided further below.
- Retail organisations: concerned that they are increasingly being viewed by authorities as the '*supply chain police'*, in the sense that "*final responsibility for the rest of the supply chain is being made into a retailer responsibility".* However, this depends very much on the level of cooperation with national control authorities, which tends to vary significantly between MS.
- Feed sector organisations: the industry considers that the feed sector is more complex and regulated than the food sector, also because of the interface with animals, and this can cause additional burden at the interface for operators when food materials move into feed. Furthermore, within the feed sector, there are complaints on the need for

[273] The caveats and challenges of undertaking a full analysis of costs and burden in the context of the present study are outlined in section II.3.2. These challenges were confirmed by the feedback received from respondents to the various consultation tools, i.e. the surveys of stakeholders and MS CAs, the SME Panel and the case studies.

[274] On a scale from 1 to 5, nearly two thirds of stakeholders provided a rating higher than midpoint (3), with over half of them rating higher than 4 (overall average rating: 3.35). In the case of MS CAs, all 25 responding MS CAs provided a rating higher than midpoint (3), with 21 of them rating higher than 4 (overall average rating: 4.25).

[275] 19 out of 67 stakeholders scored '1' or '2', of which 15 are supply chain stakeholders.

[276] These issues are analysed further in section III.3. During the consultation (case studies, surveys and SME Panel) operators noted that in the last few years there has been a trend to establish and make it a factual necessity to adhere – in addition to the legal requirement of the GFL and other secondary legislation - to a rising number of private standards (e.g. IFS, BRC, FSSC, ISO). In addition to the recurring high annual costs of adhering to the schemes, this necessitates considerable staff time to comply with the various obligations. **Overall**, as noted in sections III.3.2.1 and III.9.2.2, **private standards/certification schemes mitigate the costs of regulation but may add non-regulatory costs.** They are a mitigating factor because they largely serve as the basis for integrating regulatory requirements. They may add costs, because they also lay down additional (non regulatory) requirements. **It is not easy for operators, particularly for micro/small, to distinguish between regulatory and non-regulatory requirements of private standards and certification schemes.**

pre-market approval of feed additives (and the associated burden of the authorisation procedure) versus no approval for feed materials (see section III.4).

All the other main GFL requirements have also largely entailed a fair and proportionate burden on operators: the **requirement to establish one step back - one step forward traceability (Art. 18)** (survey results, Q4b) [277] ; the **requirements on withdrawals/recalls of food/feed at risk (Art. 19 and Art. 20)** (survey results, Q4c)[278]; the **requirement to notify public authorities in case food/feed considered at risk (Art. 19.3 and Art. 20.3)** (survey results, Q4c)[279]; and, the **requirement to collaborate with public authorities on actions taken to avoid or reduce risk (Art. 19.4 and Art. 20.4)** (survey results, Q4e)[280].

Again, despite the positive feedback, several supply chain stakeholders have commented that Articles 19 and 20 have not always contributed to fit for purpose or proportionate withdrawals and recalls. This is particularly due to implementation by MS CAs, for example in the context of the interpretation of *'unfit for human consumption'* (Article 14.2b), '*unacceptable for human consumption'* (Article 14.5), or where legal non-conformities (Article 14.7) with no risk for consumer health are systematically considered as unsafe food and subject to recalls and/or withdrawals. It was also noted that some times recalls are based on political decisions and/or triggered by public perception rather than food safety risks, with 'disproportionate' burden for operators (e.g. mycotoxins, GMOs).

Moreover, in all these areas, **operators have also highlighted a non uniform understanding and implementation between MS CAs, despite the existing EU guidelines, which therefore do not allow the full achievement of a level playing field across the EU**. This is also indicated in several other aspects of implementation as performed by MS authorities, including: **inspections** (different approaches, including at regional/local level); **data collection** activities (in some MS additional specific time-consuming data required that are irrelevant and/or overlap with existing data from other sources); lack of understanding/technical knowledge on the **purpose of the legal provisions and detailed requirements** and that they can be adapted to fit specific circumstances, e.g. the possibility to adapt hygiene requirements on the construction, layout and equipment of establishments.

Another area where the industry has expressed concerns over regulatory costs is in the field of **risk analysis**, in relation to the **specific authorisation procedures designed in other (sectoral) secondary legislation**. This is particularly where EU legislation is not yet completely harmonised, e.g. in the case of nutrition/health claims, and enriched food. As discussed in section III.4.1.3, **these cases are not directly attributable to Article 6**, but to the complexity of the specific procedures laid down in secondary legislation on food, and the fact that these specific procedures are not standardised at operational level across the

[277] On a scale from 1 to 5, a large majority (78%) of responding stakeholders provided a rating higher than midpoint (3), with over half of them rating higher than 4 (overall average rating: 3.71). Results are even more positive if only supply chain stakeholder responses are considered (average rating: 3.90). In the case of MS CAs, 24 of the 25 responding MS CAs provided a rating higher than midpoint (3), with 23 of them rating higher than 4 (overall average rating: 4.38).

[278] On a scale from 1 to 5, a large majority (79%) of responding stakeholders provided a rating higher than midpoint (3), with overall average rating of 3.53. In the case of MS CAs, 24 of the 25 responding MS CAs provided a rating higher than midpoint (3), with 21 of them rating higher than 4 (overall average rating: 4.21).

[279] On a scale from 1 to 5, a large majority (79%) of responding stakeholders provided a rating higher than midpoint (3), with overall average rating of 3.70. In the case of MS CAs, 24 of the 25 responding MS CAs provided a rating higher than midpoint (3), with 23 of them rating higher than 4 (overall average rating: 4.50).

[280] On a scale from 1 to 5, a large majority (81%) of responding stakeholders provided a rating higher than midpoint (3), with overall average rating of 3.62. In the case of MS CAs, 24 of the 25 responding MS CAs provided a rating higher than midpoint (3), with 23 of them rating higher than 4 (overall average rating: 4.42).

different sectors. In addition to the cost of preparing complex dossiers and providing demanding data requirements, the length, unpredictability and uncertainty of the outcome of the authorisation procedures is identified by operators as a major concern/burden for undertaking the investment required. Furthermore, the food sector has raised the issue of the requirement of multiple parallel or successive authorisation procedures for the same substances (e.g. for substances which are novel food, Regulation 258/97/EC) three successive authorisations are needed if they are intended for use in general food (Regulation 1925/2006/EC) and also in food for specific groups (Regulation 609/2013/EU[281]).

In the feed additives sector, where EU standards for the risk assessment of feed additives are very high, the re-evaluation of all 'existing' (old) feed additives has had, according to the industry, a considerable impact, in making it too costly for individual SMEs to compile an application for the approval of their product. However, as noted in section III.4.1.3, the EU authorisation procedure has at the same time been simplified and centralised; this new approach has also conferred important benefits to the industry, and in certain cases costs have been shared amongst operators[282].

The **most burdensome Information Obligations (IOs)**[283] stemming from the provisions of EU food law are those associated with: certification of products or processes; cooperation with audits and inspection by public authorities in the context of withdrawals/recalls (as foreseen in the GFL, e.g. Art 19 and 20); information labelling for third parties; cooperation with audits and inspection by public authorities in the context of secondary legislation, e.g. Regulation (EC) 882/2004[284]; and, application for individual authorisation or exemption. Between 42% and 51% of operators ranked these IOs as being amongst the three most burdensome obligations of EU food law (out of the 11 IOs considered)[285] (survey results, Q44) (*indicator 25.1a*).

The **administrative costs and burden** related to the implementation of EU food law, as a proportion of total operational costs and staff numbers, **generally tend to decline as the business size increases**. In particular, annual administrative costs including training, as a share of total operational costs[286], represent on average 8.5% for micro-enterprises, declining to 7.8% for small enterprises, 6.7% for medium enterprises and 5.1% for large enterprises. Similarly, the total number of FTEs involved, as a share of total staff numbers, represent on average 7.4% for micro-enterprises, 6.9 % for small enterprises, declining to 6.1% for medium and large enterprises (survey results, Q45) (*indicator 25.1b*).

[281] As previously explained, the authorisation procedure of Regulation (EU) No 609/2013 is not applicable yet (it will apply when the delegated acts become applicable). Today, old rules on dietetic foods (in particular Regulation (EC) 953/2009) are still applicable.

[282] In particular, it was noted that the current centralised EU authorisation procedure (Regulation (EC) 1831/2003) is simplified in comparison with the decentralised system in force under the previous legislation (Directive 70/524/EEC). Furthermore, for a series of feed additives, the operators' association (FEFANA) took charge of the preparation and management of applications for authorisation of 'existing' feed additives (within the categories of additives for which there is no authorisation holder, thus benefiting all operators) in order to share costs. In addition, the re-evaluation procedure was considered by the legislator as absolutely necessary in terms of safety, taking into account not only the scientific and technological developments but also the fact that certain 'existing' feed additives had never been subject to a scientific safety evaluation in the past.

[283] It is noted that about half of the supply chain stakeholders replied 'don't know' to the above questions, therefore these results have to be read with this observation in mind. In comments and during interviews, it was pointed out that this is due to the high complexity of the subject matter.

[284] Cooperation with authorities for audits and inspections are foreseen by Regulation (EC) 882/2004. Its noted that official controls that have also included inspections are also foreseen in Article 17 of the GFL. This has been distinguished in the stakeholder survey from cooperation with authorities in the context of withdrawals/recalls, as foreseen in Articles 19 and 20 of the GFL.

[285] Information obligations (IOs) defined on the basis of the Standard Cost Model (SCM).

[286] Annual operational administrative costs, including training, as % of total production costs, excluding capital investment, BAU costs, and private contractual obligations.

The case studies on traceability (Article 17: section III.3.1) and operators' primary responsibilities (Article 18: section III.3.2.1) have found that, according to operators, the benefits conferred by these provisions of the GFL outweigh the costs of setting up and operating the required systems (*indicator 25.1c*). The findings also indicate that the rules laid down in Articles 17 and 18 have ensured an efficient (fair and clear) distribution of responsibilities amongst feed/food business operators along the 'farm to table' supply chain, as well as between feed/food business operators and MS CAs (*indicator 25.1d*).

The **consultation with SME representatives and the SME panel has confirmed the above findings and provided further insights into the specific concerns relating to costs and burden for SMEs** (EQ29).

The vast majority of SME respondents to the SME Panel (**Annex 4**) are **well aware of the various basic legal requirements** that companies in this sector must meet; the awareness of small and micro enterprises is lower (around 10% less than the full sample of SMEs) (Q1). Companies are particularly well aware of the requirement to place safe food/feed on the EU market, to carry out their own checks to make sure food/feed law requirements (e.g. labelling, safety, product specifications) are met and to withdraw/recall unsafe food/feed products. **Two thirds of the SME respondents have never hired an external consultant** to help them comply with EU food/feed law; however, **several micro/small operators reported that they hired an external consultant** for the implementation of traceability, HACCP systems and labelling requirements, although these may extend beyond GFL requirements as such [287] (Q3). More than half of the SME respondents indicated that national authorities always/usually/sometimes help them meet food/feed law requirements (e.g. by providing information on food/feed rules specific to small/medium businesses, or guidelines); however, **over one third of respondents indicated that authorities rarely/never help** (Q10).

The consultation with SME sector representatives indicates that, **generally, it is not the GFL but detailed requirements in secondary legislation that contribute to the costs and burden for SMEs**. Furthermore, it is important to consider the **cumulative regulatory burden for SMEs of all EU legislation** (including for example employment laws and taxation) as this has considerably increased over time, not just the burden relating to food legislation.

SME respondents to the SME Panel ranked the costs of complying with traceability, labelling, authorisation, registration and certification as the most costly of all EU food/feed law requirements; this is followed by the costs of meeting the requirement for in-house checks of food/feed safety, with the costs of meeting contractual obligations/private standards coming in third place (Q11). Consistently with the general survey results, SME respondents indicated that the **three most demanding administrative tasks** carried out under EU food/feed law obligations are **traceability record keeping, certifying products or processes, and information labelling for customers and consumers** (Q12). It should be borne in mind that not all this cost can be attributed to the GFL as such. For example, 75% of the SMEs apply internal traceability, with two thirds of them doing this on their own

[287] For example, traceability may extend beyond Article 18 to respond to additional requirements posed by other secondary legislation and/or customers' private standards and contractual obligations (including in some cases internal traceability). In particular, according to micro/small respondents, there is a huge quantity of traceability information to be managed e.g. surveillance of allergens entering into the production process. These companies do not have enough resources to hire additional personnel in order to maintain traceability procedures. Nonetheless. respondents made some positive comments on the implementation of the traceability system, stressing that it helps to attract new customers and expand to new markets, but also to maintain consumer trust.

initiative (Q7/Q8), which increases the costs when compared to the costs of the general traceability required by Article 18 of the GFL.

The share of administrative costs spent on EU feed/food law administration varies considerably amongst businesses (this variation is not necessarily related to size[288]): for over a quarter of SMEs costs for EU feed/food law account for 0-5% of total administrative costs, for nearly one fifth around 5-10%, for one tenth between 10-15% and for another tenth they account for 20% or more (Q13) [289]. Finally, when comparing the costs and benefits of EU feed/food law, 42% of respondents consider that benefits outweigh or break even with costs, while for 32% of respondents benefits do not outweigh costs (Q14)[290].

A large number of SME respondents, particularly micro/small companies, noted that they find it **hard to understand and interpret requirements set by EU food law** (the GFL and secondary legislation), which are often too complex and can be interpreted in many ways. Also, it is **not clear to which authorities they should address** in order to obtain information and/or **local/national authorities are often unwilling to cooperate** with operators. Furthermore, **interpretations of legal requirements in the MS are found to differ**, creating additional costs and uncertainty for operators and a non-level playing field across the EU [291]. In addition, many customers require the adoption of food quality and safety standards that are not obligatory by EU law (e.g. DIN EN ISO 9001, IFS, GFSI, BRC, FSSC, ISO), GMPs and other private certification. However, it is **not easy for companies to distinguish between the requirements posed by regulatory and non-regulatory (private) standards**. The combination of all these factors makes the management of the information cumbersome and requires burdensome procedures and unnecessary documentation that consume too much time and resources, especially in small enterprises that lack resources to hire additional staff, and in view of the large product ranges that are often produced in micro/small enterprises. These issues were also highlighted in the context of the case studies on traceability and FBO responsibilities (sections III.3.1 and III.3.2.1).

In view of the potential disproportionate administrative burden, EU food law foresees **exemptions for micro-enterprises** from certain detailed requirements. The consultation with SME sector representatives indicates that, **in practice, there are not many exemptions for SMEs**. Of those that exist, some positive, best practice examples were noted. One such example is the exemption in the hygiene package for SMEs to adhere to GMPs, rather than have in place a fully-fledged HACCP for hazard management and control. Another positive example is found in the FIC Regulation, with exemptions for labelling of non-prepacked food, which would be helpful for micro-enterprises producing a large range of non-standardised products, although there is still an obligation to have information available in the premises on the allergens contained in the products sold (which does not allow micro-enterprises to capture fully the benefit of the exemption [292]). Furthermore, exemptions are always based on the size of the business whereas the factors to consider are also the nature of production and type of risk e.g. a craft producer may deal with a large number of products/suppliers whereas large firms may produce a few standardised products on a large scale with often long term suppliers that do not change very often. The SME

[288] It is noted, however, that the main survey results suggest that there is a tendency for regulatory/ administrative costs to decline as size increases (Annex 3, Q45).
[289] It is nonetheless noted that nearly 30% of respondents indicated that they do not know.
[290] Nearly a quarter of respondents indicated that they do not to know.
[291] The SME sector has highlighted that problems in practice are also a problem of MS implementation, in that there is narrow interpretation of the rules quite often by authorities. For example, the revision of the official controls legislation has highlighted many differences in approaches between MS, from overlaps in controls in some MS to more proportionate risk profiling according to need in other MS. It is noted that more than half of the SME respondents to the SME Panel indicated to trade in the EU market.
[292] For example, the bakery sector noted that any bakeries would have to deal at least with seven allergens most commonly found in bakers' premises (e.g. gluten, nuts, soy, eggs, peanuts, milk, etc.).

sector is concerned that over-regulation drives a trend for standardisation that is hindering craft production and product innovation/diversification on a small scale, thus limiting consumers' choice[293].

Generally, therefore, according to the SME consultation, **the application in practice of the concept of exemptions for micro-enterprises has not really worked in providing the intended benefits**. Having **more simplified legislation and harmonised implementation, as well as a clear and stable regulatory environment, would help more than exemptions**. This does not mean necessarily less regulation, but simpler, clearer, and proportionate rules. The exemption for small companies in the hygiene package (GMPs rather than HACCP) is quoted as a good example of such simplification. On the other hand, one area where some simplification is needed are food labelling rules.

III.9.2 Extent to which certain aspects of the GFL and its implementation act as mitigating factors

III.9.2.1 Level of prescriptiveness (EQ26)

EQ26: To what extent can some provisions of the GFL be identified as too prescriptive or too general taking into account operational implementation?

Generally, taking into account operational implementation, the **GFL is not identified to be prescriptive** (*indicator 26.1a*). Amongst the GFL Articles of the study scope, the most prescriptive would be traceability (Article 18) and requirements on withdrawals and recalls (Articles 19 and 20), but even these provisions were not identified to be overly or unduly prescriptive by any of the consulted parties.

Emphasis has therefore been placed on **investigating whether the GFL provisions are too general** (*indicator 26.1b*). This has been examined in terms of the operational implementation of the key provisions in the context of the case studies. Although in some cases, e.g. in the context of risk analysis and the precautionary principle, some problems/shortcomings such as differences in implementation were partly attributed, by some stakeholders in particular, on the provisions being 'too general', this was at the same time acknowledged as **a major strength of the GFL**.

The GFL is essentially the '*constitution'* of EU food law, laying down principles and general requirements that serve as the common basis for all secondary legislation in this field; this requires by definition a non-specific approach. Furthermore, guidelines are drafted for those provisions that are not prescriptive enough, as is the case with the GFL principles and general requirements, but also where legal provisions require detailed additional information due to their complexity (e.g. hygiene rules; labelling requirements of the Food Information to Consumers Regulation). As discussed in the following section (III.9.2.2), guidelines in particular have been useful to improve operational implementation.

The consultation, including with the experts, has highlighted that this **non-prescriptive approach confers** two major and inter-linked **advantages**: a) it allows **adaptability** of the provisions to fit all operational contexts and specific cases (e.g. markets/sectors); and b) it acts as an important **mitigating factor** against excessive (or unnecessary) burden. As already outlined, the GFL applies to a diverse sector encompassing a wide spectrum of operational contexts. These advantages allow addressing the considerable diversities that

[293] Many such examples were provided of traditional products that, according to micro/small operators, are threatened by over-regulation and the drive for standardisation; e.g. ready packed mixes of flour for bread now replacing the previous craft production recipes/methods which allowed a wider range of speciality products.

exist both at macro-level (i.e. fitting different sectors, food safety issues - secondary legislation - and geographical/cultural factors) but also at micro-level (i.e. fitting the operational reality of individual businesses, particularly SMEs). For example, in the case of risk analysis, Article 6 is not prescriptive in terms of defining the institutional structure that MS CAs have to apply to ensure compliance; nonetheless, it contributed to the centralisation of food safety analysis at MS level, although whether MS created a food safety agency or not was their right to decide. Similarly, at the level of operators, the primary responsibility principle of Article 17.1 and even the more specific traceability requirements of Article 18, are not prescriptive in the means by which they should be implemented, thus allowing operators to integrate these more smoothly in their operational context.

Although the non-prescriptive approach is generally appreciated, the analysis indicates that some requirements of the GFL that are left to MS result in differences in implementation that undermine the full and harmonised application of the GFL provisions. One of these more problematic aspects is the consistency of the liability system and penalties in place at MS level with the principles of the GFL on allocation of responsibilities (Article 17.2), including in the context of measures and penalties foreseen for fraudulent activity and food adulteration (Article 8).

Finally, from a legal perspective, no cases were identified where the lack of prescriptiveness in the GFL caused problems in European Court proceedings. When it comes to national courts preliminary rulings, the situation may differ depending on the legal approach/systems in each MS. For example, the GFL has a similar level of prescription as the UK Food Safety Act, so in the UK legal context it is considered compatible with national approaches in terms of the balance between prescriptive/broad principles. This might not work in MS with more prescriptive and/or more decentralised approaches.

III.9.2.2 Combination with other tools (EQ27)

EQ27: To what extent have other tools such as self- regulation, guidelines, code of good practices been combined with the provisions of the GFL and their implementation and has that been an efficient and effective combination of measures?

In the areas of the GFL that define core requirements for feed/food operators, in particular those relating to traceability and own verification controls (sections III.3.1and III.3.2.1), including requirements that are further defined in secondary legislation (e.g. HACCP), the study has found that **other tools (private standards, guidelines, codes of good practice) have been combined with the regulatory provisions** (*indicators 27.1a and 27.1b*). The driver for such a combined approach has been to maximise efficiency and effectiveness in the implementation of the regulatory provisions, linking them where possible with existing structures and processes in place.

The consultation has found that **great effort has been made to integrate seamlessly regulatory provisions into self-regulation, and this combined approach is considered to have improved effectiveness and efficiency in the implementation of the regulatory provisions**. Several best practices have been identified in this respect during the case studies (*indicators 27.2b and 27.3b*). For example, in the case of traceability, industry guidelines for the voluntary introduction of traceability pre-existed (FDE, 2004) and served to provide guidance to members. Similarly, in the case of operator own verification and controls, the link was made to a range of private sector tools already in place/in the process of revision/development, including guidelines, GMPs and private

standards, all of which are usually also sector specific[294]. Furthermore, in both cases, the required adjustments were for the most part integrated in existing systems, usually forming part of wider quality management systems/processes. Several operators have indicated that they have been forced to use private tools/self-regulation to reduce legal uncertainty and associated burden resulting from diverging approaches to implementation of official controls and/or enforcement of other secondary legislation at national level; thus, certification systems going beyond GFL principles have been implemented to alleviate those issues and ensure further harmonisation across MS (section III.3.2.1).

