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**COMMISSION STAFF WORKING DOCUMENT**

**THE REFIT EVALUATION**

**of the**

**General Food Law (Regulation (EC) No 178/2002)**

{SWD(2018) 37 final}

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## ABBREVIATIONS

AAC	Administrative Assistance and Cooperation
AHL	Animal Health Law
BSE	Bovine Spongiform Encephalopathy
BTSF	Better Training For Safer Food Programme
CAP	Common Agricultural Policy
Competitiveness study	The competitive position of the European food and drink industry, ECSIP consortium, Rotterdam, February 2016, published at <a href="http://ec.europa.eu/growth/sectors/food/competitiveness/studies/index_en.htm">http://ec.europa.eu/growth/sectors/food/competitiveness/studies/index_en.htm</a>
CV	Curriculum vitae
DG GROW	Commission Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
DG RTD	Commission Directorate-General for Research and Innovation
DG SANTE	Commission Directorate-General for Health and Food Safety
DoI	Declarations of interest
<i>E. coli</i>	Escherichia coli
ECDC	European Centre for Disease Control
ECHA	European Chemicals Agency
EEN	European Enterprise Network
EFSA	European Food Safety Authority
EFTA	European Free Trade Association
EMA	European Medicines Agency
EP	European Parliament
EQ	Evaluation questions
EWRS	Early Warning and Response System
EU	European Union
FAO	United Nations Food and Agriculture Organisation
FBOs	Food and feed business operators
FCEC	Food Chain Evaluation Consortium
FFN	Food Fraud Network
FTE	Full Time Employees
FVO	Audit and inspection service of the Commission Directorate-General for Health and Food Safety ('DG SANTE'), formerly known as the 'Food and Veterinary Office'
GBP	Great Britain Pound
General GFL study	Study on the evaluation of Regulation (EC) No 178/2002 ("the General Food Law Regulation"), final report, FCEC consultants, 2015
GFL	General Food Law (Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety)
GFSI	Global Food Safety Initiative
GLP	Good Laboratory Practice
GMOs	Genetically modified organisms
HACCP	Hazard Analysis and Critical Control Point
HLG	High Level Group on Better Regulation, European Commission
HSN	Health Security Network, established by Decision 1082/2013/EU on cross-border threats to health

IFGT	Institute of Food Technologists
INFOSAN	International Food Safety Authorities Network
IT	Information Technology
IPPC	International Plant Protection Convention
IOs	Information Obligations
ISO	International Organisation for Standardisation
ISG	Inter-service Steering Group
JRC	Joint Research Centre
MRLs	Maximum residue levels
MS	Member States
MS CAs	Member States' competent authorities
NCPs	National contact points (RASFF)
NGOs	Non-governmental organisations
OECD	Organisation for Economic Cooperation and Development
OIE	Office International des Epizooties (World Organisation for Animal Health)
PAFF	Standing Committee on Plants, Animals, Food and Feed
PPP	Plant Protection Products
QMS	Quality Management System (EFSA)
RASFF	Rapid Alert System for Food and Feed
RASFF study	Evaluation of the Rapid Alert System for Food and Feed and of crisis management procedures, final report, FCEC consultants, 2015
REFIT	Regulatory Fitness and Performance Programme of the European Commission
ROI	Return on investment
SCM	Standard Cost Model
SG	Secretariat-General of the European Commission
SMEs	Small- and Medium-sized Enterprises
SOPs	Standard Operating Procedures
SPS	Agreement on Sanitary and Phytosanitary measures
STEC	Shiga toxin-producing Escherichia coli
SWD 2013	Commission Staff Working Document, 'A fitness check of the Food Chain – State of play and next steps', SWD(2013)516, dated 5.12.2013
SWOT	Strengths-Weaknesses-Opportunities-Threats
TFEU	Treaty on the Functioning of the European Union
ToR	Terms of reference
TSE	Transmissible Spongiform Encephalopathies
TTIP	Transatlantic Trade and Investment Partnership
TRACES	Trade Control and Expert System
USD	US Dollars
vCJD	variant Creutzfeldt-Jakob Disease
WTO	World Trade Organisation
WHO	World Health Organisation

## COMMISSION STAFF WORKING DOCUMENT

### Fitness Check of the General Food Law (Regulation (EC) No 178/2002)

## 1 Introduction

### 1.1 Purpose of the evaluation

Under its Regulatory Fitness and Performance Programme ('REFIT'), the European Commission ('Commission') has been reviewing existing Union legislation in selected policy fields through 'fitness checks'. Fitness checks aim at keeping current legislation 'fit for purpose' by identifying excessive burdens, overlaps, gaps, inconsistencies or obsolete measures, which may have appeared over time since the Union legislation was first adopted and implemented.

Our food requires constant attention to ensure its fitness for human consumption; so does our food legislation in terms of its fitness to ensure a high level of public health and consumers' interests as well as the effective functioning of the internal market. Given the variety and number of EU acts in the area of food law, the Commission considered that a "**cascade**" approach to the evaluation of the overall body of EU food law was appropriate.

To this end, the Directorate-General Health and Consumers of the Commission carried out a mapping exercise of all EU food chain law legislation, between November 2011 and July 2013, initiating the first phase of a series of evaluations covering the food chain. This mapping was summarised in the document, a 'fitness check of the Food Chain' – State of play and next steps ('SWD 2013').<sup>1</sup>

On 2 October 2013, the Commission decided to carry out a comprehensive evidence-based policy evaluation ('Fitness Check') of Regulation (EC) No 178/2002 on General Food Law ('GFL')<sup>2</sup> for the entire food and feed sector, under the Regulatory Fitness and Performance Programme (REFIT), launching the second phase of EU food chain law evaluations.<sup>3</sup>

The GFL Regulation, adopted in 2002, has been selected for a fitness check for a number of reasons: it constitutes the foundation of the EU food and feed policy; no thorough impact assessment had been carried out prior to its adoption and it has never been evaluated since its adoption; and, last but not least, it regulates an economically and socially important sector, the food chain.

The objective of this Fitness Check is to evaluate whether the legislative framework introduced by the GFL Regulation is 'fit for purpose', taking into account the findings of the SWD 2013. The evaluation analyses whether the GFL Regulation still achieves its objectives in relation to human health, consumers' interests and the internal market and whether it reflects policy trends of today, taking into account developments at Union and international level. Being a REFIT initiative, the evaluation also examines whether there are any inconsistencies, overlaps or gaps as well as whether there is potential for simplification and reduction of regulatory costs and burdens with respect to its implementation by means of other EU secondary food legislation in the area of food chain law.

The findings of this Fitness Check will support the evidence-base of more sectorial evaluations of food chain law, which are either currently being carried out or are planned in the near future, where relevant.<sup>4</sup> These sectorial evaluations will constitute the third phase of the "cascade" approach followed to evaluate the overall body of EU food legislation in place.

## 1.2 Scope of the evaluation

The present Fitness Check focuses on the GFL Regulation, which is the **foundation of food law**.<sup>5</sup> It **elaborates on the main elements** that it has introduced, namely:

- the general principles, responsibilities and requirements governing food and feed in general, and in particular food and feed safety, as well as the common definitions and general objectives of food law;
- the establishment and the functioning of the European Food Safety Authority ('EFSA'), which aims at ensuring a strong science-based decision-making process in the context of the risk analysis principle; and,
- the main tools for food safety and the management of food alerts – Rapid Alert System for Food and Feed ('RASFF') – as well as the tools for the management of emergencies and crises, including the management of food alerts – Rapid Alert System for Food and Feed ('RASFF').

Because of the nature of the GFL Regulation as a framework legislation underpinning all legal measures taken both at Union and national level in the area of food law,<sup>6</sup> this Fitness Check cannot be performed in isolation. Therefore, it **also assesses the implementation of the main elements** of the GFL regulatory framework in **other secondary EU food legislation**, so as to assess the cumulative effects and potential overlaps and inconsistencies that may have been created by the overall legislative framework.

In that respect, the Fitness Check has identified **29 legislative (basic) acts in the area of food law**, introduced after the adoption of the GFL Regulation, which incorporate and further implement the common definitions, certain general principles (*i.e.* risk analysis principle, reliance upon international standards, protection of consumers' interests) and certain general requirements (*e.g.* primary responsibility of FBOs) of the latter framework. Moreover, as required by the GFL Regulation, pre-existing food law principles and procedures both at Union and national level were required to be adapted by January 2007 to the general principles of the GFL Regulation. To this end, EU secondary food legislation that pre-existed the GFL Regulation was either automatically aligned to the new regulatory system of scientific assessment by EFSA<sup>7</sup> or adapted accordingly.<sup>8</sup> The Fitness Check also assesses the implementation of the GFL framework in those pre-existing EU food-related basic acts (see Appendix 1). It does not, however, **assess other EU secondary food legislation as such**, but only to the extent **the latter implements the GFL framework**.

The scope of the Fitness Check, as elaborated above, allows an in-depth evaluation as to whether the legislative framework underpinning food law is still relevant and fit for purpose before muscling into the details of the EU sectorial food legislation. This evaluation addresses questions that pertain to the fitness of the GFL Regulation as the foundation of the food law. For example: Does it make sense to have common definitions across EU food law? Is the risk analysis principle still appropriate in the decision making process in food law? Have the general requirements of traceability and primary responsibility ensured the objectives of high level of protection of human health while ensuring the effective functioning of the internal market? Or is another legislative model for EU food law needed?

In addition, this evaluation explores whether there is potential for simplification and the reduction of regulatory costs and burdens, with a particular focus on small- and medium-sized enterprises ('SMEs'), as far as the requirements stemming from the GFL Regulation are concerned.



As mentioned earlier, the findings of the present Fitness Check will feed into the pending or future sectorial evaluations of other EU secondary food legislation.

The main data collection tools supporting this Fitness Check on the GFL Regulation cover the period 2002-2013 in the EU 28 Member States ('MS'), as the main two external studies were carried out in the period 2014-2015. With respect to EFSA and for the purposes of the Fitness Check, the Commission produced an internal intermediary report which updates the last mandatory evaluation of EFSA from 2012 to cover the period up to 2013-2014. Where significant, more recent data available has also been taken into account.

## 2 Background to the GFL Regulation

For the purposes of this Fitness Check, the point of reference chosen is the situation prior to the GFL Regulation in order to assess the progress made.

### 2.1 Baseline (before 2002)

On the **economic front**, by 2000, the food and drink industry was already the leading industrial sector in the EU, with an annual production worth almost €600 billion, or about 15% of total manufacturing output. The EU was considered as the world's largest producer of food and drink products. Moreover, the food and drink industry was the 3<sup>rd</sup> largest industrial employer of the EU with over 2.6 million employees, of which 30% were in SMEs.<sup>9</sup>

On the **legislative front**, by 2002, the EU had a broad body of legislation which covered primary production of agricultural products and production of processed food. It was developing, however, **from different legal bases in the Treaty, to serve different policy objectives**: either the implementation of the Common Agricultural Policy (CAP) or the completion of the internal market by removing obstacles to the free movement of goods, taking into account international standards (*e.g.* Codex Alimentarius<sup>10</sup>, World Organisation for Animal Health ('OIE') standards<sup>11</sup>). The pursuit of a **high level of protection of human health and consumers' interests was not**, however, an **explicit overriding objective** of the EU food legislation.

EU food law **was a patchwork of vertical legislation**, which did not share the same definitions, nor the same principles and procedures. For example, there was no EU definition of the term 'food'. Discrepancies between the different national definitions were negatively affecting the functioning of the internal market and the coherence of EU food law.<sup>12</sup> Moreover, there was no overarching principle at EU level that only safe food and feed may be placed on the market.

The fragmentation of EU food law and of the responsibilities amongst the Commission services in charge of food law aspects resulted also in inconsistencies in the approach followed: for example, the rules concerning official controls on live animals and products of animal origin were more detailed than the rules governing official controls on food. The Commission had no legal instrument to adopt an **emergency measure** upon its own initiative either for feed or for a processed food of non-animal origin originating from one of the MS<sup>13</sup>, although it was competent to act for food of animal origin. Even where such instruments existed, the mechanisms for their adoption were different, resulting in overlaps and inconsistencies. This fragmented approach was further complicated by issues of interpretation as regards the competence of the Commission to act.<sup>14</sup>

Where **implementing powers** were conferred to the Commission, decision-making was not satisfactory, *e.g.* disparity of applicable procedures and modalities, involvement of different committees (composed of representatives of the MS) on the same topic<sup>15</sup>, scarce and scattered resources, sectorial approach with no holistic view on the entire food chain.<sup>16</sup> As such, inconsistencies and overlaps occurred.