According to operators, all of the examined tools have been useful in that they have **helped stakeholders to save money/work more efficiently in meeting their legal obligations (GFL and secondary legislation)**. In particular, EU guidelines have been most helpful, followed by national guidelines, private guidelines, private codes of good practice, and private standards (survey results, Q47)[295] (*indicator 27.2a*). They have also **helped stakeholders to meet their legal obligations (GFL and secondary legislation) more effectively**. Again, EU guidelines have been most helpful, followed by national guidelines, private codes of good practice, private guidelines and private standards (survey results, Q48)[296] (*indicator 27.3a*).

Indeed, according to both feed/food operators and MS CAs, **EU guidelines have been very useful in assisting to comply with their respective obligations** (survey results, Q52)[297]. The consultation has found that the Commission guidance document (January 2010) has been widely used as a key source of information for further guidance, by both MS CAs and the supply chain stakeholders (usually at the level of the associations, rather than individual operators). Other particularly useful guidelines, according to operators, have been the EU Guideline on Allergens (Directive 2003/89), and EU leaflets/guidelines on the hygiene package. Amongst those (few) stakeholders that have been more sceptical of the usefulness of Commission guidance documents more generally, their main shortcomings are: a) that they are not legally binding; and/or, b) that they are not sufficiently detailed or

[294] The proliferation and central role played by private standards/schemes in the contemporary food safety governance system is reviewed in van der Meulen (ed.) (2011). Examples of self-regulation, for the different parts of the supply chain, are provided in section III.3.2.1.

[295] Share of stakeholders indicating these tools have been helpful to improve efficiency: EU guidelines (58% of stakeholders, of which 25% 'yes, systematically' and 33% 'yes, to some extent/in some cases'); national guidelines (46% of stakeholders, of which 22% 'yes, systematically' and 24% 'yes, to some extent/in some cases'); private guidelines (43% of stakeholders, of which 22% 'yes, systematically' and 21% 'yes, to some extent/in some cases'); private codes of good practice (43% of stakeholders, of which 31% 'yes, systematically' and 12% 'yes, to some extent/in some cases'); and, private standards (40% of stakeholders, of which 18% 'yes, systematically' and 22% 'yes, to some extent/in some cases'). It is noted that a large number of stakeholders replied 'don't know' to this question (between 22% in the case of EU guidelines and 39% in the case of national guidelines), largely because they were not in a position to know (e.g. because these tools are not always applicable in their case).

[296] Share of stakeholders indicating these tools have been helpful to improve effectiveness: EU guidelines (59% of stakeholders, of which 30% 'yes, systematically' and 39% 'yes, to some extent/in some cases'); national guidelines (52% of stakeholders, of which 28% 'yes, systematically' and 24% 'yes, to some extent/in some cases'); private codes of good practice (51% of stakeholders, of which 21% 'yes, systematically' and 30% 'yes, to some extent/in some cases'); private guidelines (46% of stakeholders, of which 15% 'yes, systematically' and 31% 'yes, to some extent/in some cases'); and, private standards (45% of stakeholders, of which 12% 'yes, systematically' and 33% 'yes, to some extent/in some cases'). A large number of stakeholders replied 'don't know' to this question (between 22% in the case of EU guidelines and 34% in the case of national and private guidelines), largely because they were not in a position to know (e.g. because these tools are not always applicable in their case).

[297] Stakeholders provided ratings above 4 on a scale from 1 to 5 for all of the areas of the GFL examined and in particular for the guidelines on traceability requirements (4.24) and on the determination of safe food and food safety requirements (4.16). MS CAs also highlighted the usefulness of EU guidelines in assisting them to comply with their obligations, in particular on the allocation of responsibilities between food/feed businesses and control authorities (4.17), on traceability requirements (4.16) and on withdrawals/recalls of unsafe food (4.13). Very few of the responding organisations did not find these guidelines useful. It is noted that a considerable share of stakeholders (12-34, out of 67, depending on the GFL provision) replied 'don't know' to this question, especially regarding the areas covering withdrawals/recalls and imports/exports. This was largely because these guidelines are not applicable in their case (including consumer organisations and NGOs).

practical. It was highlighted that, in some cases, the lack of detail/practical reference, such as through concrete cases and examples, can lead to further potential misinterpretation or contradiction with the interpretation of the legal provisions by the authorities, and can therefore be counter-productive.

III.9.2.3 Adaptability to national markets and cultures (EQ28)

EQ28: To what extent were differences between Member State markets and cultures taken into account in the GFL and did that improve the efficiency and effectiveness of the law?

The extent to which differences between MS markets and cultures were taken into account in the GFL links to the **situation that prevailed before the adoption of the GFL**. As discussed in the baseline, in the 1990s most of the (then EU-15) **MS already had coherent and harmonised national food laws**, ensuring public health and consumer protection, **based also on international standards** (Codex Alimentarius). The GFL has been the final outcome of a reflection process that started in the mid 1990s following the BSE crisis, to which the EU-15 MS actively participated. Thus, the GFL aimed to harmonise general food law principles and requirements already in existence at MS level, place these in the EU context and provide the basic framework of definitions, principles and requirements for EU food law. The GFL also recognises the EU's commitment to international obligations and EU food law is developed taking international standards into consideration.

It is important to bear in mind that at the time of the development of the GFL, the EU had 15 MS. Although to a certain extent a common basis existed through adherence to Codex standards and membership of Codex, the 12 MS that acceded in the EU during the past decade had to make considerable efforts to align to EU food law as part of their pre-accession efforts to implement the EU *acquis*. In this context, preparing the farming sector and the food processing industry in the new MS for adopting the EU feed/food standards has been a particular challenge[298].

All these elements corroborate the overall view expressed during the consultation that differences between MS markets and cultures were, to the extent possible, largely taken into account in the GFL (*indicator 28.1a*). As the aim of the GFL was to pursue further harmonisation, *a priori*, the objective was to address any differences between MS affecting the harmonised implementation of the principles and requirements laid down in the GFL. Furthermore, as discussed in section III.9.2.1, the consultation with all parties (including MS CAs and experts) has confirmed that the **low level of prescriptiveness of the GFL allows differences between MS markets and cultures to be more easily accommodated during implementation**, thus contributing to improve effectiveness and efficiency.

In terms of specific examples of provisions where national markets and cultures were taken into account, and the impact on improving effectiveness/efficiency of implementation, no further evidence was provided by the consulted parties. In view of the broad scope of this theme, focus has therefore been on identifying specific cases demonstrating where major deviations existed in national approaches to feed/food law from the GFL, thus necessitating considerable changes at MS level, but leading to a convergence of MS markets/cultures

[298] The obligation to fulfil EU hygiene and food safety as well as quality standards, which was partly supported by EU funds through pre-accession instruments (SAPARD and rural development funds), as well as considerable foreign direct investment in this sector, have contributed to major restructuring and modernization of the sector, and the adoption of EU standards (European Commission, 2006c).

(*indicators 28.1b and 28.3b*). The case studies have confirmed that **the GFL contributed to major changes in many of the consulted MS, particularly amongst the EU-12**. The most pertinent area in which changes, as well as a convergence, was identified is in the field of **risk analysis and transparency**, with the **creation of new administrative organisations and structures**. In particular, Article 6 contributed to the centralisation of food safety analysis at MS level, and had an impact in MS where there were no food safety agencies, although even in this case the changes introduced in some MS were also driven by other parallel developments (this aspect has been analysed in section III.4.1).

Beyond the more general advantages brought about by the **increased harmonisation pursued by the GFL and its low level of prescriptiveness**, it is **not possible to draw comprehensive conclusions on whether taking into account differences between MS markets and cultures has improved the efficiency and effectiveness of feed/food law in MS** (*indicators 28.2a and 28.3a*). Again, the **best practice case** that can be drawn in the context of this study is **in relation to risk analysis**. There, the GFL has enabled both a higher scientific standard throughout the EU and efficiencies from pooling national and EU scientific resources (particularly for those MS that do not have a large scientific capacity and cannot afford to invest to create it). Nonetheless, it is not possible to extrapolate from this example to draw conclusions on the overall impact of the GFL on effectiveness and efficiency in each and every MS context.

Nonetheless, the **broader benefits of the GFL in establishing a common framework apply for all MS, in terms of achieving a greater harmonisation of national approaches across the EU in the area of food law and in particular, an improved level of feed/food safety** (*indicator 28.3b*). These advantages particularly accrue to those MS that engage more heavily in cross-border/intra EU trade of raw materials and finished products. The consultation confirms that the legislative framework introduced by the GFL has provided major benefits, compared to what could be achieved in the absence of a common framework at national and/or regional levels or at international level (Codex, OIE). In particular, it facilitated the enforcement of food law rules across the EU; raised the overall level of food safety standards applying across the EU, including the scientific and technical soundness of these standards; and, improved coherence of food safety rules across MS (survey results, Q50) [299].

III.9.3 Potential for simplification including potential for cost and burden reduction (EQ30/EQ31)

EQ30: To what extent is there a potential for (legislative, non-legislative) simplification and reduction of regulatory costs and burdens in the area of the GFL?

EQ31: Which reduction of costs in quantitative terms can be achieved? What are the specific costs, benefits (quantitative and qualitative) and risks of these actions?

The potential for further simplification was examined with regards to: a) areas where legislation can be replaced by GMPs or guidelines; and b) areas where simplification is possible (but legislation remains essential). The premise was that a combined approach (public law/private law) may not be applicable in each area of EU food law (i.e. secondary legislation). It is noted that simplification may aim for improving the clarity and consistency,

[299] Both stakeholders and MS CAs provided average ratings that were above 4.00 on a scale from 1 to 5 for these benefits.

and/or streamlining the legal texts, and does not necessarily imply reducing or removing legal provisions.

A priori, all of the mitigating factors analysed in the previous section were expected to have contributed to 'lighten' the costs and burden associated with the implementation of the GFL. The study has found that all the three examined factors (level of prescriptiveness; combination with other tools; and adaptability to national markets and cultures) have indeed allowed an efficient, fit for purpose implementation, that matches more closely the specific operational, market and cultural needs of the diverse EU feed and food supply chain. A particular strength of the GFL in this respect has been the inherent adaptability conferred by laying down principles and general requirements rather than prescriptive rules (section III.9.2.1). The very design of the GFL, as developed 15 years ago, is considered to have brought EU food and feed law a step closer to smarter legislation. Assigning primary responsibility to operators and the adaptation of requirements according to size of business and sector, as well as the allocation of responsibilities both within the supply chain and between operators and authorities, all of which are embedded in Article 17, are key principles that encourage proportionality in regulatory burden. Furthermore, the core requirements of the GFL are now well established and integrated in the feed/food supply chain processes and structures, as outlined in section III.3. The findings of the consultation indicate that, overall, the **legislative framework introduced by the GFL has largely facilitated enforcement of rules across the EU, consistently allocated responsibilities among operators along the chain, and allowed simplification**, thus leading to a reduction in administrative costs and burden, compared to what could be achieved at national and/or regional levels or at international level (Codex, OIE) (survey results, Q50)[300].

Generally, the consultation highlighted **some potential for (legislative, non-legislative) simplification and reduction of administrative costs and burden in relation to the key obligations stemming from the GFL** (*indicators 30.1a and 30.1b*). In particular, some potential was noted by stakeholders in the areas of the obligation of verification and withdrawals and recalls (survey results, Q46)[301], as follows:

- The **obligation of verification**. This includes notably the potential for control authorities to take into account the results of operators own checks, provided that a system is in place to ensure that they are reliable. There is also potential to address the gaps/weaknesses identified in terms of the coverage of the entire supply chain (e.g. to ensure coverage of importers, e-commerce) and the consistency of national liability rules in place with the broader objectives of Articles 17.2 and Article 8.
- **Withdrawals and recalls**. A common problem with these provisions, as highlighted by the food industry, is the broad and differential interpretation by authorities in practice of Art 14.6 (namely, that the whole batch is 'unsafe for human consumption') which sometimes counteracts the goal of targeted withdrawals and leads to larger quantities of food products being removed from the market, even in cases when internal traceability may be in place[302]. The impact is even more disproportionate where it is

[300] On a scale from 1 to 5, both stakeholders and MS CAs provided average ratings on these aspects above midpoint (3) ('facilitated enforcement of rules across the EU': average rating above 4).

[301] Indicated respectively by the following shares of supply chain stakeholder respondents to the survey (N=53): obligation of verification (internal controls): 51% (of which, 'considerable potential': 17%; potential 'to some extent/in some cases': 34%); withdrawals and recalls: 43% (of which, 'considerable potential': 15%; potential 'to some extent/in some cases': 28%). It is noted that about a third of stakeholders replied 'don't know' to this question, largely due to the complexity of this matter.

[302] When operators have in place internal traceability (which is only required on a voluntary basis), this could ensure more targeted withdrawals. In the absence of internal traceability, MS CAs are obliged by Article 14(6) to presume that all the food in a batch, lot or consignment is also unsafe, unless following a detailed assessment there is no evidence that the rest of the batch, lot or consignment is unsafe. However, there are complaints by

difficult for authorities to establish a clear balance when no objective/science-based criteria exist, e.g. when 'unsafe' is established on the basis of Article 14.2(b) i.e. 'unfit for human consumption' or current legislation is not harmonised (e.g. contaminants), (which, as discussed in section III.3.3, appears to occur in practice).

On the other hand, in the case of placing safe food/feed on the markets and on traceability obligations, there is less potential for simplification and reduction of administrative costs and burden as indicated by only a third and a quarter of supply chain respondents respectively (survey results, Q46)[303].

The consultation has found that where problems/shortcomings occur in practice these stem from: a) differences in implementation/enforcement between MS; b) specific provisions in other secondary legislation, beyond the GFL; and c) lack of harmonisation. In all cases, further investigation of the **identified problems and shortcomings have not revealed any link to systemic gaps or failures in the GFL principles and general requirements *per se*.** It is noted that EU food law continues to be in a dynamic evolution with a number of revisions to secondary legislation recently concluded/currently ongoing, which aim *inter alia* to address regulatory burden, and which have therefore not formed part of this analysis[304].

Thus, the **identified potential** for simplification and reduction of regulatory costs and burden **in the area of the GFL was mainly in terms of soft interventions, including the provision of training and guidelines, and improved cooperation between national authorities and with operators** (EQ31) [305] . Beyond the GFL, **further harmonisation in secondary legislation** is considered to have the potential to allow a reduction of administrative burden, in view of the problems encountered by stakeholders and MS CAs in the areas where harmonisation is incomplete (examples include: food contact materials other than plastics; contaminants; salmonella in feed; lack of technical solution for GM food). These **broader, rather than specific, improvements are considered to have considerable potential to exert a positive impact in improving the predictability and certainty of legislation and creating a more level playing field across the EU**.

One aspect of other secondary legislation where the **potential for simplification was systematically highlighted is in the context of specific authorisation procedures designed in sectoral legislation in relation to food** (e.g. nutrition/health claims, and enriched food). Again, these cases are not directly attributable to Article 6, but to the complexity of the specific procedures laid down in secondary legislation, and the fact that these specific procedures are not standardised at operational level across the different

operators that MS CAs do not always proceed to a detailed assessment and they automatically consider the whole consignment/batch/lot as unsafe in the absence of internal traceability or even despite internal traceability.

[303] It is noted that about a third of stakeholders replied 'don't know' to this question, largely due to the complexity of this matter.

[304] Reference is made to areas where simplification is currently under way. One area where significant costs/burden have been identified is the authorisation procedure for novel foods; this is being addressed by the 2013 Novel Foods proposal streamlining *inter alia* with a centralised procedure (applications to the Commission) and a simplified procedure based on the history of use, which aims to provide a reduction in administrative burden. In terms of authorisation procedures more generally, as also highlighted in section III.4.1, initiatives are currently under way between EFSA, the Commission and stakeholders to address certain operational shortcomings. Another area is the 2013 Official Controls review; impact analysis carried out in this context indicates the aim of further simplification and regulatory burden reduction.

[305] EQ31: as the identified potential is mainly in terms of soft interventions, these have no immediate/direct implications in terms of reduction of costs, other than the potential benefits stemming from enhanced and more harmonised implementation of the legal provisions.

sectors of food legislation[306]. The potential for simplification was also noted with regard to the requirement of multiple parallel or successive authorisation procedures for the same substances.

MS CAs generally appear more sceptical than stakeholders on the potential of alternative means/measures (e.g. guidelines, private standards or codes of good practice) other than law to ensure compliance (survey results, Q49). Stakeholders are more open to endorse the potential synergies, drawing also from the positive experience gained in this respect in the implementation of the core provisions of the GFL and secondary legislation (section III.9.2.2). In particular:

- According to stakeholders, the two areas of EU food law where the above alternative means/measures could be used the most to ensure compliance are food hygiene (58% of stakeholders) and food labelling (60% of stakeholders). On the other hand, in the GFL core areas, only a quarter of stakeholders saw the potential of alternative means other than law. In all other areas of secondary legislation, between 15% of stakeholders (in the case of feed additives) and 34% of stakeholders (in the case of contaminants) indicated that alternative means could be used to ensure compliance. However, in all cases, the large number of 'don't know' responses needs to be taken into account[307]. This largely reflects uncertainty of the potential outcomes, which are considered highly dependent on the exact form of the guidelines, private standards or codes of good practice, and the way these would interface with legislation. Consumer organisations noted that for essential requirements, guidelines, codes of good practice, private standards, etc. can only come in complement to the law, not in replacement; what constitutes an 'essential requirement' derives from the level of protection of public health and consumer interests that is democratically defined by society.
- According to MS CAs, the areas where the use of alternative means/measures to ensure compliance other than law were mostly indicated, although not by a majority of MS CAs, were feed hygiene (12 of 25 responding MS CAs), feed labelling (10 MS CAs) and food labelling (8 MS CAs). In all other areas, the GFL core requirements as such, a large majority of MS CAs (from 16 to 22 MS CAs) did not see a potential to use alternative means.

Nonetheless, both MS CAs and stakeholders have for the most part indicated that, in terms of **EU guidelines**, further updates/more practical detail of existing guidelines (in particular in the area of withdrawals and recalls; also, in relation to assessing whether products are unfit for human consumption) and coverage of the GFL Articles for which no guidelines have hitherto been provided (in particular, risk analysis, the precautionary principle and public information) would be useful.

Also, in view of the general finding that problems often arise because legal requirements are interpreted differently between MS, in particular at the level of local implementation by individual inspectors or veterinarians, more **training** could be one solution to ensure a more harmonised implementation at the level of control inspections and enforcement of EU food law. Training could be addressed both to local authorities and operators, and/or training could be coordinated.

Both training and guidelines but also any new legislative initiative needs also to address all activities involving **data collection and registration**, which need to be carried out in a manner that does not cause unnecessary burden for operators, particularly small and micro-

[306] This is in relation to the legislation on food. In the feed additives sector, as noted in section III.4.1.3, whilst the re-evaluation of existing additives has been necessary, the EU authorisation procedure has already been simplified and centralised, compared to the previous approach (Directive 70/524/EEC).

[307] Ranging from 18% in the case of food hygiene and food labelling to 52% in the case of novel foods and food improvement agents, and up to 60% in the case of feed additives.

enterprises. In this context, collecting and registering data should be suitably defined to ensure simplicity and efficiency, and that the process is meaningful, relevant and necessary. Supply chain stakeholders have indicated that, from current experience in some MS, requirements for additional specific details is often irrelevant and time-consuming, while the authorities do not use information that is already available from other sources. This is the case for example with data available from other MS CAs, but also from the industry, such as results of laboratory analysis (tests performed on the request of operators) and the results of operators' own-verification controls. There are examples of some MS that foster more cooperation for data exchange between authorities and private operators, based for example on protocols and assurance schemes developed by the industry and validated by the authorities to ensure data reliability.

IV. OVERALL ASSESSMENT (ANSWERS TO EVALUATION CRITERIA)

This section presents a synthesis of the main findings for each of the main evaluation criteria/themes: relevance; effectiveness; efficiency; coherence; and, European added value. The findings are drawn on the basis of the in-depth analysis of the evaluation questions (EQs) in section III. It is noted that the EQs pertaining to the core principles and requirements of the GFL address several criteria (e.g. EQ 20, assessing the application of the risk analysis process as defined in Article 6, covers effectiveness, efficiency and coherence). However, the first two EQs (EQ1; EQ2) address, respectively, the overarching criteria of relevance and EU added value, and are therefore incorporated directly in this part of the Report.

IV.1 Relevance

Relevance[308]. *The extent to which the original objectives of the GFL correspond to current needs. In making this assessment it needs to be kept in mind that needs can evolve and so it is possible that recent events, such as the horsemeat scandal, have resulted in a different set of needs to those apparent at the time the GFL was drafted.*

Overall, this study has found that **the original objectives[309] of the GFL remain relevant in that they correspond to current needs**, despite the evolving context within which the GFL operates. In particular, **the original core objectives**, i.e. the protection of consumer health and interests and the effective functioning of the internal market **continue to be the most relevant that the GFL needs to address**.

Certain **drivers that influence the needs which are addressed by the general objectives remain at least as important as at the time of the adoption of the GFL**. In particular, the study has found that **the following needs continue to underpin the core objectives of the GFL**:

- **The need to prevent/address potential shortcomings that may lead to the negative impacts of safety and non-safety related food incidents**. Safety and non-safety related food incidents can impact consumer health and interests and lead to costs and losses for industry. Examples of these incidents range from: the human health impacts of food-safety related crises (e.g. 2011 *E. Coli* outbreak); to direct costs and losses for the affected industries (including food safety and fraud related scares e.g. 2013 horsemeat scandal); to spill-over costs and losses for indirectly affected ancillary sectors and services; and, the longer term impacts from the loss of consumer trust/confidence more generally. Misleading practices and fraud have further challenged consumer confidence and trust, and can have lasting effects, as experienced in the 2013 horsemeat scandal.
- **The need to prevent/address potential barriers to the smooth functioning of the internal market caused by different standards and approaches of feed/food law, so as to safeguard the sustainability and competitiveness of the EU agricultural, food and drink sector.** This sector remains crucial to the wider EU economy: it currently employs over 24 million people, more than 11% of the total EU workforce, and generates added value of around €650 billion per year, almost 6% of

[308] The analysis of relevance is based on an overarching assessment of the findings, including the indicators that were used to address EQ1. ***EQ1: To what extent do the original objectives of the GFL correspond to the current needs of the society within the EU, reflect policy trends of today, taking into account developments at Union and international level, and fit the Union's institutional, legal, economic and political landscape?***

[309] In particular, the analysis covered the core objectives of the GFL and other objectives to be taken into account, where appropriate (GFL, Article 5.1): animal welfare, animal health, plant health and the environment.

total EU gross value added (GVA), with a turnover exceeding €3.5 trillion. Furthermore, the sector is relatively fragmented and dominated in numbers by SMEs (including micro-businesses). These represent 99% of food and beverage manufacturing enterprises, account for over half of total turnover (52%) and almost two-thirds of total employment (64%: 2.9 million people). The EU remains the leading food and drink producer worldwide, and the largest global trader and a net exporter of food and drinks. It is noted that the value of internal trade in this sector has increased by 72% over the past decade, driven by increased harmonisation within the Union; it remains therefore particularly relevant to sustain this growth.

The **context of the GFL has evolved considerably** since the major food safety crises (e.g. BSE, dioxin) that led to its adoption in 2002. Since then, **the key drivers that influenced the prevailing needs at the time of its adoption have become even more important.** Thus, the original needs have been reinforced by developments within the Union and more globally. Some of these trends are external to the GFL framework and covered by policies outside the scope of the GFL (e.g. technological progress, globalisation of trade, post-2008 economic downturn), while others pertain to issues directly covered by the GFL (e.g. food fraud, nutrition and obesity). **Focus on nutrition and fighting the rising trend of obesity in the EU, the fight against fraud,** as well as **technological developments (including distance trading/e-commerce)** are major drivers that have gained in importance over the evaluation period. In terms of the **economic development of the sector**, over the evaluation period there has been a sharp increase in intra-EU trade and **global trade has also increased with a trend towards bilateral FTAs** (such as the currently negotiated EU-US TTIP) and international fora/agreements.

In examining the relevance of the GFL objectives within this evolving context, the study has found that the **original objectives of the GFL are adequate to address current needs arising from the key drivers and trends**. In particular:

- In the context of the economic downturn that has affected Europe since 2008, the need to ensure growth and competitiveness has become centre stage in EU policies, and promoting innovation has been signposted as a key driver to this end[310]. **The GFL was generally found adequate to address innovation and competitiveness**, because by improving harmonisation in EU food law, it has enhanced predictability and ease of implementation and has streamlined processes for companies selling products within the internal market. For example, in the case of risk analysis, the use of the principles laid down in Article 6 has provided a harmonised system to address potential divergences in scientific opinions concerning health protection more objectively, and has underpinned the streamlining of additional procedures for regulated products in some areas (e.g. food improvement agents). The analysis shows that negative impacts in practice mainly relate to shortcomings identified with other secondary legislation, mainly in partially/non harmonised areas (e.g. enriched food, food contact materials other than plastics). In these areas the implementation of authorisation procedures, as laid down in specific secondary legislation was found to have an adverse impact on innovation. However, in all cases, the identified shortcomings are not due to the risk analysis principle of Article 6 *per se*.

- In relation to **consuming healthier food/addressing the nutritional needs** of the general population, **this aspect is currently embedded and adequately addressed**

[310] In view of the important economic dimension of the food/feed supply chain, its contribution is crucial to three of the current key flagship initiatives of Europe 2020: the EU vision for industrial policy in the globalisation era (European Commission, 2010d); the EU flagship initiative 'A resource-efficient Europe' (European Commission, 2011e); and, EU initiatives aimed at fostering innovation, including the EU flagship initiative 'Innovation Union' (European Commission, 2012g).

in the GFL (e.g. Article 22 in relation to the scope of EFSA including the provision of scientific opinions on nutrition issues), in the pursuit through the GFL of a high level of human health. This trend is further addressed through specific requirements in other secondary legislation covering nutrition labelling, health and nutrition claims as well as scientific advice on nutrition issues. Furthermore, soft measures in this area, such as the voluntary initiatives taken in the context of the EU platform for diet, physical activity and health[311], which are complementary to legislation, while useful have not significantly progressed. Legislation in this area therefore remains relevant.

- In relation to food fraud, **the provisions of Article 8 envisage that MS take measures in order to prevent/address fraudulent/deceptive practices**. The study has found that measures are not always taken by MS to apply these provisions, and where taken considerable differences exist in the approach and severity of measures. Furthermore, legal provisions on liability and sanctions are subject to national law and there are considerable differences in approach between MS. The variation in MS implementation and enforcement has implications in terms of potential effectiveness to address the objectives of Article 8, in particular relating to the prevention of fraud. However, these issues **extend beyond the GFL as such.**

- The **challenges posed by increasing globalisation are adequately addressed by the current scope and provisions of the GFL**. In particular, the key requirement of the GFL provides that all operators, including importers, verify the compliance of food/feed they put on the market with the requirements of food law (Article 17) and that any food/feed that is imported into the EU shall comply with EU rules (Article 11). Exporters are also covered in accordance with Article 12: exported food shall comply with the relevant requirements of food law unless otherwise requested by the authorities of the importing country or established by the law, regulations and/or standards in force in the importing country. These **GFL provisions contribute to the increasingly needed global cooperation between all players**. Furthermore, the **GFL has laid the foundations for meeting the objectives pursued in the area of food law** (in particular a high level of feed/food safety) **in a global context,** through the general commitment of adherence to international standards (Article 5.3) and the role it has played in **promoting international food chain governance** by laying down what is recognised internationally as a high level of food safety standards. An indicator of the positive impact of the GFL in the international context has been its role in Codex Alimentarius and the fact that certain trading partners are adopting/considering the adoption of similar legislation e.g. on traceability. This contribution of the GFL is important as the future of EU food safety will depend increasingly on the actions of other global players and the extent to which cooperation can be achieved on a global scale, both regarding standards and their enforcement throughout the global food chain.

- In relation to **distance selling/e-commerce**, the adequacy of some of the GFL provisions was questioned by the various consulted parties. It is noted that distance selling/e-commerce has emerged as an important distribution channel for food/feed after the introduction of the GFL and is not explicitly mentioned in the GFL, although it has subsequently been dealt with in other secondary legislation. However, the study has found that these **shortcomings do not relate to the relevance of the GFL objectives or scope, but rather to the understanding/ interpretation of the GFL definitions**. The GFL covers all food operators carrying out an activity related to any

[311] The EU platform for diet, physical activity and health has been in place since 2005. It provides a platform to voluntarily exchange and commit to the fight against obesity through consumer education, sports, voluntary reformulation of products, limiting marketing to children, etc.

stage of production, processing and distribution of food. This therefore covers internet operators distributing food/feed. Nonetheless, a closer investigation of issues systematically raised by consulted parties highlights the potential for a broader than intended interpretation of the definitions which can result in differences in practical approaches to enforcement at national level, including the coverage and control of internet distribution. The latter raises concerns on the extent to which full chain responsibility can be achieved, covering also food/feed sold via the internet to ensure that this complies with EU food law requirements[312].

IV.2 Effectiveness

Effectiveness[313]. *The extent to which the intervention resulting from the application of the GFL (including the application of its fundamental definitions, principles and requirements in related specific pieces of food law) caused changes in the EU food safety area. This aspect of the evaluation also examines the extent to which the objectives have been achieved, identify areas where expectations have not been met, identify factors which have hindered their achievement and the role, if any, of policy measures outside the framework of food law as set out in the GFL, in the achievement of observed changes.*

Overall, the following conclusions are reached on the effectiveness of the GFL as a framework and in the application of its fundamental definitions, principles and requirements, including in related specific pieces of food law:

- The study has found that the **combined (overarching) effect of the GFL provisions has for the most part achieved the core GFL objectives**. The GFL effectively laid down a common set of principles and obligations shared and valued by consumers, the MS and the wider supply chain.
- The **GFL has, over the years, contributed to the effective harmonisation of consumer protection across the EU**. In particular:
  - The GFL provisions have **contributed to effectively address food safety risks,** thereby raising the level of food safety in the Union. It is important to bear in mind that, in pursuing the protection of public health, the ultimate aim of food law is to prevent/minimise risk. The evidence available from all major incidents that have occurred over the past decade indicates that the GFL provisions, such as traceability, withdrawals and recalls and their combined effects, have played a major role in managing risks. In this sense, the GFL is found to have adequately drawn the lessons from the food safety scares of the 1990s and laid down the right foundations to address the previous shortcomings of fragmented approaches (e.g. with regard to ensuring traceability and responsibility). The GFL has established 'chain responsibility', which is defined as the collective responsibility of all operators at all stages of production, manufacturing and marketing; this was a major novelty of EU feed/food law, compared to the pre-GFL fragmented individual responsibility approach. It is also generally acknowledged that the rigorous, science-based approach introduced to risk analysis by Article 6 not only established a harmonised basis in this field across the EU, but has overall raised the level of protection from

[312] This is compounded by the more general problem that legal provisions on liability and sanctions are national law and there are considerable differences in approach between MS (this is discussed further in section III.3.2.2).

[313] Effectiveness is a cross-cutting issue which draws on the analysis undertaken under a number of relevant EQs. A range of indicators has been used to assess the effectiveness of the GFL provisions throughout the analysis of the main findings for the different EQs. The caveats and challenges of addressing effectiveness (and efficiency) are presented in detail in section II.3. It is important to note that effectiveness and efficiency are cross-cutting themes, to some extent underpinned by the same factors determining success or failure; thus the achievement of effective outcomes is often associated with efficiency gains. The combination of effectiveness and efficiency determines the extent to which the GFL is 'fit for purpose'.

potential food safety risks, particularly when used in conjunction with the precautionary principle (Article 7) in areas where scientific uncertainty persists.
    - Furthermore, the **explicit inclusion of the protection of consumers' interests under the general objectives of the GFL** (Article 5.1) has **brought a change in approach in EU food law**. An example is food labelling legislation (Regulation 1169/2011 on Food Information to Consumers – the FIC Regulation), which puts consumer interests at the heart of the legislation: the scope of the FIC Regulation allows consumers to make informed choices according to issues of interest to them.
- The GFL has also largely **contributed to achieving the free movement of food and feed in the internal market**. The value of internal trade in this sector has increased by 72% over the evaluation period, facilitated by increased harmonisation in the Union across the various policy areas, including food law. There is no evidence of systemic problems caused by failures/gaps in the GFL provisions as such that could have created obstacles to reaching this goal.
- The GFL has also played an **important role in improving effectiveness of feed/food law implementation in the MS.** In this context, the more general advantages brought about by the increased harmonisation pursued by the GFL are noted. A best practice is in relation to risk analysis, where the GFL has enabled the achievement of a higher scientific standard throughout the EU. Nonetheless, it is not possible to extrapolate from this example to draw conclusions on the overall impact of the GFL in each and every MS context. The broader benefits of the GFL in establishing a common framework apply for all MS, in terms of achieving a greater harmonisation of national approaches across the EU.
- In terms of the **effectiveness of implementation for operators**, the study has found that the fact that the GFL lays down principles and general requirements, has allowed its **adaptability to best fit operational contexts and needs**. In this context, **other tools (private standards, guidelines, codes of good practice)** have been effectively combined with the regulatory provisions, as observed e.g. in the context of the traceability and operator responsibilities. The driver for such a combined approach has been to maximise both effectiveness and efficiency in implementation, linking them where possible with existing structures and processes in place. Great effort has been made to integrate seamlessly regulatory provisions into self-regulation, and this combined approach has helped businesses to meet their legal obligations (GFL and other secondary legislation) more effectively.

Despite the positive contribution of the GFL to improving the effectiveness of EU food law, the study has identified certain areas where expectations have not been met, with various factors hindering the achievement of the GFL objectives. Where **weaknesses** are identified, in practice these **mainly relate to differences in the implementation/application of the GFL provisions by MS, shortcomings with the implementation of other secondary legislation, and/or incomplete harmonisation in some fields**. However, for the most part, these issues are **not linked to systemic problems with the GFL provisions**[314]. These issues are highlighted in more detail in reviewing the effectiveness of the individual GFL provisions, with regard to their role and contribution to achieving the GFL core objectives, and key problems encountered (**Table 11**). In particular:

- Overall, in terms of the **GFL provisions**, the main areas identified where systematic problems occur are linked to the scope and definitions (Articles 2 and 3). Problems are identified relating to differences in the understanding and implementation of the **scope and definitions**, as well as some elements that are currently missing or not explicitly indicated in Articles 2 and 3. This has implications for the application of the GFL

[314] These weaknesses also pertain to the effectiveness of the GFL framework to address other needs and current trends. However, the relevance of the GFL in addressing other objectives, beyond its current scope, is also questioned as this is considered to risk diluting focus on the core objectives (as discussed in section IV.1).

requirements/obligations in certain sectors (e.g. problems linked to whether importers and distance trading/e-commerce are covered); hence, for ensuring an integrated approach covering the entire agri-food chain, including in the context of verifying compliance to requirements of all relevant operators (i.e. obligation for operators to have in place own checks, and audits by authorities).

- In the other areas of the GFL provisions, the study has found that a number of **tools/elements defined at MS level**, that are essential to ensure harmonised and optimal implementation, **are missing/incomplete** and different approaches prevail in practice between MS. These relate to:
  - **Variable national approaches to sanctions and liability** interfere with the ability of the current set up to ensure an effective, consistent and uniform allocation of responsibilities, thus not allowing the full benefits of the allocation of responsibilities as foreseen in Article 17. Article 17 is only one constituent of the current system which allocates responsibilities to operators and foresees that MS have in place measures and penalties applicable to infringements. However, another important constituent is the system of sanctions/penalties and the attribution of liability which are not regulated by the GFL, but by the national legal order (as foreseen respectively in Articles 17.2 and Article 21). The study findings indicate that considerable variation exists between national rules on sanctions (beyond the remedial measures foreseen in the context of EU law (Article 54 of Regulation (EC) 882/2004 on official controls));
  - **Variable national approaches to the implementation of official controls by MS CAs,** which are **not always risk-based** (authorities do not consistently take into account operators' own checks in risk profiling), while approaches may differ in enforcement at regional/local level. Nonetheless, as already noted, to some extent this also reflects differences in the reliability of operators' own checks;
  - **Measures are not always taken by MS to apply provisions that aim to the protection of consumer interests** (as foreseen in Article 8), in particular **to address fraudulent and deceptive practices**, and where taken considerable differences exist in the approach and severity of measures;
  - Furthermore, in certain areas, **inherent difficulties hinder harmonised implementation**. For example, the **absence of objective/science-based criteria in some cases** when determining the safety of feed/food that is 'unfit for human consumption' (Article 14.2(b)) and when considering other legitimate factors in the risk management decisions (in the context of risk analysis and the precautionary principle, Articles 6 and 7), inevitably leads to practical and/or case by case approaches for managing risks; however, this affects the ability of authorities to ensure fully harmonised/common approaches. Similar problems exist in the context of informing the public on food safety incidents, where there are no fixed rules on the best approach to take in balancing the need to provide additional information versus confidentiality requirements. In all these cases, the **approach in practice inevitably remains case by case**. Although this ensures that risks are managed (i.e. ultimately, that consumers are protected), it inevitably leads to variations in implementation, which may not allow a level playing field for operators i.e. consistency in the decisions taken in all comparable cases.
  - Moreover, **cooperation between MS CAs** in all of the above areas remains rather limited/ad hoc. The current level of cooperation does not allow the systematic and sufficient exchange of good/best practices. Such an exchange would have encouraged a learning process and the dissemination of good/best practices, thus contributing to some extent to addressing the above shortcomings.
- In the feed sector, the stricter approach for risk assessment of feed additives compared to feed materials, as well as the lack of sufficient controls of certain 'borderline' operators (such as operators with dual activities, e.g. raw material suppliers to feed sector and waste processors) are two major shortcomings that undermine effectiveness, within what is otherwise a strict and high standard regulatory framework.

The above shortcomings have a bearing on the extent to which 'chain responsibility' can be effectively delivered, which depends on whether there remain any weak points in the system. In this respect, the feed/food chain can be seen as any other system approach, which can only be as strong as its weakest part/link.

In determining the effectiveness of the GFL, **the study has endeavoured to separate facts from perceptions**. It is noted that **the observed achievements of the GFL in ensuring a high level of protection of consumer health and interests are often not reflected in consumers' trust and confidence in food safety and public authorities more generally**. A key issue that was raised during the consultation, more generally, was that consumers are not aware of the legal provisions therefore their confidence or trust in food is often affected by media reports or specific food incidents, despite the legal framework having achieved a higher level of food safety and the protection of consumer interests compared to the baseline, as also acknowledged by consumer organisations. **Similar issues are identified in business trust**, with businesses often focused on problems with specific legal provisions as they affect their daily operations, rather than the progress achieved over time or the overall contribution of the legal framework.

In this context, **a continuing shortcoming affecting consumer and business trust/confidence in food law, and its implementation by authorities, is the extent of transparency**. Although acknowledging that this has improved and has been applied in a more harmonised way across the EU, a perceived, and/or in some cases actual, gap in transparency was commonly observed in the analysis of the findings of the various GFL provisions. For example, consumer organisations indicate that: with regards to risk management measures, there is not sufficient information in the way the final decision is reached; with regards to the allocation of responsibilities, details of the outcome of the industry's own checks and controls are largely not communicated/are unknown to the public; with regards to withdrawals/recalls, they often lack key information on the products and on the actions taken. Concerns regarding the level of transparency have also been expressed by the industry, particularly in relation to: the risk management process and consideration of other legitimate factors (both at EU and MS level); more generally, the extent to which they are sufficiently consulted during the policy development cycle at MS level. Nonetheless, this feedback also indicates that **considerable differences persist in the approach and level of transparency between MS** (although more harmonised compared to the baseline). This is an important weakness, because **it creates perceptions and undermines the recognition of the facts in relation to the effectiveness of feed/food law**.

Table 11: Key findings of the study on the effectiveness of the GFL provisions

	Role and contribution	Weaknesses/gaps/constraints (a)
Scope and definitions (Articles 2, 3 and 4.1)	The **scope and general definitions of the GFL are sufficiently broad to ensure an integrated approach to food safety management** (*section III.2).* Having in place broad general definitions, in line with international definitions, ensures that the legal scope for control is sufficiently wide. This is one of the key factors contributing to the effective implementation of the various provisions with a view to ensuring that the GFL objectives are met. This is in line with the vision and expectations outlined in the 1999 White Paper on Food Safety (baseline).	Key problems identified include: • Cases where it is difficult to **distinguish 'food' from 'feed'** (e.g. materials of potential multiple use). • **Definitions/elements missing/not explicitly covered** (e.g. 'consumer interest'; 'local'; 'craft'; e-commerce/distance selling; elements of the supply chain, e.g. food contact materials, processing aids; definitions subsequently developed and contained in other secondary legislation). Feed for non-food producing animals are not included in Chapter II ("General Food Law"), which is not in line with secondary legislation. • **Broadness of definitions** can lead to variable implementation (e.g. 'retail').
Traceability (Article 18)	**The traceability provisions have played a key role in achieving the generalised application of the 'one step back-one step forward' requirement to cover the full supply chain** (*section III.3.1*). Its impact has been not only quantitative (from partial to complete implementation of traceability by all operators), but also qualitative (from fragmented to full application along the chain), in line with the underlying 'farm to fork' vision on food safety. The available evidence indicates that the ability to cover the full supply chain has enabled the effective tracing of affected products throughout the chain, in the event of food safety (e.g. dioxin, e-coli) and non-safety related incidents (e.g. horse meat fraud). The likely problems/gaps from the lack of an integrated approach are similar to those highlighted by the disadvantages of a sub-EU (national/regional), versus EU, approach: identification of the origin of incidents and affected products, and agreement of measures to contain the incident, would take longer and be less effective (and efficient).	***No systematic cases of failures were identified*** *in the current implementation of traceability, as laid down in Article 18.*
Allocation of responsibility (Article 17);	**The GFL provisions on the allocation of responsibility have made a positive and effective contribution towards meeting the objectives and intended outcomes** (section III.3.2). This has been achieved both for consumers (high level of protection of human health and consumers' interests), and business operators (improved trust among supply chain partners, moreover in the single market context): • **Article 17.1 established 'chain responsibility'** which has been a major novelty of EU feed/food law, compared to the pre-GFL fragmented individual responsibility approach. The obligation for FBOs to perform their own verification (internal controls) and their responsibility to place safe food/feed on the market in compliance with food/feed law, along with the other core requirements of the GFL (such as traceability and withdrawals/recalls) has had a positive impact in terms of ensuring food/feed safety in the EU. The share of responsibilities along the supply chain contributed to raise operator awareness of their responsibility to comply with the legal requirements at	The identified problems relate to the complexity of the supply chain, the implementation of other secondary legislation and/or incomplete harmonisation, rather than the legal provisions of the GFL. In practice, these problems hinder the full achievement of compliance along the full supply chain and in a uniform manner across the EU. This ultimately defines the **limits of the system in terms of its ability to deliver full 'chain responsibility'**. Key problems in this context are: • Persisting differences were identified in the **implementation of official controls** between MS. • Article 17 is only one constituent of the whole system of allocation of responsibilities. The attribution of **liability** is not regulated by the GFL, but by the national legal order (as foreseen in Article 21) and the