**Public consultation of stakeholders** during the preparation, evaluation and revision of food law at EU level was not systematic, but optional. In that respect, two advisory committees composed of stakeholders (*e.g.* trade, industry and consumer groups) had been set up: the Advisory Committee on Foodstuffs<sup>17</sup> for matters relating to the internal market of foodstuffs; and, the Advisory Committee on Agricultural Product Health and Safety as well as certain standing groups attached to it (veterinary matters, plant health, animal welfare, feed) for matters covered by the common agricultural policy.<sup>18</sup> Similarly at national level, public consultation was quite variable and highly dependent on national traditions and cultures.<sup>19</sup> The extent to which Member States provided information to the public on food safety matters and the circumstances under which this was occurring was also variable and piecemeal.<sup>20</sup> This had a negative impact on consumers' trust on food safety.

The **first major food crisis** that demonstrated the limitations of the EU food law at that time, as regards food safety and the lack of structured risk analysis in the EU decision-making, was the Bovine Spongiform Encephalopathy (**'BSE'**) crisis that struck the UK in 1995.<sup>21</sup> The BSE crisis, first and foremost, had a **direct impact on human health**: 175 cases of variant Creutzfeldt-Jakob Disease (vCJD) were reported in the UK and 49 cases in other countries from October 1996 to March 2011. It also resulted, amongst others, on a ban on the export of British beef, which remained in place for almost ten years. The EU beef market was pushed to the verge of collapse almost overnight as consumers' trust plummeted. In the period 1996-2006, the net cost borne by the EU budget alone for the BSE measures implemented was estimated at €6.9 billion.<sup>22</sup> This amount does not include the costs borne by the Member States themselves (*e.g.* it was estimated that the net loss to the UK economy in the first 12 months after the onset of the BSE crisis was between GBP 740 and 980 million)<sup>23</sup>, or the loss in earnings due to the drop in consumption or lost markets, or the impact on employment.<sup>24</sup> Almost 20 years since the emergency of the BSE crisis, its effects are still not fully overcome.

Given the magnitude of the effects of the BSE crisis, **the overall system was heavily criticized**. The Medina Ortega Report of the European Parliament in relation to the BSE crisis<sup>25</sup> identified the weaknesses of the existing regulatory framework at that time, which prevented an earlier identification that a new animal disease was transmissible to humans: poor internal management within the Commission; lack of transparency and openness in the central decision-making procedures; an unclear and unbalanced relationship between scientific opinions and political decisions; undue weight given to narrow national sectorial interests; poor implementation of the EU legal provisions on official controls. For instance, the national and EU (Scientific Committees) assessors as well as the EU and national risk managers were not sharing information amongst themselves. But most importantly, national governments had made a partial and biased reading of the advice and warning of the scientists while obstacles were put in the path of scientists adopting more critical attitudes to the inadequacy of the precautions being taken and as such, public health concerns were not taken sufficiently seriously in risk management decisions. This was due to the fact that scientific advice was not independent from risk management.<sup>26</sup>

In response to the BSE crisis, the Commission published in 1997 a **Green Paper** on the General Principles of Food Law in the European Union<sup>27</sup>, launching a public debate on the future orientation of the EU food law. This was followed by the **Communication on Consumer Health and Safety**<sup>28</sup>, which outlined a new organisation of the Commission services, of the scientific system supporting the Commission across all policies, and of the control and inspection services ('1997 reform').

Pursuant to the 1997 reform, scientific opinions were provided by eight sectorial Scientific Committees, five of which covered the agri-food area,<sup>29</sup> while an additional Scientific Steering Committee was providing advice on multidisciplinary matters and coordinated the different Scientific Committees. The scientific Committees were composed of independent scientific experts<sup>30</sup>, and their work was supported by a Commission Directorate of around 40 staff. In the period June 1997–January 2000, those Committees had provided 256 opinions.<sup>31</sup> Despite the reform in 1997, certain shortcomings remained:<sup>32</sup>

- **A global high-quality scientific view of the food chain was not guaranteed** at all times. Not all EU food legislation was adequately based on independent scientific advice. Even in the areas where consultation was mandatory, the system of scientific committees lacked the capacity to provide the necessary scientific advice: it was struggling to cope with the increase in the demands placed upon it, both in relation to the safety evaluation of scientific dossiers and to the assessment of broader public health issues. This lack of capacity led to delays with negative consequences both for the Commission's ability to respond to consumer health problems through legislative initiatives and for the industry where commercial dossiers were involved. In addition, it was not always clear whether scientific advice was given appropriate weight in the decision-making process.
- Risk assessment **was not organised independently from the risk management**: the Scientific Committees, operating under the auspices of the Commission, had no autonomous funding and they continued to work on the basis of mandates, lacking any authority to self-task or of risk communication at its own initiative.
- Access to scientific data and knowledge needed for a high-quality risk assessment and to better identify emerging risks was not ensured as specific support mechanisms for the provision of accurate, up-to-date scientific data as well as scientific networks with Member States to support the Scientific Committees barely existed. Links with international risk assessment bodies were also lacking. This had a negative impact on the robustness of the scientific advice, where provided.
- There were no links established between the EU Scientific Committees and the national and international scientific food safety bodies.
- The fact that EU legislation was not systematically underpinned by scientific advice had also an **impact on international trade**; for instance, the EU was increasingly required to provide scientific justification for its measures at international level, which diverged from international standards.
- Public opinion was also becoming increasingly sensitive, following the BSE crisis, to the emergence of new risks relating to environment or health, for which scientific research had not yet been able to fully illuminate the problems (*e.g.* BSE being able to also be transmitted to humans). The BSE crisis demonstrated the **lack of a specific tool to allow decision makers to adopt provisional measures without having to wait for full scientific knowledge**.
- Lack of transparency in the entire decision-making cycle of EU food law.