	Role and contribution	Weaknesses/gaps/constraints (a)
	each level of the chain and across the EU. The study has found that operators endorsed the concept as the backbone of sustaining consumer trust and confidence, but also improving trust within the supply chain. • **Article 17.2**, with its general requirements for national authorities to maintain a system of controls for monitoring and verification of operator's compliance, **and the existing risk based approach to official controls (Regulation 882/2004), have the potential to allow national authorities to develop a more harmonised and a better targeted, thus more effective, risk oriented approach to official controls.** • Effectiveness also depends on the **extent to which penalties and other measures have been introduced and applied by MS, and whether these are sufficiently dissuasive (Article 17.2)**. Although it was not possible in the course of this evaluation to collect systematic data (e.g. trend during the evaluation period) on penalties/other measures applied by authorities (Article 17.2), where new rules/provisions have been introduced/changed in MS' national legislation as a result of the GFL, both penalties and measures (other than remedial measures) were generally indicated by MS CAs to be an effective tool to deter operators from committing infringements; however, **MS CAs were unable to provide explicit evidence of this**.	specific infringed legislation. • There are **28 different national sanction systems within the EU** and there is **no functional administrative assistance/cooperation between MS CAs**. Not only **penalties/other measures** are not harmonised but there indications that they **may not be effective**. This is due to several reasons: lack of resources to pursue the infringing parties; insufficient training for CA staff; outdated/ insufficient national legislation; and/or, maximum fines not providing a sufficient deterrent. Nonetheless, it is noted that there are a number of mandatory administrative actions not subject to a national liability system and that can be rather high such as the closure of food businesses, which are provided in Article 54 of Regulation 882/2004 on official controls. It is broadly considered particularly relevant, in the current context of financial resource constraints, to ensure that the allocation of responsibilities between businesses and national CAs is both effective and efficient.
Withdrawals/ recalls (Articles 19 and 20)	**The GFL provisions have contributed to fit for purpose withdrawals and recalls** (this refers both to their effectiveness and the efficiency) (section III.3.3). Both traceability (in particular when further enhanced by internal traceability, where this is voluntarily put in place by operators), and cooperation between operators and MS CAs (including the exchange of helpful advice and good practices) are two key factors that improve the effectiveness (and efficiency) of withdrawals/recalls. Both of these factors have greatly improved over the last decade as a result of the GFL. The findings indicate that the combined effect of these requirements has brought an **increased harmonisation in the way withdrawals and recalls are performed compared to the situation prior to the GFL**. In terms of effectiveness, the speed of reaction has greatly improved. During the 1999 dioxin crisis, it took several weeks to get traceability information both upstream and downstream the supply chain; now it is possible to get information to trace the products (one step up - one step down) in hours and this enables the effective (speedier; more targeted) conduct of any subsequent inspections by CAs and more effective (and efficient actions) by operators and authorities.	Several shortcomings have been identified: • The **variable level of implementation of withdrawals/recalls between MS**, including in terms of determining the course of action to be taken in similar cases, cooperation between authorities and operators, and informing consumers/transparency. • This is also due to **inherent difficulties to determine feed/food safety**, with regards to: o Articles 14.7/9 and 15.4/6 (food/feed compliant with EU/MS legal provisions deemed to be safe). o Articles 14.8 and 15.5 (food/feed suspected to be 'unsafe' despite legal compliance). o In interpreting the concept of non-compliance to legislation versus assessing safety for human health, it is difficult for authorities to establish a clear balance when no objective/science-based criteria exist, e.g. when 'unsafe' is established on the basis of Article 14.2(b) i.e. 'unfit for human consumption' or current legislation is not harmonised (e.g. contaminants).
Risk analysis (Article 6)	**The risk analysis provisions have largely been effectively implemented and results have been effectively delivered** (section III.4). The separation of risk assessment from risk management was effectively implemented at both MS	Problems relate to the complexity of the risk analysis process, the implementation of other secondary legislation and/or incomplete harmonisation, rather than

	Role and contribution	Weaknesses/gaps/constraints (a)
	level (including, in some MS, the establishment of independent scientific bodies), and at EU level with the creation of EFSA, as an autonomous agency to carry out risk assessment, separated from the risk management function of the Commission. The risk analysis process, including consideration of other legitimate factors, has had a substantial positive impact on promoting the protection of consumer health: • At EU level, the **centralisation of risk assessment at EFSA, as well as risk management, have generally contributed to more proportionate, effective measures**, both in terms of the protection of human health/life and allowing free movement within the internal market and innovation. The advancement of knowledge and tools to improve the scientific basis of risk assessment, *inter alia* through the synergies created between the EU and national scientific capabilities and resources, is considered a key factor for ensuring more proportionate and effective, fit for purpose, risk management measures (as well as efficiency gains). • **Where national and EU measures on feed/food have been adopted on the basis of a risk analysis, positive outcomes have been achieved and measures have largely been effective and proportionate**. Positive examples of a harmonised risk based approach at EU level include all areas where the risk analysis process has been applied, especially where harmonisation is more complete. This includes the management of biological, chemical and physical risks, as well as additional procedures for regulated products (e.g. the authorisation procedures for food improvement agents; the setting of migration limits in food contact material (plastics); and the harmonisation of maximum residue levels (MRLs) of pesticides in food/feed). It is noted that the **positive impacts of Article 6 as such cannot be isolated from other relevant concurrent developments**, in particular the establishment of EFSA and the increased level of harmonisation in EU feed/food law. This continues to be a dynamic process, particularly at MS level (e.g. continuous restructuring/ reorganisation of relevant authorities/bodies; in some MS plans to establish risk assessment bodies currently being considered).	the legal provisions of the GFL: • Article 6, and the creation of EFSA, have led to scientifically more sound, yet more **complex authorisation procedures**. Moreover, these are running concurrently during relatively short time periods. This makes it difficult to cope with in terms of procedures for EFSA. • Complexity of risk management, in particular **consideration of other legitimate factors which inevitably requires a case by case approach**, leads to a lack of a harmonised implementation. This also creates a perception amongst stakeholders of lack of transparency, whereby the validity of the final decision is often questioned. For example, the shortcomings raised by the industry relate mainly to a perception of insufficient transparency/ communication of the role/weight of 'other legitimate' factors versus scientific assessment in the final risk management decision.
Transparency: public information in case of risk (Article 10)	The **process of informing the public that a food/feed may present a risk has improved over time**, in particular taking into account lessons learnt from poor communication and its impact during previous crises (e.g. dioxin, E.coli, etc.). Authorities tend to inform the general public in an order of priority that is generally defined and is proportionate to the level of the potential food/feed safety risk, and the type of information provided (in the case of recalls) is generally adequate/appropriate. This has had a positive impact in more effectively managing food and feed emergencies.	Despite progress, national differences are persisting and considerable. Authorities highlight that there are no fixed rules on the best approach to take, particularly in balancing the need to provide additional information versus confidentiality requirements, which also depends on the circumstances and the case (i.e. trigger point; food safety issue). The RASFF study also highlighted persisting shortcomings/gaps remain, including different understanding and implementation of the rules by MS CAs on what type of information should be provided and how to address professional secrecy, particularly when additional information may play an important role to address public health risks.

(a) It is noted that in all cases, the **overall assessment of effectiveness** of the GFL and contribution/role of the individual provisions **is positive**. Nonetheless, the problems or shortcomings that were identified in certain areas highlight factors that hinder the full achievement of the GFL core objectives.

Source: Agra CEAS Consulting, based on study findings

IV.3 Efficiency

Efficiency*[315]*. *The extent to which the costs involved from the application of the GFL (including the costs generated by the application of its fundamental definitions, principles and requirements in related specific pieces of food law) have been justified given the effects achieved. Actions to reduce regulatory burden, potential alternative policy instruments or mechanisms that could improve cost-effectiveness are also assessed.*

The GFL as a regulatory framework has aimed to achieve a high level of consumer protection whilst ensuring the effective functioning of the internal market. The analysis of its effectiveness concludes that the GFL has largely delivered on both objectives (section IV.2). Recognising that ultimately the GFL has largely achieved the outcome for which it was designed, this section focusses on the costs at which these outcomes have been delivered. The aim is to identify whether there are areas in which efficiency can be improved. It is noted that the **potential for reduction of regulatory burden is bound by the wider objective of the GFL to ensure a high level of consumer protection** (i.e. any potential reduction cannot risk undermining this objective).

Overall, the findings indicate that the **legislative framework introduced by the GFL has largely facilitated the implementation and enforcement of rules across the EU, consistently allocated responsibilities among operators along the chain, and allowed simplification**. All this has implied a reduction in administrative costs and burden, and therefore an increase in efficiency, compared to what could be achieved at national and/or regional levels or at international level (Codex, OIE). Where problems/shortcomings in terms of efficiency occur in practice these stem from: a) differences in implementation/enforcement between MS; b) specific provisions in other secondary legislation; and c) lack of harmonisation. In all cases, **further investigation of the identified efficiency problems/shortcomings have not revealed any link to systemic gaps or failures in the GFL principles and general requirements** *per se*. This is in line with our findings on the effectiveness of the various provisions of the GFL, as also implemented in other secondary legislation (section IV.2, **Table 11**).

In particular, the analysis of the costs and burden of the GFL (section III.9)[316] has demonstrated that **all of the core GFL requirements for business operators** (as laid down in Articles 14, 15, 17, 18, 19 and 20) **have entailed a fair and proportionate burden**. The findings indicate that the **rules laid down in Articles 17 and 18 have ensured an efficient (fair and clear) distribution of responsibilities** amongst feed/food business operators along the 'farm to table' supply chain, as well as between feed/food business operators and MS CAs. The analysis of the GFL requirements on traceability (Article 18) and operators' primary responsibilities (Article 17) has concluded that the **benefits conferred by the relevant GFL provisions outweigh the costs of setting up and operating the required systems**. In particular:

[315] Efficiency is a cross-cutting issue which draws on the analysis undertaken under a number of relevant EQs. A range of indicators has been used to assess the efficiency of the GFL provisions throughout the analysis of the main findings for the different EQs. As already indicated, effectiveness and efficiency are cross-cutting themes, underpinned by the same determinant factors; thus, the achievement of effective outcomes is often associated with efficiency gains.

[316] The challenges and caveats for conducting a full quantitative analysis of costs and burden (as well as benefits) of EU food law (i.e. the GFL and other secondary legislation based on the GFL) in the context of the present study are outlined in section II.3.2.

- In terms of the costs, the study has found that the **level of prescriptiveness, the combination of the legal requirements with self-regulation, and adaptability to national markets and cultures have acted as important mitigating factors that allowed an efficient, fit for purpose implementation**, tailored more closely to the specific operational, market and cultural needs of individual business operators within an extremely diverse EU feed and food supply chain. A particular strength of the GFL in this respect has been the inherent adaptability conferred by laying down principles and general requirements rather than prescriptive rules. This has allowed an efficient response to address the diversity of the chain, which encompasses a range of product sectors, operations along the chain (from production of raw materials for the feed and farming sectors, to farming, processing, distribution storage and logistics to retailing, catering and hospitality sectors), MS structures and cultures, and markets (from local to international).

- In terms of the effects, the costs and burden of complying with the core provisions of the GFL is justified in view of the achieved outcomes. A key benefit is the **reduction in the costs of risk/crisis management**, which *inter alia* can be attributed to the enhanced and harmonised traceability system in place. For example, although the costs of recalls/withdrawals are not comparable before and after the GFL or between different incidents, the cost of the dioxin crisis back in the late 1990s was estimated at nearly €1 billion, while the cost of the dioxin contamination in Ireland in 2008 was estimated at €200 million and of the aflatoxin crisis in 2012 was estimated at €100 million [317].

Furthermore, the **implementation of the risk analysis provisions of Article 6 has also resulted in important efficiency gains**, in terms of:

(a) Cost savings from the central approach followed at EFSA. For authorities, this has reduced the need for national risk assessments, particularly in smaller MS that cannot afford to invest in the required scientific capacity. For businesses, the GFL principles applying harmonised risk analysis procedures are acknowledged to have had a positive impact in supporting innovation in the single market context.
(b) The benefits of pooling the scientific resources involved in EU and national assessment bodies. The establishment of national risk assessment bodies, in parallel with EFSA, which has responded to the continuing need for national risk assessments, has generated efficiency gains from access to a larger, complementary pool of EU and national scientific expertise. The creation of these national structures strengthened the scientific dialogue with all EU MS, thus ensuring common scientific views across the EU. Nonetheless, a constraint to the cumulative availability of scientific capacity across the Union has been the increasing budgetary pressures over the last years on the funding available to national agencies, which constrains their resources and their ability to contribute to EFSA work.

Despite the generally positive assessment of the above GFL provisions, certain areas of concern were identified.

The **burden** for operators from the implementation of the primary responsibility obligation (Article 17.1) and placing safe feed/food on the market (Articles 14/15) **of the GFL is**

[317] These figures are not directly comparable. All figures are expressed in nominal terms.

intertwined with the impact of additional requirements posed by other secondary legislation and differential implementation by MS CAs[318].

In terms of implementation at MS CA level, the **non-uniform understanding and practical approach between MS CAs**, despite the existing EU guidelines, does not result in a level playing field across the EU. Cases where this occurs, according to operators, include the risk-based approach for the performance of official inspections, data collection activities, and lack of understanding/technical knowledge on the purpose of the legal provisions and detailed requirements. For example, it was noted that the implementation of Articles 19 and 20 by MS CAs has not always contributed to fit for purpose or proportionate withdrawals and recalls, such as in the context of the interpretation of 'unfit for human consumption' (Article 14.2.b and 14.5), or where legal non-conformities (Article 14.7) not posing food safety risks are identified. Also, as it currently stands, MS CAs do not consistently take into account operators' own checks in their risk profiling and control plans; only in a minority of MS, control authorities adopt such an approach. Nonetheless, to some extent, this also reflects differences in the reliability of operators' own checks, while it remains important for MS CAs to ensure that operators meet the primary responsibility requirement in every step of the food chain, in line with the rationale of Article 17.1.

These shortcomings are important because they determine the extent to which 'chain responsibility' is efficiently delivered, which depends on the allocation of responsibilities amongst operators, but also whether there remain any weak points in the system. For example, if operators incur different costs depending on the approach followed by national authorities, this does not allow a level playing field for all operators along the chain and across the EU.

Negative impacts on innovation and/or trade were also noted in the case of the **authorisation procedures** instituted under Article 6. In addition to the cost of preparing dossiers/providing data requirements, the length, unpredictability and uncertainty of the authorisation procedures is identified by operators as a key problem with regard to innovation. More generally, there were concerns that authorisation procedures are cumbersome and time-to-market delays take too long compared to other parts of the world, while the final outcome is uncertain in view of the consideration of other legitimate factors, thus creating uncertainty and acting as a disincentive for innovation. For smaller businesses, in particular, authorisation procedures required for health claims or novel foods or feed additives are considered too costly and difficult to navigate. However, these negative impacts are **not directly attributed to Article 6, but to the operational challenges of the current set up and workload in relation to the specific procedures** outlined in other secondary legislation, and/or incomplete harmonisation, in particular in the case of nutrition/health claims, enriched food[319].

The study has also found that the **regulatory costs and burden related to the implementation of EU food law, as a proportion of total operational costs and staff**

[318] Furthermore, as outlined in section III.9.1, a caveat constraining the calculation of burden stemming from regulatory requirements is the presence of private standards: private standards add to the regulatory costs and burden, while their distinction is not straightforward, as these are often intertwined with regulatory requirements.

[319] Some further cases were identified. In the case of food improvement agents, despite the positive impact of the streamlining of procedures, the assessment process is not complete (e.g. for food flavourings). In the feed sector, a further specific unintended effect is that as there are different provisions for the placing on the market of feed additives (which require pre-market approval) versus feed materials (which do not), while the classification of products under each category is not always straightforward and many borderline cases exist. Furthermore, the food sector has raised the issue of the requirement of multiple parallel or successive authorisation procedures for the same substances, e.g. for substances which are novel food.

numbers, generally tend to decline as the business size increases. Annual administrative costs including training, as a share of total operational costs, represent on average on average 8.5% for micro-enterprises, declining to 7.8% for small enterprises, 6.7% for medium enterprises and 5.1% for large enterprises (survey results, Q45) (*indicator 25.1b*). Similarly, the total number of FTEs involved, as a share of total staff numbers, represent on average 7.4% for micro-enterprises 6.9 % for small enterprises, declining to 6.1% for medium and large enterprises. The most burdensome Information Obligations (IOs) stemming from EU food law are those associated with: certification of products or processes; cooperation with audits and inspection by public authorities in the context of the GFL, e.g. Art 19 and 20; information labelling for third parties; cooperation with audits and inspection by public authorities in the context of other secondary legislation, e.g. Regulation (EC) 882/2004 (not linked to the GFL); and, application for individual authorisation or exemption.

Business size is not the only factor that determines the relative impact of regulatory costs and burden on overall production costs and competitiveness [320]. Nonetheless, all other factors being equal, in general terms the above findings suggest that the current regulatory environment generally creates a relative cost advantage for larger-scale operators, which makes it harder for smaller-scale operators to compete. The consultation with SME representatives and the SME Panel results (**Annex 4**) confirmed the above findings and highlighted **specific concerns relating to costs and burden for SMEs, particularly for small and micro-enterprises[321]**.

Although the majority of SME respondents generally provided positive feedback, nonetheless a large number of SME respondents, particularly micro/small companies, noted that: they find it hard to understand and interpret requirements set by EU food law (the GFL and other secondary legislation); it is not clear which authorities they should approach in order to obtain information; and/or, local/national authorities are often unwilling to cooperate with operators. Furthermore, interpretations of legal requirements in the MS are found to differ, creating additional costs and uncertainty for operators and a non-level playing field across the EU. In addition, it is not easy for companies to distinguish between the requirements posed by regulatory and non-regulatory (private) standards. About a third of respondents also reported that they hired an external consultant for the implementation of traceability, HACCP systems, labelling requirements, and the application of legal requirements and staff training more generally. The SME sector is concerned that over-regulation drives a trend for standardisation that is hindering craft production and product innovation/diversification on a small scale, such as in the case of traditional products.

Nonetheless, SMEs, particularly small and micro-enterprises, also noted that it is not the GFL but detailed requirements in other secondary legislation that contribute to the costs and burden. Furthermore, it is **important to consider the cumulative regulatory burden for SMEs of all EU legislation** (including for example employment laws and taxation) as this has increased considerably over time. The findings confirm that the share of administrative costs stemming from EU feed/food law varies considerably amongst businesses, from 0-5% to over 20% of total administrative costs [322].

[320] Other factors to consider include *inter alia* the range of products, the product sectors and markets in which a business operates, the processes involved, the type of risk, the number of products/suppliers and the level of standardisation.
[321] The food and drinks manufacturing sector is dominated in numbers by SMEs (section IV.1). The consultation has focussed particularly on the impact on micro and small enterprises.
[322] The share of administrative costs stemming from EU feed/food law varies from 0-5% of total administrative costs (for over a quarter of respondents) to over 20% (for a tenth of respondents). According to the results of the

In terms of the provision of **exemptions/simplified rules for micro-enterprises** from certain detailed legal requirements, notable best practice examples have been: the exemption provided in the hygiene package (to apply good manufacturing practices (GMPs) rather than fully-fledged HACCP systems), and the exemptions for labelling of non-prepacked food under the FIC Regulation. Beyond these, the study has found that, in practice, there are not many such exemptions in current food law, and the concept has not really worked in providing the intended benefits. It is noted, that the intention is to simplify while maintaining the same level of food safety. This conditionality is an important factor explaining to some extent the limited presence of exemptions: in the area of food safety, exemptions cannot easily get granted as there is a risk of jeopardising the main objective.

In view of the above findings, generally the study highlighted **some further potential for legislative simplification and reduction of regulatory costs and burden.** In particular:

- **In relation to the direct application of the GFL key obligations:** the identified potential was **mainly in terms of soft non-legislative interventions**. The aim is to improve clarity to ensure more harmonised application, such as through the provision of training and guidelines. Examples include those provisions of the GFL that lay down principles for MS implementation, but where there is evidence of persisting differences in approach and application between MS. This is in relation in particular to: the provision to lay down and apply penalties and other measures for infringements (Article 17.2); the public information provisions of Article 10; the provisions to introduce specific legislation in application of Article 8, particularly to address food fraud and adulteration; and, the provisions relating to risk analysis and the precautionary principle (Articles 6 and 7), in particular the consideration of 'other' legitimate factors.
- **Beyond the GFL**, the past decade has seen major reviews in most areas of EU feed/food law, enacting the principles and general requirements laid down in the GFL. Nonetheless, the study has found that, in view of the problems encountered by stakeholders and MS CAs in the areas where harmonisation is incomplete, **further simplification and harmonisation in some fields of other secondary legislation** has the potential to allow further reduction of regulatory costs and burden. Examples of other secondary legislation identified during the study where problems persist due to incomplete harmonisation include[323] [324]: food contact materials other than plastics; contaminants; salmonella in feed; lack of technical solution for GM food; novel foods; setting of minimum and maximum levels of vitamins/minerals added in food and in food supplements. Furthermore, SMEs have noted that having in place more simplified legislation and harmonised implementation, as well as a clear and **stable regulatory environment**, would generally help more than specific exemptions (although the positive impact of certain best practice exemptions was noted). These broader, rather than specific, improvements are considered to have substantial potential to exert a **positive impact in improving the predictability and certainty of legislation** and creating a more level playing field across the EU. It is noted that EU food law continues

SME Panel (**Annex 4**, Q13), this variation is not necessarily related to business size. However, as indicated above, the main survey results (**Annex 3**, Q45) indicate a tendency for regulatory/administrative costs to decline as business size increases.

[323] Despite the advanced level of harmonisation in most areas of EU feed/food law, some areas remain partly harmonised such as contaminants, food contact materials, and microbiological safety criteria. In the specific case of legislation laying down authorisation/ML setting procedures, harmonisation continues to be more advanced/ complete in certain sectors (e.g. food improvement agents, including additives, flavourings, enzymes; feed additives; undesirable substances in feed) and less in others (e.g. food contact materials; food contaminants).

[324] There are also problems from lack of review in some cases, e.g. setting of specific MRLs for pesticides (default levels exist under Regulation (EC) 396/2005).

to evolve dynamically with a number of revisions to legislation in this field recently concluded/currently ongoing, which aim *inter alia* to reduce the regulatory burden.