A second food crisis occurred in 1999: **the Belgian dioxin crisis**. Dioxin was introduced into the Belgian food chain, through contaminated fat used in animal feed supplied to Belgian, French and Dutch farms. Meat products from poultry, pigs and cattle as well as eggs were contaminated with high levels of dioxin, endangering human health. The food crisis had a considerable negative impact on the Belgian meat industry, which exported at the time half of its products. The losses for the Belgian economy together with a temporary disturbance of the food sector were estimated at €1.5-2 billion.<sup>33</sup>

The Belgian dioxin crisis confirmed a **lack of an integrated approach** across the entire food chain. EU food law was not recognising the inextricable link between feed and food despite the inherent risk to feed to pass diseases to, or contaminate food-producing animals and food. Feed businesses were not subject to similar requirements and controls as the food businesses (*e.g.* no legal requirement imposing internal controls and contingency plans). It further demonstrated the following additional shortcomings in the existing system:

- There was **no general traceability requirement covering the entire food chain, including feed**. A specific traceability regime existed only in the beef sector<sup>34</sup>, following the BSE crisis. Feed and food business operators ('FBOs') therefore were applying traceability on a voluntary basis only. Although it is not possible to provide a global estimate on the rate of application of traceability in the feed and food sector prior to 2002, according to the General GFL survey, 44.2% of food and feed business operators indicated that they were applying traceability on a regular basis and another 38.5% were applying it but not in a systematic manner, prior to 2002.<sup>35</sup> Because of the lack of traceability, it took approximately 6 months to identify the FBOs and the products concerned. But even then, there was still uncertainty about the real extent of the dioxin contamination; as a result, extensive and unnecessary withdrawals of suspected foods of animal origin took place and an embargo on all Belgian food products of animal origin was imposed by EU and non-EU countries.
- There were **no established procedures** to be followed **as regards crisis management**, *e.g.* coordination tools and the possibility of a quick scientific advice as regards the risk involved. As a result, the Belgian dioxin crisis was managed on *ad hoc* basis and in an informal way, with the Commission and the Member States being uncertain about the role each of them had to fulfil. This aggravated the disruptions to trade both within the EU and in the international area while consumers' trust was shaken.

Similarly, **the existing surveillance system was also not fully effective** before 2002 and did not allow the detection of BSE or the dioxin issues. Originally established by Decision 84/133/EEC, the Rapid Alert System concerning notifications of risks amongst MS was integrated into Council Directive 92/59/EC on General Product Safety and it covered both food and non-food products. It required the notification of 'serious and immediate risk' going beyond country borders. The Rapid Alert System did not, however, cover live animals and feed. Therefore, it was not involved in the BSE crisis, while in the context of the Belgian dioxin crisis, it was only notified when the dioxins were discovered in the meat and not when the animals were becoming sick. Notifications on border rejections and informing non-EU countries about food risks were carried out on a voluntary basis.<sup>36</sup>

By 2002, consumers had **no confidence that public health** in relation to the consumption of foods was an absolute priority at all times in EU food law. This loss of consumers' trust had a negative

impact on the proper functioning of the internal market, e.g. ban on British beef, bans on Belgian produce implicated in the dioxin crisis.

It therefore became apparent that the **Union needed to develop a new coherent legislative framework** that would strengthen EU food law – especially food safety requirements – and provide a strong foundation for the further development of the EU agri-food sector. Such a policy needed to be based on a preventive approach which would recognise the inter-linked nature of the food chain.

In 2000, the Commission published its White Paper on Food Safety<sup>37</sup>, which announced the revamp of the EU food policy with the imminent adoption of the GFL Regulation along with a considerable number of new legislative actions to improve food safety standards. It was recognised that the effective functioning of the internal market for food may only be achieved if there is a high degree of EU harmonisation at all stages of the food chain.

**2.2 Adoption of the GFL Regulation**

The GFL Regulation was adopted in 2002 setting out a comprehensive harmonised legal framework, addressed to EU institutions and Member States as well as to FBOs. It covers the entire food chain, i.e. all stages of production, processing and distribution of food and feed, including import (**'farm to fork' approach**). It follows a framework approach providing the basis for developing both EU and national food law.

**Figure 1:** GFL at a glance

<b>GFL at a glance</b>	
Core objectives	<ol style="list-style-type: none"> <li>1. High level of protection of human health and consumers' interests</li> <li>2. Effective functioning of the internal market</li> </ol>
Common definitions	'food', 'food law', 'food business', 'food business operator', 'feed', 'feed business', 'feed business operator', 'retail', 'placing on the market', 'risk', 'risk analysis', 'risk assessment', 'risk management', 'risk communication', 'hazard', 'traceability'
General principles	<ol style="list-style-type: none"> <li>1. Risk analysis principle               <ol style="list-style-type: none"> <li>a. Risk assessment: Scientifically-based process consisting of four steps, i.e. hazard identification, hazard characterisation, exposure assessment and risk characterisation. At EU level it is carried out by European Food Safety Authority (EFSA);</li> <li>b. Risk management: Measures to take into account risk assessment as well as other legitimate factors and, where appropriate, the precautionary principle;</li> <li>c. Risk communication: Interactive exchange of information and opinions throughout the risk analysis process.</li> </ol> </li> <li>2. Principle of protection of consumers' interests</li> <li>3. Principles of transparency: Public consultation and public information</li> </ol>

	4. International standards to be taken into account in the development of EU food law	
General requirements	On FBOs	<ol style="list-style-type: none"> <li>1. Primary responsibility of FBOs (compliance and own controls)</li> <li>2. Safety requirements of food and feed</li> <li>3. Withdrawal of unsafe food and feed</li> <li>4. Traceability for food safety purposes</li> <li>5. Imported food and feed to comply with EU food law</li> <li>6. Exported food and feed to comply with EU law or requirements set up by the Non-EU importing Country</li> </ol>
	On MS CAs	Carry out official controls
Tools for the prevention and management of food crises	<ol style="list-style-type: none"> <li>1. RASFF</li> <li>2. EU or national emergency measures</li> <li>3. General plan for crisis management</li> <li>4. Crisis Unit</li> </ol>	

**Core objectives**

It has two core objectives: (a) a high level of protection of **human health and consumers' interests** in relation to food at all times both at EU and national level; and, (b) the **effective functioning of the internal market**.

**Common definitions**

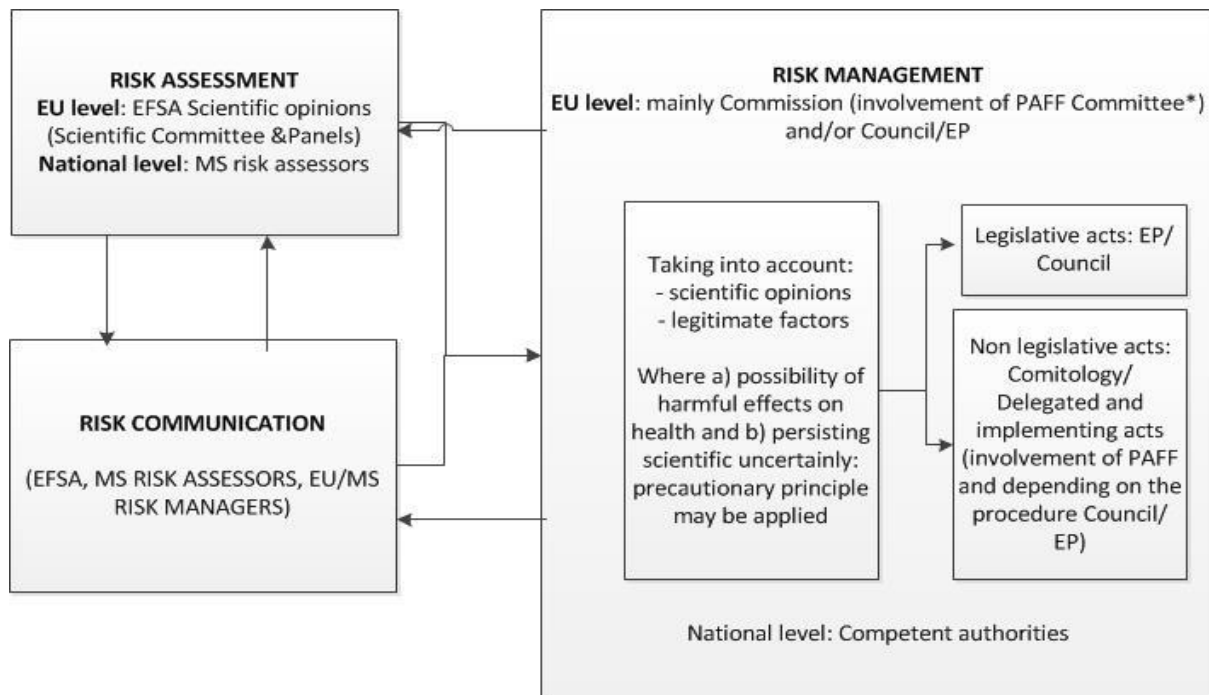
To meet these objectives, it sets out **common definitions** to be relied upon in all future EU and national food law. A common definition of 'food' and 'food law' was laid down for the first time.

**General principles**

The GFL Regulation establishes **certain general principles** to underpin all future EU and national food law.

The most important of these is the **risk analysis principle**, part of which is also the **precautionary principle**. The risk analysis principle consists of three separate but interrelated components: risk assessment, risk management and risk communication. These three components are not always subsequent phases of a linear 'risk analysis' process (see Figure 2). As regards EU measures, the GFL Regulation requires the Commission, the MS and EFSA to cooperate so as to ensure the coherence of the risk analysis process.

**Figure 2:** Overview of the risk analysis principle



\*PAFF committee: Committee composed of MS Representatives

- a) **Risk assessment:** Risk assessment at EU level is to be carried out by an autonomous agency, the European Food Safety Authority (EFSA), separately from the risk management function of the EU Institutions (and mainly that of the Commission). Its primary mission is to provide scientific advice at the request of the Commission, Member States and the European Parliament and on its own motion ('self-tasks'). Its mandate is broad and covers: all issues impacting directly or indirectly on food and feed safety (including the safety evaluation of dossiers put forward for the approval of substances); animal health and animal welfare; plant health; human nutrition; and GMOs issues. In addition, EFSA is entrusted with the tasks to collect and analyse data linked to the safety of the food chain, to provide technical support to the Commission, to identify emerging risks and provide scientific support in case of crisis. EFSA is also responsible for providing the public with information concerning risk assessments. The GFL Regulation also sets out specific provisions on its independence, *e.g.* EFSA's management board not representing national governments, declarations of interests of EFSA's experts and members of its management bodies. Other GFL provisions ensure the openness and transparency of EFSA's operation, *e.g.* publication of scientific opinions, declarations of interests being public. Scientific cooperation with the Member States is ensured, amongst others, through the EFSA Advisory Forum, composed by representatives of the national risk assessment bodies. A more complete presentation of EFSA's work is to be found in Appendix 7. The GFL Regulation does not include details on how risk assessment is conducted at national level.
- b) **Risk management:** Risk managers are responsible for taking appropriate measures. To do so, they are required to take into account EFSA's opinions but also other legitimate factors and, where appropriate, the precautionary principle. The GFL Regulation does not define exhaustively the **legitimate factors** to be taken into account: an indicative list includes societal, economic, traditional, ethical and environmental factors as well as the feasibility of controls. To address cases where (i) following an assessment of available information, the possibility of harmful

effects on health has been identified and (ii) scientific uncertainty persists, the GFL Regulation provides that risk managers **may opt** to adopt **provisional risk management measures** on the basis of **the precautionary principle (optional use)**.<sup>38</sup> Risk management measures can take different forms varying from information campaigns to bans and withdrawals of products from the market. When, however, provisional measures are taken on the basis of the precautionary principle, these must be proportionate and must be reviewed as soon as new scientific evidence becomes available. In any event, the application of the precautionary principle is part of the risk management process and not an alternative to the latter or to the use of risk assessment to underpin decision-making. For the **development of EU measures** in the food chain, risk management is entrusted mainly to **the Commission**, as well as to the **Council and the European Parliament (EP)** in certain cases depending on the subject-matter at issue. The Commission in particular is assisted by a **single and overarching Committee for the entire food chain**, currently called the Standing Committee on Plants, Animals, Food and Feed (**PAFF**)<sup>39</sup>, composed of representatives of Member States, in accordance with the applicable comitology procedures.<sup>40</sup> The PAFF Committee replaced four pre-existing Standing Committees on Foodstuffs, the Standing Committee for Feeding-stuffs, the Standing Veterinary Committee as well as the Standing Committee on Plant Health as regards regulatory activities relating to plant protection products and the setting of maximum residue limits. Its mandate covers the entire food and feed chain as well as animal health and plant health issues. As such, it is divided into 14 different sections, of which the first one covers issues related to the GFL Regulation. For **national measures** in the same area, risk management is **entrusted to the Member States**.