IV.4 Coherence

Coherence. *This term encompasses the extent to which the GFL has contributed to the internal coherence of EU food law, its external coherence with other MS interventions which have similar objectives, and its complementarity to other EU interventions/initiatives in the field of food policy such as the Common Agricultural Policy (CAP).*

Overall, the legislative framework introduced by **the GFL has largely contributed to improving the internal coherence of food safety rules across MS, as well as between the key areas of other secondary legislation, compared to the baseline**. The GFL has created a common framework for addressing food safety and has formalised the various concepts, provisions and procedures that existed in individual MS and/or sectors/fields of food law. It has instituted a chain approach, thus contributing to address/remove the shortcomings of previous fragmented, piecemeal approaches. It has established a more comprehensive approach to applying comitology in the food chain, through the replacement of all previous standing committees with a single Standing Committee (the Standing Committee PAFF)[325]. Creating this common ground has been an important contribution of the GFL, from providing common definitions, to defining common objectives, to laying down base principles and general requirements (risk analysis; precautionary principle; transparency; allocation of responsibilities to operators and authorities for ensuring food safety; traceability; and withdrawals/recalls). It is noted that the ongoing proposals for the new Animal Health Law and for the new Plant Health Law broadly follow the structure of the GFL[326].

In terns of the **external coherence** of the GFL with other MS interventions that have similar objectives, this is demonstrated by the creation of independent scientific bodies at MS level for risk assessment[327]. As discussed in section III.4, the GFL - in conjunction with parallel developments in MS that occurred at the time of its introduction, all of which were motivated by the need to respond to the safety crises of the late 1990s - has been a driving force for a major re-organisation of the food safety structures in the MS. The study has found that such national interventions have been coherent with the GFL objectives, i.e. they aimed to improve the governance structures in place to deliver food safety objectives. These

[325] Following the adoption of the GFL, the regulatory committees consisting of representatives of the Member States that have a key role in decision-making on food safety issues were reorganised within a single new structure, established by Article 58(1), the Standing Committee on the Food Chain and Animal Health; this Standing Committee replaced the Standing Veterinary Committee, the Standing Committee on Foodstuffs, the Standing Committee on Animal Nutrition and part of the Standing Committee on Plant Health (plant protection products and pesticides residues). This is now the Standing Committee on Plants, Animals, Food and Feed (PAFF). The PAFF it has a mandate that covers the entire food supply chain, from animal health issues on the farm to the product on the consumer's table. It is divided into fourteen different sections, of which the first section covers issues related to the GFL. It is a Committee in the meaning of Regulation (EU) No 182/2011 (the 'comitology' Regulation); comitology refers to a set of procedures through which EU countries control how the European Commission implements EU law.

[326] For example, the proposal for a single, comprehensive animal health law, which was adopted by the European Commission on 6 May 2013 aims a to replace the large number of legal acts relating to animal health and complicated rules currently in place. The current legislation relating to animal health would be streamlined into a single law. The proposal also clarified responsibilities for all stakeholders involved in this sector and for MS CAs and more flexibility to adjust rules to local circumstances.

[327] In examining external coherence aspects with other MS interventions that have similar objectives, the focus of the study has been on the creation at MS level of independent scientific bodies for risk analysis, which has been a key intervention of relevance to the GFL objectives identified in the context of this study.

national structures have largely worked in synergy, i.e. have been complementary, to the EU food safety structures established by the GFL (EFSA). On the other hand, beyond the GFL as such, some shortcomings persist with the application of the mutual recognition principle in partially harmonised areas, including food additives and food supplements[328].

The study has found that the EU food safety policy framework established by **the GFL and the Common Agricultural Policy (CAP) are complementary to one another[329].** By definition there is complementarity between the CAP and food safety policy objectives: although not mentioned explicitly in the CAP objectives[330], food safety is an essential attribute expected of food produced in the EU. The **food safety objectives of the GFL underpin the CAP objectives, by ensuring a safe and therefore viable supply of raw materials and food products**. The production of unsafe food would clearly not be compatible with the objectives of the CAP: for example, food safety and non safety scares have generated significant market disturbances in the past (some over a long period such as the BSE) which required financial intervention from the CAP. The **evolution of the CAP** objectives, measures and tools, which has continued with a series of reforms since the adoption of the GFL, aiming to a shift from market support to market orientation, **has increased the interconnection of the EU agricultural policy and food safety goals**. Due to the evolution of the CAP which is and will be more market oriented in future, most of the traditional legal instruments available for intervention to stabilise prices are no longer available and as regards, for instance, support to recover consumer confidence following food safety and non-safety related scares, are all subject to financial discipline within the CAP budget. This has increased further the relevance and contribution of food safety (and non safety) objectives. The **underlying link to food safety has become an important dimension of the evolved CAP**: food safety is more explicitly included in the guiding principles of the CAP strategy to 2020 (COM(2010) 672 final) and the GFL is specifically referenced in the CAP financial instrument (Regulation (EU) No 1306/2013). Despite the complementarity in objectives, the CAP tools have been developed and are designed to address primarily agricultural policy objectives. For example, the cross-compliance requirements laid down in the CAP, although establishing a link between food safety and CAP objectives[331], apply only to primary producers that receive direct payments.

Other areas of coherence/complementarity and consideration of other Union interventions/initiatives that touch on the field of food policy, including environmental, trade, and growth and competitiveness aspects are discussed in the context of other objectives and their relevance for the GFL (see sections III.8.3 and IV.1, respectively). **Coherence is generally found to be ensured during the full policy cycle**, through: regular dialogue with all relevant stakeholders including public consultation; as well as inter-services consultation of the relevant CAs. Both of these aspects have improved over the

[328] Other interventions of relevance relate to the application of the principle of mutual recognition (Regulation (EC) No 764/2008), the review of which is currently on-going for the European Commission. The first Report of the Commission on the application of the principle by MS (COM(2012) 292 final) identified some shortcomings, including with national measures taken by MS in the field of food law, such as in the partially harmonised areas of food additives and food supplements.

[329] In examining complementarity aspects with other Union policies, the focus of the study has been on the Common Agricultural Policy (CAP).

[330] The objectives of the CAP, as laid down in Article 39 of the Treaty on the Functioning of the European Union, are to increase agricultural productivity, ensure a fair standard of living for the agricultural community, to stabilise markets, ensure availability of supplies and reasonable prices for consumers.

[331] Regulation (EU) No 1306/2013 on the financing, management and monitoring of the CAP explicitly references the GFL under Statutory Management Requirement (SMR) number 4 in relation to cross-compliance rules (Article 93 and Annex II), and strict penalties are also foreseen in the case of non-compliance (Art. 97). The GFL provisions specifically mentioned in SMR4 include Articles 14 and 15 which do not permit the placing on the market of unsafe food or feed and Articles 17, 18, 19 and 20 on responsibilities of operators and traceability requirements.

evaluation period at both EU and MS level, and the GFL has partly contributed to this improvement. However, at MS level, there remain considerable differences in approaches and cultures amongst MS.

IV.5 European added value

European added value[332]. *This term refers to the benefits accruing from establishing the GFL at the EU level rather than having Member States operating national or regional policies. The relationship to international obligations (Codex, OIE) is also important here.*

Overall, as demonstrated throughout this study, the legislative framework introduced by the GFL has provided important benefits, compared to what could be achieved in the absence of a common framework by MS at national and/or regional levels or at international level (Codex, OIE). The analysis of the performance of the core GFL provisions, particularly in the areas covered by the case studies, demonstrates that **EU measures and actions are particularly relevant to ensure both a harmonised and a more global approach across the EU**. Feed/food law/measures have the greatest effect when taken at EU level, also in terms of improving consistency/coherence in implementation and facilitating enforcement. This ultimately leads to a more uniform level of consumer protection across the EU and contributes to creating a level playing field.

In particular, **the GFL has provided the basis for a single, uniform framework and principles to develop EU rules in other secondary legislation on feed/food safety**, thereby also improving internal coherence of feed/food law. Furthermore, it has **raised the overall level of food safety standards applying across the EU**, including the scientific and technical soundness of these standards. It has **improved external coherence** with interventions at MS level that have similar objectives, such as the creation of independent scientific bodies for risk assessment. The GFL has **facilitated enforcement of rules across the EU and allowed simplification**, thus leading to a reduction in administrative costs and burden. The GFL has also brought important **advantages in terms of international trade**, in that it allowed both EU and third country food/feed supply chains a unique reference to food safety standards applying across the EU, provided improved EU product safety recognition worldwide, and contributed to an improved quality perception for EU products in third country markets. Furthermore, at a conceptual level, the global and modern approach of the GFL, which ensures a 'farm to fork' application while allowing adaptability, has contributed to projecting a high standard model of food safety recognised around the world and this contributes to the influence of the EU model, as demonstrated by recent/ongoing reviews of food law in third country trading partners and in the literature.

Furthermore, these key benefits of the GFL pertain to the broader range of stakeholders affected by the GFL, as follows:

- From a **consumers' perspective**, a key added/value benefit of the GFL is that it has **improved the harmonisation of food safety standards and the protection of consumer health and interests across the EU**. This has contributed to fostering a 'race to the top' approach in food safety standards, not just at EU level but also in the international context. Other secondary legislation introduced following the GFL -

[332] The analysis of the European added value is based on an overarching assessment of the findings, including the indicators that were used to address EQ2. ***EQ2: What is the European added value of the EU food safety regulatory framework established by the GFL (compared to what could be achieved by MS at national and/or regional levels as well as international (Codex, OIE) level)?***

including e.g. food labelling (the FIC Regulation), authorisation procedures, risk management measures - demonstrates the change in the approach brought about by the application of the GFL base principles and provisions, with the protection of health and consumers' interest put at the heart of the policy objectives. The focus on consumer interest is considered to be one of the key improvements introduced by the GFL in the field of consumer protection.

- From the **perspective of MS CAs**, the GFL has brought a relatively pioneering application of a **global safety approach to the food chain at national level**. This was a challenge given that there were separate bodies covering food safety issues in most MS. For example, almost all MS previously had food control and veterinary services separately; this had been the case for 80 years or so in most MS.

- From a **supply chain perspective**, as discussed in the baseline, in 2002 there was an urgent need for a framework, for instance setting a harmonised definition of food. The GFL was a very positive piece of legislation for the EU feed and food sector. The fact that legislation switched from Directives to Regulations has also improved the harmonisation in implementation/enforcement, thus contributing to the more general goal of ensuring the effective functioning of the internal market. The harmonisation of requirements has been particularly beneficial for companies located in multiple MS. Nonetheless, the full reaping of the benefits is to some extent hampered by discrepancies/ inconsistencies in implementation in the different MS, and lack of full harmonisation in some fields.

The benefits of the EU approach in implementing food/feed law, in terms of enabling a more harmonised level of consumer protection and the functioning of the internal market, were more generally highlighted in the context of effectiveness of the various GFL provisions (section IV.2, **Table 11**). These include *inter alia* the following examples of concrete benefits demonstrating the EU added value of the various GFL provisions:

- The **traceability provisions (Article 18) have played a key role in achieving the generalised application of the requirement to cover the full EU feed/food supply chain**; its impact has been not only quantitative (from partial to complete implementation of 'one step back-one step forward' traceability by all operators), but also qualitative (from fragmented to full application along the chain), in line with the underlying "farm to fork" vision on food safety. Given the extent of cross-border trade in the internal market, only EU-level traceability can ensure the effective tracing of food/feed in the EU. Various incidents that have occurred in the last ten years demonstrate that the current traceability set up has worked to rapidly contain a food incident, whether involving food safety risks e.g. E-coli, or fraudulent practices e.g. the recent horsemeat scandal.
- The **risk analysis principles (Article 6) have enabled a harmonised risk based approach at EU level in the management of biological, chemical and physical risks, including additional procedures for regulated products**, especially where harmonisation is more complete. Greater harmonisation from following an EU approach in these areas has enabled both an enhanced consumer protection and a more level playing field for business (although in some of the above cases the scope for completing the harmonisation process was also highlighted). For example:
    - Risk analysis has contributed to improved management of biological risks, a major source of food-borne diseases in humans, including notably salmonella in food. More recently, following the 2011 E.coli case, food safety microbiological criteria for STEC in sprouts and rules for sampling and testing by food producers have been established.

- In terms of additional procedures for regulated products, the positive impact of risk analysis includes: the establishment of common authorisation procedures for food improvement agents; the reassessment of food additives (establishment of positive lists and conditions of use); the "cleaning up" of previously unjustified health claims; the setting of migration limits in food contact material (plastics); and, in-depth assessments of pesticides and the harmonisation of maximum residue levels (MRLs) of pesticides in food/feed. For example, the positive impact of harmonised risk analysis procedures in supporting trade and innovation in the single market context has largely been achieved with the legislative package on food improvement agents that was adopted in 2008, streamlining rules and procedures applying to food additives, food enzymes and flavourings.

The **benefits of harmonisation in enabling the functioning of the internal market and innovation can be demonstrated by the problems from a sub-EU-level approach** in the case **in fields of feed/food law that are not yet harmonised or are only partially harmonised**. Such problems were highlighted in particular in the context of the risk analysis case study. For example: in the case of enriched food, actual MLs of vitamins, minerals and other substances are not yet set; in the case of GMOs, the lack of a 'technical solution' for food. This contrasts with the positive impacts where harmonisation is more advanced, such as in the case of food improvement agents (although the assessment is not yet complete e.g. food flavourings), or the existence of a technical solution for GM feed.

V. CONCLUSIONS

The overall conclusion of the evaluation [333] is that **the GFL** has made a **positive contribution to the EU legislative *acquis* of relevance to the food and feed chain.** The **positive impacts** of the GFL **are widely acknowledged by all consulted parties,** from consumers to business operators, to MS Competent Authorities (CAs), and the FCEC Food Law Expert Advisory Panel members. Given the baseline situation at the time of the introduction of the GFL in the aftermath of BSE and other food scares in the 1990s which had shaken consumer trust and confidence in the EU food chain (as underlined in the White Paper on Food Safety - COM(1999) 719 final), there is **consensus that, as a framework, the GFL has established a new era in EU feed/food policy design and implementation**.

Taking into account the evolving context within which the GFL operates, this evaluation can conclude that **the original objectives of the GFL** i.e. the protection of consumer health and interests and the effective functioning of the internal market **continue to be the most relevant that the GFL needs to address, in that they correspond to current needs**. Safety and non-safety related food incidents that have occurred over the evaluation period (e.g. 2011 E. Coli outbreak; 2013 horsemeat scandal) have impacted consumer health and interests, affected consumer confidence and led to costs and losses for industry. The EU agricultural, food and drink sector remains crucial to the wider EU economy: it currently employs over 24 million people, more than 11% of the total EU workforce, with a turnover exceeding €3.5 trillion. Furthermore, the sector is relatively fragmented and dominated in numbers by SMEs (including micro-businesses). In terms of trade, the EU remains the leading food and drink producer worldwide, and the largest global trader and a net exporter of food and drinks. The value of internal trade in the EU market in this sector has increased by 72% over the past decade, driven by increased harmonisation.

These original objectives are adequate to address the current needs arising from key drivers and trends observed over the period since the GFL was adopted. In the context of the economic downturn that has affected Europe since 2008, and the need to ensure growth and competitiveness, **the GFL was generally found adequate to address innovation and competitiveness.** By improving harmonisation in EU food law, it has enhanced predictability and ease of implementation and has streamlined processes for companies selling products within the internal market. Examples include the use of the risk analysis principles laid down in Article 6 which have provided a harmonised system to address potential divergences in scientific opinions concerning health protection more objectively. In relation to **consuming healthier food/addressing the nutritional needs** of the general population, this aspect is currently embedded and adequately addressed in the GFL (although not explicitly stated), in the pursuit through the GFL of a high level of human health. This trend is addressed through requirements in other secondary legislation covering nutrition labelling, health and nutrition claims as well as scientific advice on nutrition issues.

[333] The GFL has been evaluated according to five key criteria (relevance, effectiveness, efficiency, coherence and European added value: section IV), on the basis of the collected evidence and analysis of findings as outlined in section III. This has been a complex and challenging exercise. The GFL provides a framework legislation which lays down common principles and general requirements that form the basis of more detailed rules and requirements in other secondary legislation, which were progressively introduced/revised since the GFL came into effect. There are further successive layers of implementation in terms of: implementing acts; guidelines (Commission/MS CA/private); and, final enforcement. Furthermore, the field of application of feed/food law (the GFL and other secondary legislation; as well as national legislation, where applicable) extends over a wide range of stakeholders involved in the 'farm to fork' supply chain, encompassing business operators, consumers and NGOs. This has implications and poses challenges in terms of assessing the relevance, effectiveness, efficiency, coherence and European added value of the GFL, with a view to identifying opportunities for simplification.

Similarly, the **challenges posed by increasing globalisation** are adequately addressed by the GFL: its provisions have contributed to the increasingly needed global cooperation between all players and have played a key role in promoting international food chain governance by laying down an internationally recognised high level of food safety standards, and a general commitment of adherence to international standards. An indicator of the positive impact of the GFL in the international context has been its role in Codex Alimentarius and the fact that certain trading partners are adopting/considering the adoption of similar legislation e.g. on traceability.

The analysis of **shortcomings** that were identified **in addressing the needs raised by some current drivers and trends** can conclude that these **are due to continuing failures and gaps with the completion and/or implementation of other secondary legislation and/or persisting national differences in areas that are not harmonised**. For example, negative impacts on **innovation** mainly stem from shortcomings identified with the implementation of authorisation procedures foreseen in other secondary legislation in partially/non-harmonised areas (e.g. enriched food, food contact materials other than plastics). In terms of **preventing/addressing fraudulent/deceptive practices**, the current regulatory framework and control system which extend beyond the GFL as such, have been criticized for not being sufficiently equipped to prevent, detect and sanction fraud. Finally, in relation to the emerging trend of **distance selling/e-commerce**, the identified shortcomings do not relate to the relevance of the GFL objectives or scope which covers all food operators, but rather to the understanding and interpretation of the GFL definitions.

In terms of effectiveness, the evaluation can conclude that the **combined (overarching) effect of the GFL provisions has for the most part achieved the core GFL objectives**. In particular, the GFL has, over the years, contributed to the **effective harmonisation of consumer protection across the EU**. The evidence available from all major incidents that have occurred over the past decade indicates that the core GFL provisions, such as traceability, withdrawals and recalls and their combined effects have played a major role in **effectively addressing food safety risks**, thereby raising the level of food safety in the Union. More recently, these provisions have also shown their effectiveness to address non-safety related incidents such as in the case of the horsemeat scandal. Furthermore, the explicit inclusion of the protection of consumers' interests in the general objectives of the GFL (Article 5.1) has brought a change in approach in EU food law, as demonstrated by the Regulation on Food Information to Consumers (the FIC Regulation), which puts consumer interests at the heart of the legislation. The GFL has also largely contributed to achieving the **free movement of food and feed in the internal market**, which as indicated above has grown substantially over the evaluation period.

The GFL has also played an important role in **improving the effectiveness of feed/food law implementation in the MS**, with the more general advantages brought about by the increased harmonisation demonstrated in the context of specific provisions. A best practice is in relation to risk analysis, where the GFL has enabled the achievement of a higher scientific standard throughout the EU. It has also contributed to more **effective implementation for operators**: by laying down principles and general requirements, the GFL has allowed its **adaptability to best fit operational contexts and needs**. In this context, **other tools (private standards, guidelines, codes of good practice)** have been effectively combined with the regulatory provisions, as observed for example in the context of the traceability and operator responsibilities.

Where **weaknesses** are identified, in practice these **mainly relate to differences in the implementation/application of the GFL provisions by MS, shortcomings with the**

implementation of other secondary legislation, and/or incomplete harmonisation in some fields. However, for the most part, these issues are **not linked to systemic problems with the GFL provisions.** In relation to the GFL as such, more systematic problems occur in relation to differences in the understanding and implementation, as well as some elements that are currently missing or not explicitly indicated, in its **scope and definitions (Articles 2 and 3)**: this has implications for the application of the GFL requirements/obligations in certain sectors, thus ensuring an integrated approach covering the entire agri-food chain (e.g. problems linked to whether importers and distance trading/e-commerce are covered).

In terms of the other GFL provisions, a number of tools/elements defined at MS level, that are essential to ensure harmonised and optimal implementation, are missing/incomplete and different approaches prevail in practice between MS – these include: variable national approaches to sanctions and liability; implementation of official controls by MS is not always risk-based; measures not always taken by MS and/or considerable differences in the approach and severity of measures are to address fraudulent and/or misleading practices (Article 8). In some cases, **inherent difficulties hinder harmonised implementation**, such as the **absence of objective/science-based criteria inevitably requires a case by case approach in practice**: e.g., when considering other legitimate factors in the risk management decisions or when determining the safety of feed/food that is 'unfit for human consumption'. Moreover, the current level of cooperation between MS CAs in all of the above areas remains rather limited/*ad hoc* and does not allow the systematic and sufficient exchange of good/best practices.

Furthermore, **considerable differences persist in the approach and level of transparency between MS** (although more harmonised compared to the baseline). This is an important shortcoming affecting consumer and business trust/confidence, as **it creates perceptions and undermines the recognition of the facts in relation to the effectiveness of feed/food law**.

In terms of efficiency, the **legislative framework introduced by the GFL has largely facilitated the implementation and enforcement of rules across the EU, consistently allocated responsibilities among operators along the chain, and allowed simplification**. In particular, the analysis of the GFL requirements on traceability (Article 17) and operators' primary responsibilities (Article 18) has concluded that the **benefits** conferred by the relevant GFL provisions **outweigh the costs** of setting up and operating the required systems. In terms of costs, the low level of prescriptiveness, the combination of the legal requirements with self-regulation, and adaptability to national markets and cultures have acted as **important mitigating factors** that **allowed an efficient, fit for purpose implementation**, tailored more closely to the specific operational, market and cultural needs of individual business operators within an extremely diverse EU feed and food supply chain. A key benefit of the core GFL provisions is the **reduction in the costs of risk/crisis management**, which *inter alia* can be attributed to the enhanced and harmonised traceability system in place. Similarly, the implementation of the risk analysis provisions of Article 6 has also resulted in important efficiency gains in terms of cost savings from the central approach followed at EFSA and the pooling the scientific resources involved in EU and national assessment bodies.