- c) *Risk communication*: It is defined as the interactive exchange of information and opinions throughout the risk analysis process as regards hazards and risks, risk-related factors and risk perceptions amongst risk assessors, risk managers, consumers, FBOs, the academic community, including the explanation of risk assessment findings and the basis of risk management decisions. This task is a **shared competence between EFSA and the risk managers (EU and MS)**. Risk communication plays an important role in maintaining consumers' trust (especially in light of the volatility of consumers' trust in the area of food and feed) as well as in avoiding unsubstantiated criticisms of the role of science in decision-making.

Other general principles include: the principle of **protection of consumers' interests**, the principle of **public consultation** throughout the decision-making cycle, the right of the **public to be informed** where there are reasonable grounds to suspect that a food may present a risk to health (public information) as well as the requirement that **international standards** must be taken into account in the development of EU food law, where relevant.

### **General requirements**

The GFL Regulation provides certain **general requirements** to strengthen compliance in the field and prevent food crises. These are **goal oriented** as they only provide the objective to be achieved and not the means. The means are left to the addressees (and in particular to the FBOs), who decide on the best way to meet the objective.

1. The GFL Regulation sets out **the primary responsibility** of FBOs: they must (a) ensure compliance with all EU and national food law that is relevant to their activities and within the businesses



under their control and (b) perform their own controls. This is a key element in the prevention of food crises as it introduces multiple control points throughout the food chain.

2. Food placed on the market must be safe, *i.e.* food must not be potentially injurious to health or unfit for human consumption (**food safety requirement**). Similarly, feed placed on the market must be safe (**feed safety requirement**).<sup>41</sup>
3. Where FBOs consider or suspect that food or feed is not safe, they must **withdraw or recall**<sup>42</sup> such products and notify the competent authorities under certain conditions ('withdrawal requirement').<sup>43</sup>
4. All FBOs must be able to identify from whom and to whom a product has been supplied (**'one step back – one step forward' traceability**) and to have systems and procedures in place that allow for this information to be made available to the competent authorities upon request. Traceability, under the GFL Regulation, is a tool to trace food and feed **for safety purposes** and to allow appropriate action to take place, when required. The GFL Regulation does not require internal traceability (*i.e.* a link to be established between incoming and outgoing products or records identifying how batches are split or combined within a business to create particular products or new batches). Traceability requirements **for purposes other than food safety** are developed in other EU secondary food legislation in the area of food, but **fall out of the scope** of the present exercise as they are not linked with the GFL Regulation.<sup>44</sup>
5. Feed and food **imported into the EU** must comply with all requirements of EU food law.
6. Feed and food **exported from the EU** must comply with EU law or the requirements set up by the importing party. In all other circumstances, food and feed can only be exported or re-exported, if the importing country has expressly agreed. Nevertheless, even where there is express agreement of the importing country, food injurious to health or unsafe feed is prohibited to be exported from the EU.
7. National competent authorities are responsible for enforcing food law, verifying that food and feed placed on the EU market are safe and applying effective, proportionate and dissuasive measures and penalties where a violation of food law is detected.

Some of these general requirements either form part of what a legitimate FBO active in the food supply chain is in any event expected to comply with so as to remain on the market (*e.g.* for a FBO to be commercially viable in the food and drink sector, it must ensure the safety of its products or that it complies with the food law requirements applicable in the relevant markets) or consist of a codification of practices that were already applied – albeit not in a systematic manner – by FBOs prior to the GFL Regulation (*e.g.* traceability).

### **Tools for the prevention and management of food crises**

The GFL Regulation also sets out a **set of tools for the prevention and management of food crises** that build upon the traceability requirement, the primary responsibility and the official controls:

- The strengthened **Rapid Alert System for Food and Feed (RASFF)**, a network for the swift exchange of information in cases of direct or indirect risks to human health deriving from food and feed, consisting of the Commission, the MS, the EFTA Surveillance Authority and EFSA.
- EU-wide **emergency measures** may be adopted in response to food or feed originating in the EU or imported from a non EU Country that is likely to constitute a serious risk to human health, animal health, or the environment.<sup>45</sup> In addition, the GFL Regulation provides for the MS to