Where inefficiencies occur in practice these stem from the same constraints and shortcomings that hinder effectiveness, and the evaluation **has not revealed any link to systemic gaps or failures in the GFL principles and general requirements** *per se*. In particular, the burden for operators stemming from the GFL provisions is intertwined with the impact of additional requirements posed by other secondary legislation, such as in the

case of specific authorisation procedures outlined in other secondary legislation, due to increased complexity and/or incomplete harmonisation (e.g. in the case of nutrition/health claims, and enriched food). Also, differences in implementation by MS CAs (as highlighted above) do not allow a level playing field across the EU; these are often due to a non-uniform understanding and/or practical approach between MS CAs.

Regulatory costs and burden stemming from the implementation of EU food law vary considerably amongst businesses as a proportion of total operational costs and staff numbers, but generally tend to decline as a proportion as the business size increases. Although size is not the only determinant factor, all other factors being equal, findings suggest that the current regulatory environment generally creates a relative cost advantage for larger-scale businesses, which makes it harder for small and micro businesses to compete. For example, for smaller businesses, authorisation procedures required for health claims or novel foods are considered too costly and difficult to navigate. Furthermore, micro/small companies in particular noted that they find it hard to understand and interpret requirements set by EU food law, do not know which authorities to approach and find that authorities are often unwilling to cooperate. Nonetheless, SMEs, particularly small and micro-enterprises, noted that it is not the GFL but detailed requirements in other secondary legislation that contribute to the costs and burden, although it is important to consider **the cumulative regulatory burden for SMEs of all EU legislation**. The concept of providing exemptions/simplified rules for micro-enterprises has not really worked in providing the intended benefits, except in few best practice examples (notably, the exemption provided in the hygiene package to apply good manufacturing practices (GMPs) rather than fully-fledged HACCP systems and the exemptions for labelling of non-prepacked food under the FIC Regulation)[334].

In view of the above findings, the study highlighted **some further potential for simplification and reduction of regulatory costs and burden**, bearing in mind that this is bound by the wider objective of the GFL to ensure a high level of consumer protection (i.e. any potential reduction cannot risk undermining this objective). In particular:

- In relation to the **direct application of the GFL key obligations**, the identified potential was mainly in terms of **soft non-legislative interventions**.
- Beyond the GFL, **further simplification and harmonisation in some fields of other secondary legislation** has the potential to allow further reduction of regulatory costs and burden, mainly in the following areas: food contact materials other than plastics; contaminants; salmonella in feed; lack of technical solution for GM food; novel foods; national measures providing additional mandatory particulars); setting of minimum and maximum levels of vitamins/minerals added in food and in food supplements (**Table 12**). Furthermore, SMEs have noted that having in place more simplified legislation and harmonised implementation, as well as a clear and stable regulatory environment, would generally help more than specific exemptions (although the positive impact of the above best practice exemptions was noted).

[334] As indicated in section III.9.3, in the case of food/feed safety, no exceptions can be granted because the objective pursued would be jeopardised. This is in line with the holistic 'systems' approach pursued by the GFL, aiming to cover the entire supply chain, as any weak elements would risk undermining the strength of the chain.

Table 12: Areas of food/feed law where problems were identified due to incomplete harmonisation *(a)*

	Main issues identified (lack of harmonisation)
Regulation (EC) 1925/2006	**Enriched food**: MLs (minimum and maximum levels) of vitamins/minerals and certain other substances added in food and in food supplements are not yet set.
Regulation (EC) 1331/2008	**Food improvement agents**: assessment incomplete, e.g. for food flavourings (Regulation (EU) 872/2012)
food contact materials	**Food contact materials**: rules on all food contact materials, other than plastics, are not harmonised. MS can fix different MLs/tolerance levels.
contaminants	**Contaminants**: rules in several areas are not yet harmonised. MS can fix different MLs/tolerance levels. **Microbiological contamination:** rules on salmonella in feed are not harmonised. MS can fix different MLs/tolerance levels.
Regulation (EC) 1924/2006	**Health/nutrition claims**: Rules on health claims on botanicals not yet established. Absence of nutrient profiles.
GM food	**GM food**: lack of 'technical solution' for food, such as that existing for methods of sampling and analysis for the official control of feed as regards low level presence of GM material in feed (Regulation (EC) 619/2011)

(a) The above issues were systematically raised in the course of the evaluation of the GFL, and are not an exhaustive list of all areas of EU feed/food law where the potential may exist for simplification and/or reduction in administrative burden from further harmonisation.

Source: Agra CEAS Consulting, based on study findings

The **EU added value** of the GFL has been demonstrated throughout the evaluation. In particular, the analysis of the performance of the core GFL provisions demonstrates that **EU measures and actions are particularly relevant to ensure both a harmonised and a more global approach across the EU**. Feed/food law/measures have the greatest effect when taken at EU level, also in terms of improving consistency/coherence in implementation and facilitating enforcement. This ultimately leads to a more uniform level of consumer protection across the EU and contributes to creating a level playing field.

The GFL has also fostered **coherence**, both **within the body of EU law** of relevance to the food chain and **across MS**, *inter alia*, through the introduction of definitions, overarching guiding principles and base requirements, on which other secondary legislation is built. Complementarity with the Common Agricultural Policy (CAP) is inherent, as the CAP objectives include food safety policy goals; the food safety focus has gained momentum with the evolution of the CAP from price support towards increased market orientation.

Overall, the evaluation can conclude that **the GFL is fit for purpose**, in terms of broadly fulfilling all five criteria on the basis of which it has been assessed (relevance; effectiveness; efficiency; EU added value; and coherence). This is **in line with the vision and expectations outlined in the White Paper on Food Safety**. The observed fitness of the GFL to serve the purpose for which it has been set is a particularly important achievement given the difficulties of having a one size fits all framework legislation in this policy area. Considering the challenges of the diverse interests that the GFL aims to address, it has generally succeeded in providing a fit to purpose solution for the range of issues, sectors and affected stakeholders.

Nonetheless, the GFL for the most part provides a framework of general principles and requirements on which further implementing provisions through other secondary legislation are based (with the exception of certain directly applicable provisions of the GFL e.g. on traceability and withdrawals/recalls). A common finding of the evaluation, which runs across the assessment of the various provisions and all five criteria, is that **gaps/shortcomings arise mainly from interpretation, implementation and enforcement**, at MS level. This

confirms previous key findings of the Fitness Check on the food chain (Commission Staff Working Document, SWD(2013) 516 final) that many problems in the wider body of food legislation stem from interpretation and implementation. These **shortcomings have a bearing on the extent to which the integrated approach pursued by the GFL in terms of ensuring 'chain responsibility' can be effectively and efficiently delivered**, which depends on whether there remain any weak points in the system. In this respect, the feed/food chain can be seen as any other system approach, which can only be as strong as its weakest part/link.

Furthermore, the analysis of the collected evidence corroborates that, **where problems systematically occur, these are identified mostly at the level of other secondary legislation rather than the GFL *per se***. Such problems are particularly identified in areas where harmonisation has not been achieved or is not complete. In all cases, further investigation of the identified problems and shortcomings have **not revealed any link to systemic gaps or failures in the GFL principles and general requirements**. On the contrary, an overarching conclusion of the evaluation is that the **general rather than specific design of the GFL**, in the form of defining broader principles and requirements rather than specific rules, is its **strength**, not only in the current context, but also **making it '*future-proof*' in an evolving global context**.

Thus, generally, the study highlighted **relatively limited further potential for simplification and reduction of regulatory costs/burden** in relation to the **key obligations** stemming from the GFL. As noted by small and micro-enterprises in particular, it is **important to consider the cumulative regulatory burden of all EU legislation** (including for example employment laws and taxation) as this has increased considerably over time. It is noted that EU food law continues to evolve dynamically with a number of revisions to other secondary legislation recently concluded/currently ongoing, which aim *inter alia* to reduce the regulatory burden. This includes ongoing proposals for the new Animal Health Law, and for the new Plant Health Law, both of which follow the structure of GFL.

VI. RECOMMENDATIONS

The broader message from the conclusions of the evaluation needs to be borne in mind. **The GFL is generally fit for purpose, but problems arise from interpretation/ implementation/enforcement (both within the GFL and other secondary legislation) and/or incomplete harmonisation in other secondary legislation**.

Nevertheless, the analysis of the state of play of the implementation of the EU feed/food law legislative framework (core principles/requirements and other secondary legislation) according to the five key evaluation criteria (relevance; effectiveness; efficiency; coherence; added value) highlights certain issues – not necessarily related to the GFL itself. The recommendations below are drawn with a view, in particular, to the identified **potential for simplification and/or reduction in administrative burden**[335].

The recommendations below distinguish between the GFL and other secondary legislation.

In terms of the **GFL**, the investigation of the identified problems and shortcomings has not revealed systemic gaps or failures in the GFL principles and general requirements *per se*. Nonetheless, several areas were identified where differences in understanding and/or interpretation of some GFL provisions prevail. Furthermore, the analysis has shown that these differences can have important implications for the effectiveness and efficiency of implementation, in terms of whether the intended integrated approach to ensure 'chain responsibility' and a level playing field is actually delivered. Recommendations are provided mainly in the form of soft, non-legislative interventions, with a view to addressing these differences, thus aiming to more harmonised implementation/enforcement. In particular:

- **Definitions (Articles 2 and 3)**: generally, the GFL does not have all definitions subsequently developed and contained in other secondary legislation and the available evidence indicates that this poses problems in interpretation/differential implementation by authorities depending on which legal basis they consider as applicable. It is therefore recommended to:
  - Provide a **consolidated list of definitions**, including those developed subsequent to the GFL in other secondary legislation.
  - Furthermore, the list could include a **glossary of definitions**, thus clarifying certain gaps identified in interpretation by MS authorities and operators of certain definitions (e.g. operator), or missing definitions (e.g. e-commerce) (**Table 3**).
- **Risk analysis and precautionary principle (PP) (Articles 6 and 7)**: several problems were identified. These are linked to the complexity of process/field of application and the diversity of issues to which these principles apply, which makes it difficult to provide an 'one fits all' solution. It is therefore recommended to:
  - Develop **guidelines** for the application of Articles 6 and 7. These could provide, by way of illustration, practical examples of application, clarifying the use of other legitimate factors, the process of reaching the final risk management decision, and the procedure/conditions for using the precautionary principle (in particular clarifying the concept of 'scientific uncertainty').
  - **Review the actual application of the precautionary principle in the field of food law**. Given the relatively considerable misunderstanding surrounding the application of this principle, including a lack of clarity on the cases where it has

[335] It is noted that the potential for reduction of regulatory burden is bound by the wider objective of the GFL to ensure a high level of consumer protection (i.e. any potential reduction cannot risk undermining this objective).

actually been applied, an in-depth review of the experience gained to date and lessons learnt from both EU and national implementation, is recommended.
    - **Provide general principles of risk communication.** Principles of risk communication are missing from the GFL (e.g. Article 6), although a general definition is provided in Article 3.13. There is currently sometimes conflicting communication from European vs. national risk assessors; there are also discrepancies between EFSA, the Commission (COM) and national level communications. It is recommended to lay down general principles, with a view to ensuring that the communication issued from different sources is better aligned.
- **Feed/food safety requirements (Articles 14/15), allocation of responsibilities (Article 17) and withdrawals/recalls (Articles 19/20)**. Different levels of implementation by national authorities between MS or even within MS (at regional/local level), are identified as a shortcoming in the application of all these provisions. MS CAs do not consistently take into account operators' own checks in their risk profiling and control plans. Shortcomings are also often attributed to interpretation of the rules and implementation at local level, e.g. of official controls by inspectors rather than design of the official control plans. With a view to addressing these shortcomings it is recommended to:
    - **Provide training** (e.g. through BTSF), including also simulation exercises (e.g. in the context of withdrawals/recalls).
    - **Consider an update of the existing guidelines**. Although the Commission guidance document (January 2010) has been widely used by both MS CAs and the industry, the latter have been sceptical of its usefulness in that it is not sufficiently detailed or practical. It was highlighted that, in some cases, the lack of detail/practical reference, such as through concrete cases and examples, can lead to further potential misinterpretation or contradiction with the interpretation of the legal provisions by the authorities, and can therefore be counter-productive. Both operators and authorities therefore request more specific, practical guidance to serve as a reference point for more uniform implementation by authorities. For example, operators with activities in different MS have indicated that national authorities can reach different decisions using the same food safety criteria, such as e.g. in taking into account the analytical results showing that MRLs have been exceeded, or assessing whether foods are 'unfit for human consumption'.
- **Transparency provisions**: some differences in approach were identified between national authorities, to some extent due to cultural differences. With a view to encouraging more uninform implementation, it is recommended to develop **guidelines** for Article 9 (public consultation) and, in particular, for Article 10 (public information).

Beyond the GFL, it is noted that the evaluation covered other secondary legislation only to the extent that problems identified therein were due to the GFL provisions as such. Nonetheless, the study has identified certain areas where the potential for further simplification and/or reduction in administrative burden exists in other secondary legislation, as follows[336]:

- **Review the application of exemptions/simplified rules for micro-enterprises** from certain detailed legal requirements. It is noted again that any simplification in this policy area must not undermine the objective of pursuing a high level of protection of human health and interests. Notable best practice examples of simplification, in line

[336] The recommendations provided here should be read in the context of the present study scope (the evaluation of the GFL), and are not an exhaustive list of all areas of EU feed/food law where the potential for simplification and/or reduction in administrative burden may exist.

with this objectives, have been the exemptions provided in the hygiene package (to apply good manufacturing practices (GMPs) rather than fully-fledged HACCP systems) and in the FIC Regulation (exemptions for labelling of non-prepacked food). Beyond this, in practice, there are not many such exemptions in current legislation, and the current application of the concept has not really worked in providing the intended benefits. In common with evaluations of law in other sectors, micro and small enterprises reiterate their call for EU legislation more generally to be simplified. They do not necessarily require exemptions, simplification tailored to their specificities and needs, whether concerning obligations at EU level or at national/local level would be sufficient.

- **Completing the harmonisation process in other secondary legislation** is considered to have the potential to allow a reduction of regulatory costs and burden, in view of the problems encountered by both stakeholders and MS CAs in the areas where harmonisation is incomplete. Problems related to incomplete harmonisation were repeatedly highlighted, for example, in the case of the additional authorisation procedures laid down in specific secondary legislation. Examples include: food contact materials other than plastics; contaminants; salmonella in feed; lack of technical solution for GM food; enriched food; health and nutrition claims; food improvement agents (**Table 12**). These broader, rather than specific, improvements are considered to have considerable potential to exert a positive impact in improving the predictability and certainty of legislation and creating a more level playing field across the EU.
- More generally, it is recommended to **examine the feasibility of potentially laying down common principles and requirements** regarding the different authorisation procedures that apply in sectoral legislation, with a view to streamlining and the potential impact of this for further simplification and reduction in administrative burden**.** In this context, the positive impact of the adoption of common authorisation procedures for food additives, food enzymes and food flavourings (food improvement agents: Regulation (EC) No. 1331/2008) was noted during the evaluation.

More generally, it is noted that legislation cannot foresee everything and a common sense approach should be applied in interpretation/enforcement of legislation. The **update of existing guidelines** (with a view to practical improvements) and development of further guidelines, further **training**, as well as **encouraging more cooperation and exchange of best practices between MS CAs** are soft interventions that can help improve interpretation, implementation and enforcement. This applies both to the above general principles and requirements of the GFL and to other secondary legislation. For instance, the development/revision of EU guidelines is considered useful for other secondary legislation, including notably: the addition of vitamins and minerals to food; contaminants; food improvement agents; and, labelling.

Annexes

Annex 1: ToR

Provided in separate attachment

Annex 2: Judgement criteria, indicators and methodological tools

*Note: This Annex includes two files (**in separate attachments**), as follows:*

- *Annex 2a: A mapping of the EQs, establishing the logical framework and links between the EQs;*
- *Annex 2b: A mapping of the judgment criteria and indicators used to address each EQ. A background of the approach that led to the development and selection of these indicators is provided in the main report, section II.3.3.*

Annex 3: Analysis of consolidated survey results (MS CAs and stakeholders)

Provided in separate file

Annex 4: Analysis of SME Panel results

Provided in separate file

Annex 5: Data collection tools

*Note: This Annex includes several files (**in separate attachments**), as follows:*

- ***Annex 5a**: Questionnaire for the on-line survey of stakeholders;*
- ***Annex 5b**: Questionnaire for the on-line survey of Member State Competent Authorities (MS CAs);*
- ***Annex 5c**: Questionnaire for the SME Panel;*
- ***Annex 5d**: Working document for stakeholder workshop*;*
- ***Annex 5e**: Working document for MS CA workshop*;*
- ***Annex 5f**: Guide for the interviews with Third Countries*

---

* The working documents contained detailed questions on the case studies as follows: case studies 1 and 2: traceability and FBO responsibilities (presented to stakeholders on 19 December 2014); case studies 3 and 4: risk analysis and transparency (presented to MS CAs on 16 January 2015).

Annex 6: Background documents

Annex 6.A. Conclusions of the Commission's fitness check of relevance to the GFL

Annex 6.B. Description of specific procedures for risk analysis in specific sectors

Annex 6.A. Conclusions of the Commission's fitness check of relevance to the GFL

The Commission Staff Working Document on the Fitness Check on the food chain (SWD(2013) 516 final) sets out a list of **problems identified in the context of the comprehensive fitness check of all legislation with relevance to the food chain**. These are discussed below because they are relevant to the GFL and there is likely to be some overlap. These issues therefore provide some early guidance in terms of the key areas of concern:

- **Complexity.** There is a lot of legislation covering the chain and this has largely been developed in a piecemeal fashion since the 1960s. The GFL has provided common ground through definitions and guiding principles to bring together further secondary legislation in a coherent group, while aiming to keep this streamlined and clear for implementation. We have therefore considered the extent to which the GFL has actually, in practice, reduced complexity and whether there is scope to reduce complexity still further. Complexity can refer to both content and presentation. E.g. Wijnands, *et al* (2006) concluded that there was a need to codify legislation.
- **Duplication and overlaps.** The framework approach of the GFL should reduce the possibility of duplication and overlap, but there might be areas where duplication could be avoided. There may also be cases of superfluous legislation.
- **Inconsistencies in approach.** The REFIT exercise identified cases where there are different solutions for similar needs. This should not be the case under the GFL which was, in part, designed to prevent this. However, given the complexity of the legislative framework, it is possible that some inconsistencies may be identified.
- **Absence of important elements in legislation.** The most important omission identified by the REFIT exercise related to food fraud (whether intended or unintended[337]). Elements required to address food fraud, specifically traceability and recall systems, are covered under the GFL and the scope of the GFL (and other relevant secondary legislation, in particular Regulation (EC) 882/2004 on official controls).
- **Difficulties in interpretation and implementation.** The REFIT exercise is clear that many of the identified problems with the wider body of legislation in the food sector relate to interpretation and implementation rather than the legal texts themselves. Although the GFL is a Regulation and therefore does not require national interpretation to become law, it provides a framework for implementation which as such may allow for national differences. It has therefore been important to consider the **differences between Member States** in their implementation approach.

[337] *Article 8:* **Protection of consumers' interests:** 1. Food law shall aim at the protection of the interests of consumers and shall provide a basis for consumers to make informed choices in relation to the foods they consume. It shall aim at the prevention of: (a) fraudulent or deceptive practices; (b) the adulteration of food; and (c) any other practices which may mislead the consumer.

Annex 6.B. Description of specific procedures for risk analysis in specific sectors

Note: The description below summarises the latest specific procedures for product authorisation and setting of maximum limits, as laid down in other secondary legislation in each of the focus sectors of the case study (food additives; feed additives; food contact materials; and, contaminants). This has been drawn for the purpose of the case study and is not meant to provide a complete overview of the applicable legislation. More information on the legislation can be found at the DG SANTE website.

Implementation of risk analysis in specific procedures laid down in other specific secondary legislation (focus sectors only)

Sector	Legislation	Key provisions	Rationale
Food contact materials (FCM)	Framework Regulation EC 1935/2004; Legislation on specific materials (e.g. plastics: Regulation (EU) 10/2011); National legislation on materials/articles for which no EU legislation in place	***Not fully harmonised*** Regulation establishes 17 groups of materials and articles which may be covered by specific measures (specific legislation in the form of individual Regulations). Authorisation requires **scientific opinion by EFSA and validation by Standing Committee PAFF.** Substances for use in FCM are presently only authorised under Regulation (EU) 10/2011 on plastic materials (listed in table 1 of Annex I).	Food contact materials are materials and articles intended to come into contact with foods such as: packaging materials; cutlery and dishes; processing tools and equipment; containers. FCM shall not release their constituents in amounts harmful to human health, or affect the quality of the food. For most of the substances authorised under Regulation (EU) 10/2011, a Specific Migration Limit (SML) is set out on the basis of a toxicological evaluation.
Food additives	Regulation EC 1333/2008; Regulation EU 257/2010 (re-evaluation of approved food additives); Regulation EU 234/2011 (common authorisation procedure); Regulation EU 231/2012	***Fully harmonised.*** All additives in the EU must be authorised and listed with conditions of use in the EU's 'positive' list. If the requested use is liable to have an effect on human health, authorisation requires **scientific opinion by EFSA and validation by Standing Committee PAFF.** Authorised additives are listed in an EU Food Additives database.	Applicants send their applications to the Commission. If the requested use is liable to have an effect on human health, the Commission will ask EFSA for an opinion. The proposed regulation can be adopted with regulatory procedure with scrutiny (Art. 5a of Decision 1999/468/EC).
Feed additives	Regulation (EC) No 1831/2003	***Fully harmonised.*** Only authorised additives may be placed on the EU market and be used in the EU. Authorisations are granted for specific animal species, specific conditions of use and for ten year periods. This requires **scientific opinion by EFSA and validation by Standing Committee PAFF.** Authorised additives are listed in the EU Register of Feed Additives.	Feed additives may only be placed on the market after authorisation, following a scientific evaluation demonstrating that the additive has no harmful effects on human and animal health and on the environment (as well as efficacy criteria). Maximum residue limits (MRLs) and post market monitoring plan may be established for a feed additive if deemed necessary.
Food contaminants	Council Regulation 315/93/EEC; MLs are set in Commission Regulation (EC) No 1881/2006	***Not fully harmonised:*** General rules to minimise contaminant presence in food, though setting **maximum levels (MLs)** for certain contaminants in order to protect public health. This requires **scientific opinion by EFSA and validation by Standing Committee PAFF.** EU measures (establishment of MLs) have been taken for the following contaminants: mycotoxins (aflatoxins, ochratoxin A, fusarium-toxins, patulin, citrinin), metals (cadmium, lead, mercury, inorganic tin), dioxins and PCBs, polycyclic aromatic hydrocarbons (PAH), 3-MCPD, melamine, erucic acid and nitrates.	Contaminants are substances not intentionally added to food. These substances may be present in food as a result of the various stages of its production, packaging, transport or holding. They also might result from environmental contamination. Since contamination generally has a negative impact on the quality of food and may imply a risk to human health, the EU has taken measures to minimise contaminants in foodstuffs.