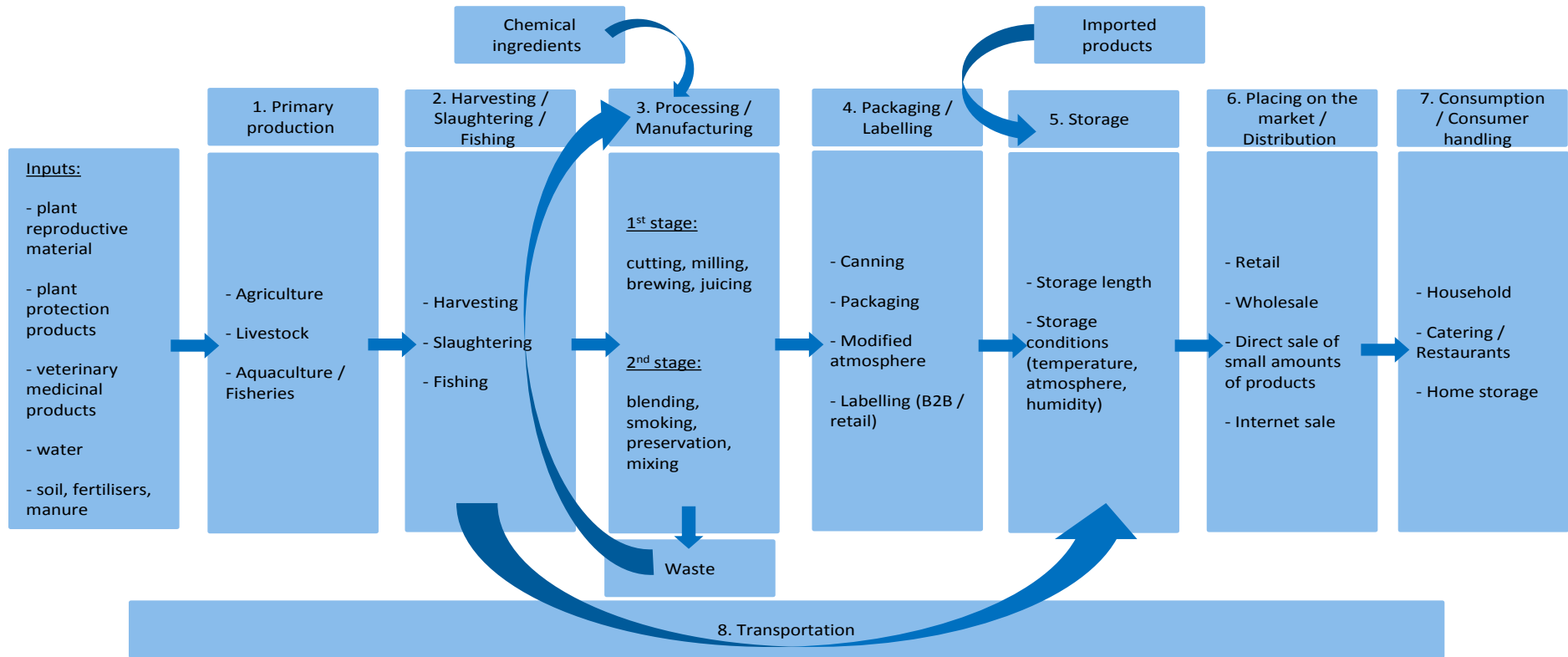
adopt national interim protective measures, should the Commission not proceed to EU emergency measures.<sup>46</sup>

- The establishment of a comprehensive plan for crisis management (**the general plan**) to specify the case where a crisis Unit is to be activated as well as the practical procedures to manage a crisis, including a communication strategy while taking into account the principle of transparency.
- The setting up of a crisis Unit, under the auspices of the Commission and with the participation of EFSA to address cases where direct or indirect risks to human health deriving from food and feed are not likely to be eliminated or reduced to an acceptable level by provisions in place or cannot adequately be managed solely by the above-mentioned emergency measures.

The GFL Regulation entered into force in 2005. By January 2007, pre-existing food law principles and procedures both at Union and national level were required to be adapted to the general principles of the GFL Regulation. To this end, EU secondary food legislation that **pre-existed the GFL Regulation** was **either automatically aligned** to the new regulatory system of scientific assessment by EFSA<sup>47</sup> or **adapted accordingly**.<sup>48</sup> In addition, the common definitions, certain general principles (*i.e.* risk analysis principle, reliance upon international standards, protection of consumers' interests) and certain general requirements (*e.g.* primary responsibility of FBOs) of the GFL Regulation **were further implemented** in **29 subsequent legislative (basic) acts** (see Appendix 1). Most of these acts were adopted in the six years following the adoption of the GFL Regulation and regulate in detail specific food law sectors (*e.g.* food improvement agents, feed materials, feed additives *etc.*) or areas (official controls). To ensure the direct application in the national legal orders, the overwhelming majority of those acts (26) are in the form of Regulations. The remaining three are Directives, which were 'recast' in 2009 with respect to the applicable committee procedures; as such no national transposition was required. Figures 3 and 4 provide an overview of the food supply chain and the applicable EU food law.

Figure 3: Overview of the food chain<sup>49</sup>

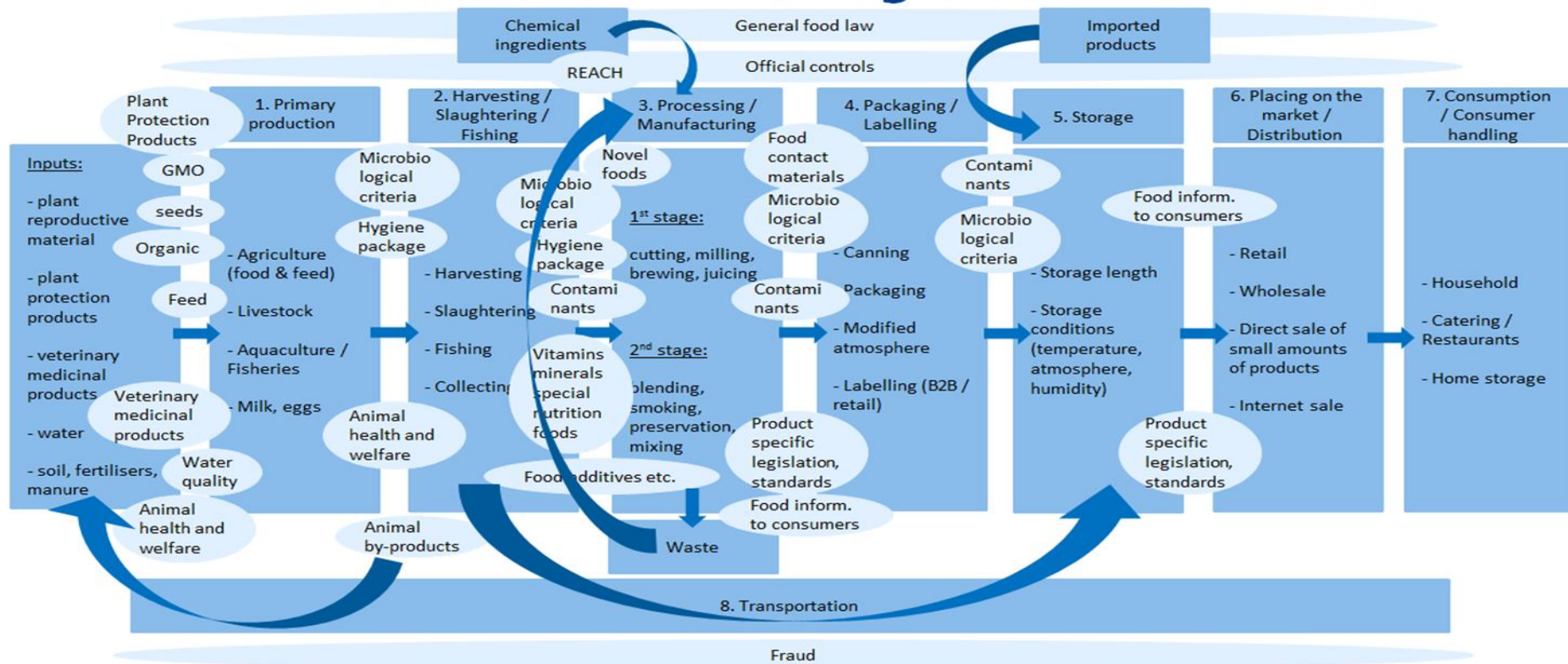
# The food chain overview



Modified from: Commission SWD (2013) 516 final 'A fitness check of the food chain: State of play and next steps'