Source: Agra CEAS Consulting, based on EU legislation

A. Food additives: *fully harmonised*

Food additives are:
- Sweeteners to sweeten foods or in table-top sweeteners;
- Colours adding or restoring colour in a food;
- Preservatives prolonging shelf-life of foods by protecting them against deterioration by micro-organisms;
- Antioxidants prolonging shelf-life of foods by protecting them against oxidation e.g. fat rancidity, colour changes;
- Stabilisers to maintain the physico-chemical state of a foodstuff;
- Emulsifiers to maintain the mixture of oil and water in a foodstuff.

Added to food for technological purposes in its manufacture, processing, preparation, treatment, packaging, transport or storage, food additives become a component of the food.

Base legislation relevant to Food Additives:
- Regulation EC 1333/2008 - food additives;
- Regulation EU 257/2010 - programme for the re-evaluation of approved food additives;
- Regulation (EC) No. 1331/2008 (common authorisation procedure) and Regulation EU 234/2011 implementing a common authorisation procedure for food additives, food enzymes and food flavourings (food improvement agents);
- Regulation EU 231/2012 laying down specifications for food additives.

Regulation EC 1333/2008 sets the rules on food additives. **All additives in the EU must be authorised and listed** with conditions of use in the EU's 'positive' list based on:
- ***A safety assessment***;
- The technological need;
- Ensuring that use of the additive will not mislead consumers.

The Commission will change the EU lists of food additives with regulations through regulatory procedure with scrutiny (Decision 1999/468/EC). Producers must inform the Commission of new information which may affect the safety assessment of the food additive.
There is an EU Food Additives database.

Applying for an authorisation:
The Commission, a EU country or an interested party *can start the procedure* through an application for updating the EU lists of authorised food additives, food enzymes and flavourings.
"Updating the Union list" means:
- Adding a substance;
- Removing a substance;
- Adding, removing or changing conditions, specifications or restrictions related to the presence of a substance.

Procedure
Applicants send their applications ***to the Commission***. If the requested use is liable to have an effect on human health, the Commission will ask the ***European Food Safety Authority (EFSA) for an opinion (RA).*** EFSA must give an opinion within 9 months of receipt of a valid application. The Commission submits a draft regulation to the ***Standing Committee on Plants, Animals, Food and Feed (PAFF) (RM).*** The proposed regulation can be adopted with regulatory procedure with scrutiny (Art. 5a of Decision 1999/468/EC).

Requirements for the application:
- Administrative data;

- General data required for risk assessment;
- Specific data required for risk assessment;
- Data required for risk management of food additives, food enzymes and flavourings.

Requirements are set in Regulation EU 234/2011 as amended by Commission Implementing Regulation (EU) No 562/2012 including:

- Measures on the content, drafting and presentation of applications;
- How to check the validity of applications;
- Information that should be included in the opinion of EFSA.

B. Feed additives: fully harmonised

Feed additives are products used in animal nutrition for purposes of improving the quality of feed and the quality of food from animal origin, or to improve the animals' performance and health, e.g. providing enhanced digestibility of the feed materials. ***Feed additives may not be placed on the EU market nor be used unless authorisation has been given*** following a scientific evaluation demonstrating that the additive has no harmful effects on human and animal health and on the environment.

Regulation (EC) No 1831/2003 sets out new rules for the authorisation, supervision and labelling of feed additives: only additives that have been through an authorisation procedure may be placed on the EU market and used. ***Authorisations are granted for specific animal species, specific conditions of use and for ten years periods***.

Additives may be classified into the following categories:

- Technological additives (e.g. preservatives, antioxidants, emulsifiers, stabilising agents, acidity regulators, silage additives)
- Sensory additives (e.g. flavours, colorants)
- Nutritional additives (e.g. vitamins, aminoacids, trace elements)
- Zootechnical additives (e.g. digestibility enhancers, gut flora stabilizers)
- Coccidiostats and histomonostats

The European Food Safety Authority (EFSA) is ***responsible for conducting the evaluation of the data (RA)*** submitted requesting authorisations. After a favourable opinion of the EFSA, the Commission prepares a draft Regulation to grant or refuse authorisation, within the ***Standing Committee PAFF (RM).***

Maximum residue limits (MRLs) and post market monitoring plan may be established for a feed additive if deemed necessary.

The Regulation also contains certain provisions regarding the labelling and packaging of feed additives and procedures for supervision, modification, suspension, revocation and renewal of authorisations, and about confidentiality and data protection. The Regulation also contains certain provisions regarding transitional measures about the status of products placed on the market before the entry into force of Regulation (EC) No 1831/2003.

There is the **European Union Register of feed additives**.

C. Food contact materials: not fully harmonised

Food contact materials (FCM) are materials and articles intended to come into contact with foods such as: Packaging materials; Cutlery and dishes; Processing machines; Containers; Materials and articles in contact with water for human consumption. Materials and articles in contact with water for human consumption do not include drinking water before the point of compliance specified in the Drinking Water Directive 98/83/EC, thereafter only if the water meets the definition of food in the GFL, and is therefore considered a food.

Food contact materials and articles are regulated by:

- ***Framework Regulation EC 1935/2004*** - general requirements for all food contact materials.
- Legislation on specific materials - groups of materials and articles listed in the Framework Regulation. The Regulation establishes 17 groups of materials and articles which may be covered by specific measures (specific legislation in the form of individual Regulations). There are specific measures for ceramics, regenerated cellulose, plastics, recycled plastics and active and intelligent materials and articles. For example, Regulation (EU) 10/2011 on plastic materials;
- Directives on Individual Substances or groups of substances used in the manufacture of materials and articles intended for food contact;
- ***National legislation covering groups of materials and articles for which EU legislation is not yet in place.***

Safety with respect to FCM is based on the issues of migration of food contact materials' components into food. Food contact materials must not transfer their components into the foods in unacceptable quantities (migration). FCM shall not release their constituents in amounts harmful to human health, or affect the quality of the food.

Regulation (EU) 10/2011 lays down requirements on the composition of plastic FCM. Only listed substances can be used as starting substances or additives in the manufacture of plastic materials. For most of these substances a Specific Migration Limit (SML) is set out on the basis of a toxicological evaluation. SML is set according to the Acceptable Daily Intake or the Tolerable Daily Intake established by EFSA (or by the Scientific Committee on Food prior to 2002). The limit is set on the assumption that every day throughout lifetime, a person weighing 60kg eats 1kg of food packed in plastics containing the substance in the maximum permitted quantity.

There is an overall migration limit for plastic materials in Regulation (EU) 10/2011, set at 10mg of substances/dm² of the food contact surface for all substances that can migrate from food contact materials to foods.

The **Framework Regulation** - in force since 3 December 2004 – requires that food contact materials:

- Are safe;
- Must not transfer their components into food in quantities that could endanger human health, change food composition in an unacceptable way or deteriorate its taste and odour.
- Are manufactured according to good manufacturing practice
- An article intended for food contact must be labelled or bear the glass-and-fork symbol. This labelling is not obligatory if food contact is obvious by the article's nature e.g. knife, fork, wine glass.
- Labelling, advertising and presentation of food contact materials must not mislead consumers.
- Information on the appropriate use of food contact materials or articles must be provided, if necessary
- Are traceable throughout the production chain.

Procedure for authorisation

The Regulation establishes the authorisation procedure for:

- Substances for use in food contact materials and articles, specifically:
- Substances used in plastic materials and articles;
- Substances used for active or intelligent functions in active and intelligent materials
- Substances used in regenerated cellulose films (cellophane)
- Materials and the articles themselves;
- Manufacturing processes of food contact materials and articles specifically:

- Mechanical recycling processes for plastics to be used in plastic food contact materials

Applicants must:
- Prepare applications in accordance with the guidance of the European Food Safety Authority (EFSA);
- Submit applications **via a national contact point** ;

EFSA evaluates applications and gives an opinion *(RA)*.
The Commission prepares a draft measure.
The Standing Committee PAFF gives an opinion on the draft measure *(RM)*.

Authorisation is granted by listing the substance in legislation.

D. Contaminants in food: *not fully harmonised*

Contaminants are substances that have not been intentionally added to food. These substances may be present in food as a result of the various stages of its production, packaging, transport or holding. They also might result from environmental contamination. Since contamination generally has a negative impact on the quality of food and may imply a risk to human health, the EU has taken measures to minimise their presence in food, i.e. though the setting of maximum limits (MLs).

EU measures have been taken for the following contaminants: mycotoxins (aflatoxins, ochratoxin A, fusarium-toxins, patulin), metals (cadmium, lead, mercury, inorganic tin), dioxins and PCBs, polycyclic aromatic hydrocarbons (PAH), 3-MCPD and nitrates).

The basic principles of EU legislation on contaminants in food are in **Council Regulation 315/93/EEC of 8 February 1993**:
- food containing a contaminant to an amount unacceptable from the public health viewpoint and in particular at a toxicological level, shall not be placed on the market
- contaminant levels shall be kept as low as can reasonably be achieved following recommended good working practices
- **maximum levels (RA/RM)** must be set for certain contaminants in order to protect public health

Maximum levels for certain contaminants in food are set in **Commission Regulation (EC) No 1881/2006.** This Regulation entered into force on 1 March 2007. Maximum levels in certain foods are set for the following contaminants: : mycotoxins (aflatoxins, ochratoxin A, fusarium-toxins, patulin, citrinin), metals (cadmium, lead, mercury, inorganic tin), dioxins and PCBs, polycyclic aromatic hydrocarbons (PAH), 3-MCPD, melamine, erucic acid and nitrates. **The setting of MLs involved risk assessment by EFSA and risk management by the Standing Committee PAFF.**

Provisions **for the sampling and analysis** for the official control of the maximum levels for contaminants have been laid down as follows:
- for levels of mycotoxins: Commission Regulation (EC) 401/2006 as amended by Commission Regulation (EU) 178/2010
- for levels of heavy metals, 3-MCPD, inorganic tin and benzo(a)pyrene levels in: Commission Regulation (EC) No 333/2007.
- for dioxin and PCBs levels: Commission Regulation (EU) No 589/2014.
- for levels of nitrates in Commission Regulation (EC) 1882/2006.

E. Contaminants (undesirable substances) in feed: *largely harmonised*

As in the case of contaminants in food, since contamination generally has a negative impact on the quality of feed and may imply a risk to animal/human health, the EU has taken measures to minimise the presence of undesirable substances in feed, i.e. though the setting of maximum limits (MLs). The basic principles are the same as for contaminants in food.

EU legislation on undesirable substances in feed dates back to 1974 and is therefore more comprehensive than EU legislation on contaminants in food (which started only in 1997; furthermore, there was at that time already quite some national legislation in place which was allowed to keep in place until it was overruled by EU legislation). EU legislation has been further harmonised in 2002 (Directive 2002/32/EC) based on the principles of risk assessment as foreseen in GFL. The assessments provided by the European Food Safety Authority (EFSA) form the basis of EU risk management decisions. This sector is not yet fully harmonised, as there are contaminants in feed which are not (yet) regulated at EU level and could be subject to national rules.

Annex 7: Stakeholder mapping

Note: The stakeholder 'map' provides the list of stakeholders targeted by the consultation in the context of this evaluation. It includes the relevant stakeholders in the food/feed supply chain from 'farm to fork', and relevant NGOs, as identified during the study course. ***It lists organisations active at EU level only****. National member organisations of these stakeholders were targeted via their EU counterparts.*

Type (if not industry representative)	Name	Full name	Member of:	Member of the Advisory Group on the Food Chain
		All EU-level associations		
	AAF	European Starch Industry Association	PFP	n
	AESGP	Association of the European Self-Medication Industry		y
	AIJN	European Fruit Juice Association	FDE	n
	AIPCE-CEP	Association des industries du poisson de l'Union européenne		n
NGO	ANIMALS ANGELS	Animal Welfare Association		n
	AVEC	Association of Poultry Processors and Poultry Trade in the EU		y
NGO	BEUC	Bureau européen des unions de consommateurs		y
	CAOBISCO	Chocolate, biscuits & confectionery of Europe	FDE	n
	CEEREAL	European Breakfast Cereal Association	FDE	n
	CEEV	Comité Européen des Entreprises Vins		n
	CEFIC	Conseil Européen des fédérations de l'industrie chimique		y
	CEFS	Comité Européen des Fabricants de Sucre	PFP; FDE	n
	CELCAA	Comité Européen de Liaison des Commerces AgroAlimentaires		y
NGO	CES/ETUC	Confédération Européenne des Syndicats/European Trade Union		n
	CIBE	International Confederation of European Beet Growers		n
	CLITRAVI	Liaison Centre for the Meat Processing Industry in the EU	FDE	n
	COCERAL	Comité du commerce des céréales, aliments du bétail, oléagineux, huile d'olive, huiles et graisses et agrofournitures de l'Union Européenne		y
	COFALEC	Confederation of EU Yeast Producers	FDE	n
	COPA-COGECA	Committee of Agricultural Organisations in the EU		y
	CULINARIA EUROPE	Federation of Associations and Enterprises of Industrial Culinary Product Producers in Europe	FDE	n
	ECA	European Cocoa Association	PFP	n
	ECCA	European Crop Care Association		n
	ECF	European Coffee Federation	FDE	n
	ECFF	European Chilled Food Association		n
	ECPA	European Crop Protection Association		y
	ECSLA	European Cold Storage and Logistics Association		n
	ECVC	European Coordination Via Campesina		n
	EDA	European Dairy Association	FDE	y
	EFBW	European Federation of Bottled Waters	FDE	n

Type (if not industry representative)	Name	Full name	Member of:	Member of the Advisory Group on the Food Chain
	EFFAT	European Federation of Food, Agriculture and Tourism Trade Unions		n
	EFPRA	European Fat Processors and Renderers Association		n
	EFM	European Flour Millers	PFP	n
	EHIA & ETC	European Herbal Infusions Association and European Tea Committee	FDE	n
	EHPM	European Federation of Associations of Health Product Manufacturers		y
	ELC	Federation of European Specialty Food Ingredients Industries		n+
	EMRA	European Modern Restaurant Association		y
	ENSA	European Natural Soyfood Association		n
NGO	EPHA	EU Public Health Alliance		n
Forum	ERRT	European Retail Round Table		n
	ESA snacks	European Snacks Association	FDE	n
	ESA spices	European Spice Association	FDE	n
	ESA seeds	European Seed Association		n
	EUCOFEL	Trade of fruit and vegetables		n
	EUPPA	European Potato Processors	FDE	n
	EUROCHAMBRES	Association of European Chambers of Commerce and Industry		n
	EUROCOMMERCE	European Representation of Retail, Wholesale and International Trade		y
	EUROCOOP	European Community of Consumer Cooperatives		y
	EUROGLACES	European Ice Cream Association	FDE	n
NGO	EUROGROUP FOR ANIMALS	Eurogroup for animal welfare		y
	EUROPABIO	European Association of Bioindustries		y
	EUSALT	European Salt Producers' Association		n
	EUVEPRO	European Vegetable Protein Federation	PFP	n
	EUWEP	European Union of Wholesale with Eggs, Egg Products and Poultry and Game		n
	FDE	FoodDrink Europe		y
	FEDIMA	Federation of EU manufacturers and suppliers of ingredients to Bakery, Confectionary and Patisserie industries	FDE	n
	FEDIOL	European Vegetable Oil and Proteinmeal	PFP	n
	FEDIAF	European Pet Food Industry Federation	FDE	n
	FEEDM	European Federation of Honey Packers & Distributors	FDE	n
	FEFAC	European Feed Manufacturers' Federation		y
	FEFANA	EU Association of Specialty Feed Ingredients and their Mixtures		y
	FERM	Federation of European Rice Millers		n
NGO	FESASS	Fédération européenne pour la santé animale et la sécurité sanitaire		y
NGO	FoEE	Friends of the Earth Europe		y

Type (if not industry representative)	Name	Full name	Member of:	Member of the Advisory Group on the Food Chain
	FOODSUPPLEMENTS EUROPE			n+
	FOODSERVICE EUROPE	European Federation of Contract Catering Organizations		y
	FRESHFEL	European Fresh Produce Association		y
	FRUCOM	European Federation of the Trade in Dried Fruit, Edible Nuts, Processed Fruit & Vegetables, Processed Fishery Products, Spices, Honey and Similar Foodstuffs		n+
NGO	FVE	Federation of Veterinarians of Europe		n
	HOTREC	European Trade Association of Hotels, Restaurants and Cafés in Europe		n
NGO	IFAH-EUROPE	International Federation for Animal Health Europe		y
NGO	IFOAM-EU GROUP	International Federation of Organic Agriculture Movements — European Union Regional Group		y
	IMACE	International Margarine Association of the countries of Europe	FDE	n
	INDEPENDENT RETAIL EUROPE	EU representation of groups of independent retailers to EU and international institutions		y
NGO	Labelling Matters	Labelling Matters		n
	OEIT	European Organisation of Tomato Industries		n
Forum	PAN EUROPE	Pesticides Action Network		y
	PFP	Primary Food processors		y
	PROFEL	European Association of Fruit and Vegetable Processors	FDE	n
	SpiritsEUROPE	European Spirits sector	FDE	n
	SEMOULIERS	Union des Associations des Semouliers de l'UE		n
	SLOW FOOD	Slow Food Associazione Internazionale		y
	SNE	Specialised Nutrition Europe	FDE	n
	The Brewers of Europe	The Brewers of Europe	FDE	n
	UEAPME	European Association of Craft, Small and Medium-sized Enterprises.		n
	UECBV	Union européenne du commerce du bétail et de la viande		y
	UNAFPA	Union of Organisations of Manufacturers of Pasta Products of the European Union	FDE	n
	UNESDA	Union of European Beverages Associations	FDE	n

Note: n+ indicates stakeholders that are not members of the Advisory Group on the Food Chain but who have requested to attend the Advisory Group for issues relating to the GFL.

Annex 8: Reviewed literature

Note: This list excludes references to legislation (adopted Regulations and Directives) and guidance documents for the GFL or other secondary legislation.

- Advisory Group on the Food Chain and Animal and Plant Health. (2014). First Working Group Meeting on the Fitness Check of Regulation (EC) No 178/2002 - 4 March 2014.
- Agence Fédérale pour la Sécurité de la Chaîne Alimentaire (AFSCA). (2012). Plan de contrôle pluriannuel intégré de la Belgique 2012-2014.
- Agra CEAS Consulting (Bureau Européen de Recherches). (1996). The Single Market Review Series - Impact on manufacturing: Processed foodstuffs.
- Alemanno, A. (2007). Trade in food - Regulatory and judicial approaches in the EC and the WTO.
- Alemanno, A., & Gabbi, S. (2014). Foundations of EU Food Law and Policy - Ten Years of the European Food Safety Authority. (Ashgate, Ed.).
- AND International. (2015). Evaluation of EU beef labelling rules. Final Report.
- Angot, J. (2011). E.Coli crisis : lessons learnt 1- HUS and FBO survey in France.
- Arthur Cox. (2012). Food and Feed Alerts in the EU : A Legal Overview (Vol. 353, pp. 1–3).
- Arthur Cox. (2013). Public Notification of Food Safety Risks: Recent Developments (pp. 1–2).
- B2B platform of the High Level Forum for a Better Functioning Food Supply Chain. (2011). Vertical relationships in the Food Supply Chain: Principles of Good Practice.
- BEUC. (2014). Discussion Paper on the REFIT Fitness Check of Regulation (EU) N.178/2002 (Vol. 32).
- BfR. (2012). Acting in Times of Crisis and Crisis Prevention.
- BfR. (2014). EU Food Safety Almanac 2014.
- Bishop, J., & Savelli, C. (n.d.). INFOSAN: International Food Safety Authorities Network.
- CEPS. (2013). Assessing the costs and benefits of regulation.
- Charlebois S., Sterling B., Haratifar S., Naing S.K. (2014). Comparison of Global Food Traceability Regulations and Requirements. Comprehensive Reviews in Food Science and Food Safety, Volume 13, Issue 5, September 2014 (pp. 1104-1123).
- COCERAL-FEDIOL-FEFAC. (2010). Response to RASFF working document.
- COCERAL-FEDIOL-FEFAC. (2014). EU Commission decision concerning vital food and feed import urgently needed to secure food and feed supply to the EU (Vol. 32, pp. 29–30).
- Codex Alimentarius. (2003). General principles of food hygiene - CAC/RCP 1-1969.
- Copa-Cogeca. (2014a). Copa-Cogeca's contribution to the DG SANCO/FVO project on HACCP principles.
- Copa-Cogeca. (2014b). Preliminary views on possible issues to be examined as part of the Fitness Check of Regulation (EU) No 178/2002.
- Defra UK. (2013). Cumulative Impact of Forthcoming Regulatory Proposals on the Economics of Farming in England.
- CPRA. (2011). Assessing farmers' cost of compliance with EU legislation in the fields of environment, animal welfare and food safety. FINAL REPORT for the European Commission, DG AGRI.
- Deloitte-Capgemini-Ramboll. (2009). EU project on baseline measurement and reduction of administrative costs - Report on the Food Safety Priority Area (Vol. 281).
- Detken, D. (2013). The role of EFSA in the Rapid Alert System for Food and Feed.
- Deutscher Bundesrechnungshofes. (2012). Organisation des gesundheitlichen Verbraucherschutzes: Schwerpunkt Lebensmittel. Der Präsident des Bundesrechnungshofes als Bundesbeauftragter für Wirtschaftlichkeit in der Verwaltung.
- EDES. (2014). Case study of risk communication in food outbreaks.
- EEA (European Environment Agency). (2013). Late lessons from early warnings: science, precaution, innovation. EEA Report No 1/2013.
- EFSA. (2014a). Discussion Paper: Transformation to an "Open EFSA."
- EFSA. (2014b). Indicative timelines for submitting additional or supplementary information to EFSA during the risk assessment process of regulated products.
- EFSA. (2014c). The European Union Summary Report on Trends and Sources of Zoonoses, Zoonotic Agents and Food-borne Outbreaks in 2012 (Vol. 12).
- Ernst&Young. (2011). External Evaluation of EFSA.
- EuroCommerce. (2014a). Briefing - Regulatory Fitness and Performance Programme (REFIT).
- EuroCommerce. (2014b). Public Consultation: Impact Assessment Guidelines - Position paper.
- European Centre for Disease Prevention and Control (ECDC). (2011). Understanding the 2011 EHEC/STEC Outbreak in Germany.

- European Commission. (n.d.-a). Report: Small and Medium Sized Enterprises and the Transatlantic Trade and Investment Partnership.
- European Commission. (n.d.-b). The key obligations of food and feed business operators.
- European Commission Food and Veterinary Office. (n.d.-c). Official controls of procedures based on the HACCP principles
- European Commission. (1997). The General Principles of Food Law in the European Union - Commission Green Paper.
- European Commission. (2000a). White Paper on Food Safety - COM(1999) 719 final (2000).
- European Commission. (2000b). Communication from the Commission on the precautionary principle - COM(2000) 1 (2000).
- European Commission. (2003). Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (2003).
- European Commission. (2004). Commission Decision concerning the adoption of a general plan for food/feed crisis management (2004).
- European Commission. (2005). Directive 2005/29/EC concerning unfair business-to-consumer commercial practices in the internal market (2005).
- European Commission. (2006a). Communication from the Commission: Better training for safer food - COM(2006) 519 final (2006).
- European Commission. (2006b). Special Eurobarometer 238 -Risk Issues.
- European Commission. (2006c). Enlargement, two years after: an economic evaluation. Bureau of European Policy Advisers and the Directorate-General for Economic and Financial Affairs. European Economy, Occasional papers, No 24. May 2006.
- European Commission. (2007). Food Traceability - Commission factsheet.
- European Commission. (2008a). Commission Decision on guidelines to assist Member States in preparing the annual report on the single integrated MANCP (2008).
- European Commission. (2008b). Communication from the Commission: "Think Small First" - A "Small Business Act" for Europe - COM(2008) 394 final (2008).
- European Commission. (2008c). Impact Assessment COM (2008) 124 final - Commission Staff Working Document accompanying the Regulation on the placing on the market and use of feed.
- European Commission. (2009a). Report from the Commission to the Council and the European Parliament on the experience gained from the application of the hygiene Regulations (EC) No 852/2004, (EC) No 853/2004 and (EC) No 854/2004.
- European Commission. (2009b). Commission Staff Working Document accompanying the Report from the Report from the Commission to the Council and the European Parliament on the experience gained from the application of the hygiene Regulations - SEC(2009) 1079 final (Vol. 2009).
- European Commission. (2010a). Guidance on the implementation of Articles 11, 12, 14, 17, 18, 19 and 20 of Regulation (EC) No 178/2002 on General Food Law (2010).
- European Commission. (2010b). Report from the Commission on the effectiveness and consistency of sanitary and phytosanitary controls on imports of food, feed, animals and plants - COM(2010) 785 final.
- European Commission. (2010c). Special Eurobarometer 354 - Food-related risks.
- European Commission. (2010d). Communication from the Commission: An integrated industrial policy for the globalisation era: putting competitiveness and sustainability at centre stage. COM (2010) 614 final.
- European Commission. (2010e). Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions. The CAP towards 2020: Meeting the food, natural resources and territorial challenges of the future. COM(2010) 672 final.
- European Commission. (2011a). Commission Staff Working Document: Lessons learned from the 2011 outbreak of Shiga toxin-producing Escherichia coli (STEC) O104:H4 in sprouted seeds.
- European Commission. (2011b). Communication from the Commission: Review of the "Small Business Act" for Europe - COM(2011) 78 final (2011).
- European Commission. (2011c). Report from the Commission: Minimizing regulatory burden for SMEs - Adapting EU regulation to the needs of micro-enterprises - COM(2011) 803 final (2011).
- European Commission. (2011d). Special Eurobarometer 363 - Internal Market: Awareness, Perceptions and Impacts.
- European Commission. (2011e). Roadmap to a Resource Efficient Europe. COM(2011)571 final.
- European Commission. (2012a). Commission Staff Working Document: Action Programme for Reducing Administrative Burdens in the EU accompanying the Communication on EU Regulatory Fitness - SWD(2012) 423 final.
- European Commission. (2012b). Communication from the Commission: EU Regulatory Fitness - COM(2012) 746 final.
- European Commission. (2012c). Fitness checks (2012).
- European Commission. (2012d). Roles of Member States and European Institutions in Case of Crisis: Legal background.

- European Commission. (2012e). Standard Operating Procedures for food/feed crisis management (Commission Decision 2004/478/EC).
- European Commission. (2012f). Communication from the Commission to the European Parliament and the Council: First Report on the application of Regulation (EC) No 764/2008 of the European Parliament and of the Council of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State - COM(2012) 292 final.
- European Commission. (2012g). Communication on the European Innovation Partnership 'Agricultural Productivity and Sustainability'. COM(2012)79 final.
- European Commission. (2013a). Communication from the Commission: Regulatory Fitness and Performance (REFIT): Results and Next Steps - COM(2013) 685 final.
- European Commission. (2013b). Annex to the Communication from the Commission on "Regulatory Fitness and Performance (REFIT): Results and Next Steps" (2013).
- European Commission. (2013c). Commission Staff Working Document: A fitness check of the food chain: State of play and next steps - SWD(2013) 516 final.
- European Commission. (2013d). Commission Staff Working Document: Impact Assessment accompanying the proposal for a Regulation laying down general provisions for the management of expenditure in the field of food chain, animal health and welfare, and on plant health and plant reproduction materials.
- European Commission. (2013e). Communication from the Commission: Commission follow-up to the "TOP TEN" Consultation of SMEs on EU Regulation - COM(2013) 446 final.
- European Commission. (2013f). Communication from the Commission: Smart regulation - Responding to the needs of small and medium-sized enterprises - COM(2013) 122 final.
- European Commission. (2013g). Impact Assessment accompanying the document: Proposal for a Regulation on official controls and other official activities - SWD(2013) 167 final.
- European Commission. (2013h). Executive summary of the Impact Assessment accompanying the document: Proposal for a Regulation on official controls and other official activities - SWD(2013) 166 final.
- European Commission. (2013i). "Fitness check" on EU law in the area of Information and Consultation of Workers - SWD(2013) 293 final.
- European Commission. (2013j). Proposal for a Regulation laying down general provisions for the management of expenditure in the field of food chain, animal health and welfare, and on plant health and plant reproductive material - COM(2013) 327 final.
- European Commission. (2013k). Proposal for a Regulation of the European Parliament and of the Council on consumer product safety - COM(2013) 78 final.
- European Commission. (2013l). Proposal for a Regulation on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health, plant reproductive material and plant protection products - COM(2013) 265 final.
- European Commission. (2013m). Smarter rules for safer food: a review of the EU legislation for the animal, plant and food production chain.
- European Commission. (2014a). Communication from the Commission on Regulatory Fitness and Performance Programme (REFIT): State of Play and Outlook - COM(2014) 368 final
- European Commission. (2014b). Commission Staff Working Documents accompanying the document: Regulatory Fitness and Performance Programme (REFIT): State of Play and Outlook - SWD(2014) 192 final
- European Commission. (2014c). Discussion Paper on the REFIT Fitness Check of Regulation (EU) N° 178/2002.
- European Commission. (2014d). Expert Group on Regulation (EC) No 178/2002 - Summary report of the meeting held on March 3rd 2014 in Brussels.
- European Commission. (2014e). Impact Assessment accompanying the document: Regulation on the manufacture, placing on the market and use of medicated feed - SWD(2014) 271 final.
- European Commission. (2014f). Proposal for a Regulation on the manufacture, placing on the market and use of medicated feed - COM(2014) 556 final.
- European Commission. (2015a). Trade and Investment Barriers Report 2015. Report from the Commission to the European Council - COM(2015) 127 final.
- European Commission. (2015b). Small and Medium Sized Enterprises and the Transatlantic Trade and Investment Partnership. Report.
- European Commission. (2015c). RASFF for safer food — The Rapid Alert System for Food and Feed — 2014 annual report.
- European Commission Food and Veterinary Office. (2010). Overview report of a series of audits in Member States in order to asses the official control systems in place for food hygiene, traceability, labelling and bottled water - DG(SANCO)2010-6217 final.
- European Commission Food and Veterinary Office. (2012a). Overview report of a series of audits carried out in Member States from 2006 to 2011 - Official controls on feed legislation.

- European Commission Food and Veterinary Office. (2012b). Overview report of a series of audits carried out in seven Member States in order to evaluate the operation of controls over the traceability and labelling of beef and beef products - DG(SANCO)2012-6624.
- European Commission Food and Veterinary Office. (2013a). Microbiological criteria for food - Overview of FVO reports.
- European Commission Food and Veterinary Office. (2013b). Overview report of a series of audits in order to evaluate the official controls related to slaughter and processing of fresh meat, in particular fresh equine meat - DG(SANCO)2013-6950.
- European Commission Food and Veterinary Office. (2013c). Report on the overall operation of official controls in the Member States on food safety, animal health, animal welfare and plant health - COM(2013) 681 final.
- European Commission Food and Veterinary Office. (2014a). DG SANCO/FVO project on HACCP - Consultation with stakeholders.
- European Commission Food and Veterinary Office. (2014b). Final report of an audit carried out in the United Kingdom in order to evaluate measures in place for the identification of hazards and management of risks along the feed chain, including for oils, fats and products derived thereof.
- European Commission Food and Veterinary Office. (2014c). HACCP Project in EU Member States - objectives and experiences so far.
- European Commission Food and Veterinary Office. (2014d). Overview of findings in relation to laboratories in Member States.
- European Commission Food and Veterinary Office. (2014e). Report of the multiannual national control plan network meeting - 14 and 15 May 2014.
- European Commission Food and Veterinary Office. (2014f). Work Programme 2014.
- European Commission Food and Veterinary Office. (2014g). Overview report of a series of fact-finding missions carried out in 2013 and 2014 in order to gather information on emergency preparedness arrangements. Final Report No 2014-7651.
- European Commission Food and Veterinary Office. (2015). Overview report: Better HACCP implementation. Final Report No 2015-7752.
- European Commission Joint Research Centre. (2007). Cost Analysis of the implementation of electronic identification according to Regulation 21/2004.
- European Commission Press Release. (2013a). 2012 Report on Europe's Rapid Alert System for Food and Feed: Questions & Answers "What is RASFF?."
- European Commission Press Release. (2013b). REFIT - Fit for growth - Commission takes ambitious next steps to make EU law lighter.
- European Commission Press Release. (2014). Making EU law lighter, simpler and less costly – taking stock of achievements, pp. 1–3.
- European Competition Network (ECN) subgroup food. (2012). Report on competition law enforcement and market monitoring activities by European competition authorities in the food sector.
- European Parliament. (2015). TTIP: Challenges and Opportunities for Consumer Protection. In-depth analysis for the IMCO Committee. DG for Internal Policies. IP/A/IMCO/2014-12. June 2015.
- European Policy Evaluation Consortium (EPEC). (2011). Evaluation of the EU legislative framework in the field of cultivation of GMOs under Directive 2001/18/EC and Regulation (EC) No 1829/2003, and the placing on the market of GMOs as or in products under Directive 2001/18/EC.
- EY-Cambridge Econometrics-Arcadia International. (2014). The economic impact of modern retail on choice and innovation in the EU food sector.
- FAO-WHO. (n.d.). The application of risk communication to food standards and safety matters.
- FAO-WHO. (2011). FAO/WHO guide for application of risk analysis principles and procedures during food safety emergencies.
- FCEC. (2006). Evaluation of the Community Animal Health Policy (CAHP) 1995-2004 and alternatives for the future (Vol. 3). Food Chain Evaluation Consortium.
- FCEC. (2008a). Evaluation of the Community acquis on the marketing of seed and plant propagating material (S&PM). Food Chain Evaluation Consortium.
- FCEC. (2008b). Study on fees or charges collected by the Member States to cover the costs occasioned by official controls - Part One: Main study and Conclusions (Vol. 3). Food Chain Evaluation Consortium.
- FCEC. (2008c). Study on fees or charges collected by the Member States to cover the costs occasioned by official controls - Part Two: Case Studies (Vol. 3). Food Chain Evaluation Consortium.
- FCEC. (2009). Feasibility study on animal welfare labelling and establishing a Community Reference Centre for Animal Protection and Welfare - Part 1: Animal Welfare Labelling. Food Chain Evaluation Consortium.

- FCEC. (2010a). Best Practices in Sanitary and Phytosanitary Training. Food Chain Evaluation Consortium.
- FCEC. (2010b). Evaluation of the Community Plant Health Regime. Food Chain Evaluation Consortium.
- FCEC. (2010c). Evaluation of the EU legislative framework in the field of GM food and feed. Food Chain Evaluation Consortium.
- FCEC. (2011). Quantification of costs and benefits of amendments to the EU plant health regime. Food Chain Evaluation Consortium.
- FCEC. (2013). Scoping study: Delivering on EU food safety and nutrition in 2050 - Scenarios of future change and policy responses. Food Chain Evaluation Consortium.
- FCEC. (2015). Evaluation of the RASFF and of crisis management procedures. Food Chain Evaluation Consortium.
- Federation of European Specialty Food Ingredients Industries (ELC). (2014). Evaluation of General Food Law: Outline ELC input, based on a proposed selection of relevant evaluation questions listed in the Terms of Reference.
- FEFAC. (2000). Briefing paper on Commission proposal COM(2000) 716 laying down the general principles and requirements of food law, establishing the European Food Authority and laying down procedures in matters of food safety.
- FEFAC. (2011). Dioxin crisis management by the EU feed industry.
- FEFAC. (2012). The European Feed Manufacturers' Guide EFMC (pp. 1–7).
- FEFAC. (2014). FEFAC preliminary position on the recasting of the EU medicated feed legislation (Vol. 2014, pp. 3–5).
- Fisher, E., Jones, J., & von Schomberg, R. (2006). The precautionary principle and its normative challenges. Implementing the Precautionary Principle: Perspectives and Prospects, Chapter 2. p19–42.
- Food for thought: A vision for unlocking the potential of agriculture and the food industry in the EU. (2014). Nature (Vol. 511).
- Food Standards Agency (FSA). (2012). 2012 UK Annual Report - Progress towards implementation of the Multi-Annual National Control Plan for the United Kingdom.
- Food Standards Agency (FSA). (2014). Multi-Annual National Control Plan for the United Kingdom - April 2013 to March 2015 (updated May 2014) (Vol. 2015).
- FoodDrinkEurope (FDE). (2013). Novel Foods Regulation: FoodDrinkEurope calls for a clear framework to facilitate innovation.
- Frohberg, K., Grote, U., & Winter, E. (2006). EU Food Safety Standards, Traceability and Other Regulations: A Growing Trade Barrier to Developing Countries' Exports?
- Fulponi (2006). Private voluntary standards in the food system: The perspective of major food retailers in OECD countries, Food Policy, Volume 31, Issue 1, 2006, pages 1-13.
- Garcia, R., & Jukes, D. (2004). The Spanish system of food controls––its administration and enforcement. Food Control, 15(1), 51–59.
- German Federal Ministry of Food Agriculture and Consumer. (2013). Food Safety Strategies.
- Giorgi, L., & Lindner, L. F. (2008). The contemporary governance of food safety: taking stock and looking ahead. Quality Assurance and Safety of Crops & Foods.
- GS1. (2013). Research support for an informal expert group on product traceability.
- GS1. (2014). EU Expert Group Highlights: Global Best Practices for Product Traceability.
- Heads of European Food Safety Agencies (HoA). (2012). Transparent Use of Risk Assessment in Decision Making.
- Heads of European Food Safety Agencies (HoA). (2014). Sharing protocols, experiences and knowledge on management and communication during food crisis.
- High Level Forum for a Better Functioning Food Supply Chain. (2014). Report 2014.
- Hornsby, D. J. (2008). Review of Alberto Alemanno's book "Trade in Food." Global Law Books.
- HOTREC. (2005). Food - HOTREC position on the EU food safety framework.
- Houghton, J. R., Rowe, G., Frewer, L. J., Van Kleef, E., Chryssochoidis, G., Kehagia, O., Strada, A. (2008). The quality of food risk management in Europe: Perspectives and priorities. Food Policy, 33, 13–26.
- House of Lords (UK). (2014). Counting the Cost of Food Waste : EU Food Waste Prevention.
- Houses of the Oireachtas (Ireland). (2009). Report on the Contamination of Irish Pork Products. Joint Committee on Agriculture, Fisheries and Food, First Report, May 2009, PRN No. A9/0686.
- ICF GHK. (2013). Consumer Willingness to Pay for Food safety health outcomes.
- Jia, C., & Jukes, D. (2013). The national food safety control system of China – A systematic review. Food Control, 32(1), 236–245.
- Kobusch, A. (2010). Linking the levels: independence and influence in the European two-tiered network of food safety agencies. Universität Tübingen.
- Kobusch, A., & Abels, G. (2010). Regulation of food safety in the EU: Changing patterns of multi-level governance. Universität Tübingen.
- Leon-Guzman, M. (2011). L'obligation d'auto-contrôle des entreprises en Droit européen de la sécurité alimentaire.

- Marvin, H. (2007). Identification of Emerging Food Safety Risks: new developments.
- Mathieu, E. (2014). Networks, committees or agencies ? The many faces of the EU regulatory space. German Research Institute for Public Administration Speyer (GRIP), (June), 1–27.
- National Audit Systems Network. (2014). Auditing effectiveness of official control systems.
- OECD. (2014a). OECD Framework for Regulatory Policy Evaluation. OECD Publishing.
- OECD. (2014b). OECD Regulatory Compliance Cost Assessment Guidance. OECD Publishing.
- OECD. (2014c). Health at a Glance: Europe 2014. OECD Publishing
- Office for National Statistics. (n.d.). Administrative Burdens of Regulation – Office for National Statistics.
- Prechal, S., & Leeuw, M. E. De. (n.d.). Transparency : A General Principle of EU Law?, (April 2008).
- Primary Food Processors (PFP). (2013a). Concerns for Primary Food Processors with regards to the scope of the definition of Novel Food in the proposal for a Regulation of the European Parliament and of the Council on Novel Foods COM (2013) 0894.
- Primary Food Processors (PFP). (2013b). The views of the EU Primary Food Processors on the European Commission's Package on Official Controls.
- Rodríguez Font, M. (2012). The "Cucumber Crisis ": Legal Gaps and Lack of Precision in the Risk Analysis System in Food Safety. Rivista Di Diritto Alimentare, (Anno IV, numero 2).
- SIRA consulting. (2013). The CAR-Methodology applied to SME bakeries and a Scoping Comparison of Regulatory Burden in four EU Member States Final Report.
- Stakeholder Dialogue Group on Food Sustainability. (2014). Actions towards a more sustainable European food chain.
- Stéphanie Vanhaeren. (2011). Risk communication and food safety policies: conflicting claims about bisphenol A.
- Szajkowska, A. (2012). Regulating food law. Wageningen Academic Publishers.
- The European Files. (2011). Food safety in Europe: developments and prospects, (23).
- Thomson, B., Poms, R., & Rose, M. (2012, June 3). Incidents and impacts of unwanted chemicals in food and feeds. Quality Assurance and Safety of Crops & Foods.
- UEAPME. (2014a). Position Paper - UEAPME position on the Discussion Paper on the REFIT Fitness Check of Regulation (EU) No 178/2002 and proposal for a study (Vol. 32).
- UEAPME. (2014b). Position Paper - UEAPME position on the Stakeholder Consultation on HACCP (Vol. 32).
- Van der Meulen, B. (2006). The system of food law in the European Union.
- Van der Meulen, B. (2010). The Function of Food Law - On the objectives of food law, legitimate factors and interests taken into account. EFFL, (2), 83–90.
- Van der Meulen, B. (ed.) (2011): Private food law: Governing food chains through contract law, self-regulation, private standards, audits and certification schemes.
- Van der Meulen, B. (2013). The Structure of European Food Law. Laws, 2(2), 69–98.
- Varzakas, T., & Jukes, D. (2006). The role of the Hellenic Food Safety Authority in Greece—Implementation strategies. Food Control, 17(12), 957–965.
- Wifo-CEPS. (2006). Pilot project on administrative burdens.
- Wijnands, J. H. M., van der Meulen, B., & Poppe, K. J. (2006). Competitiveness of the European Food Industry: An economic and legal assessment.