Figure 4: Overview of the food chain system with the major EU food-related legislation<sup>50</sup>

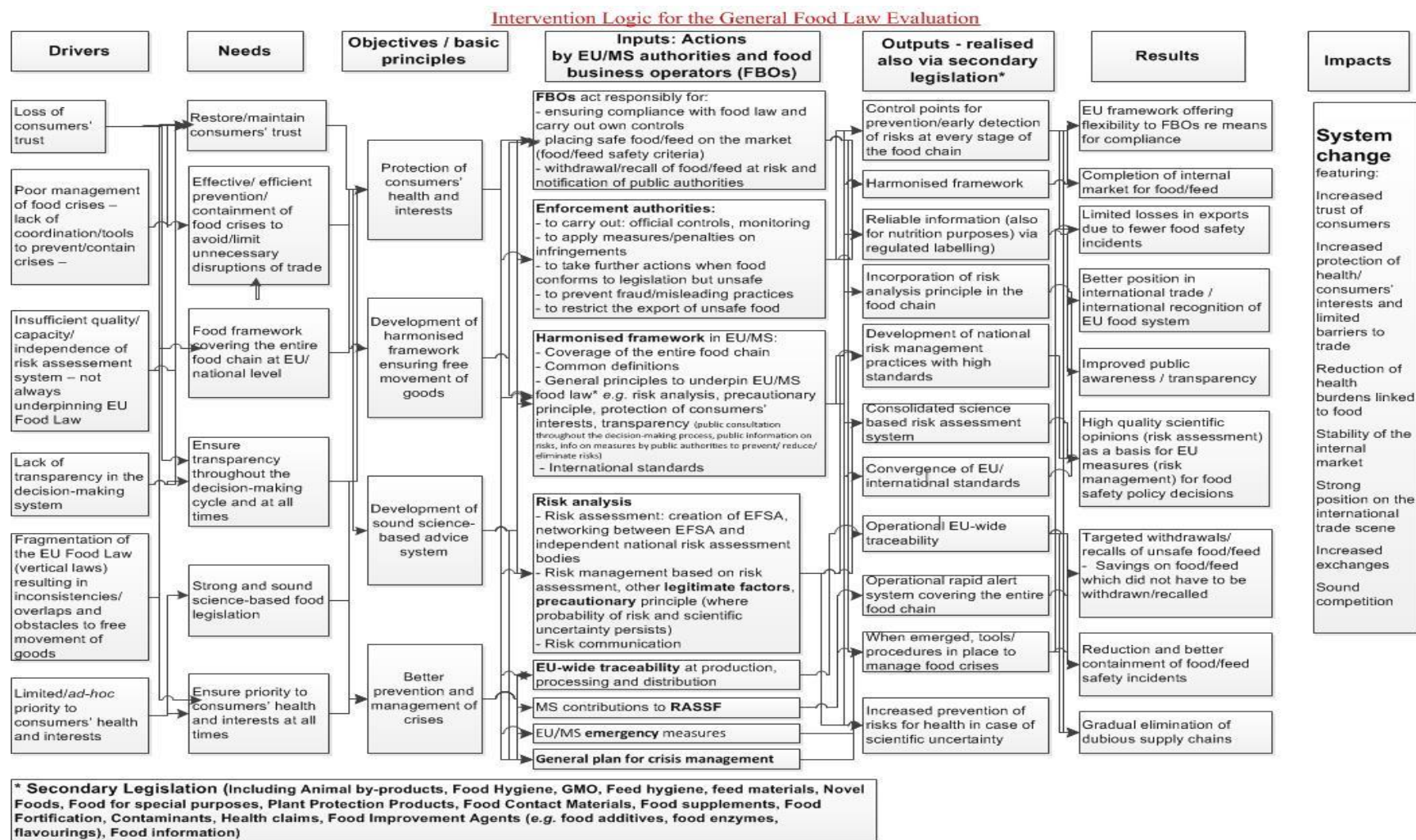
# The food chain and legislation overview



Modified from: Commission SWD (2013) 516 final 'A fitness check of the food chain: State of play and next steps'

## 2.3 Intervention logic

The intervention logic of this evaluation is presented below:



### 3 Methodology of the Fitness Check

This evaluation was carried out as a joint evaluation of the Commission and the Member States, through the High Level Group on Better Regulation ('HLG'), composed of national experts from all Member States. The Commission has made an effort to gather all available evidence from different sources and to ensure the active participation of the whole spectrum of stakeholders in the food chain (from industry players to consumer groups and NGOs) both at Union and national level, as well as national competent authorities, as elaborated below. The members of the HLG were also invited to carry out their own case-studies and consultations so as to complement the present Fitness Check.

#### 3.1 Method

To support the evaluation and to build upon the findings of the SWD 2013, the Commission procured two external studies in the period 2014-2015: (a) on the general part of the GFL Regulation, *i.e.* Articles 1-21, ('General GFL study')<sup>51</sup> and (b) on the RASFF/emergencies/crisis management provisions, *i.e.* Articles 50-57, ('RASFF study').<sup>52</sup>

EFSA's operation is subject to a mandatory external evaluation every 6 years, under the GFL Regulation. The last external evaluation of EFSA dates back to 2012, which covered the period January 2006 to December 2010 ('EFSA 2012 external evaluation').<sup>53</sup> As time had elapsed since 2010 and since the next external evaluation was scheduled for 2017-2018, the Commission proceeded to an internal intermediary report of EFSA covering the period up to 2013-2014 to support this Fitness Check. The intermediary report updates the EFSA 2012 evaluation, on the basis of input received from EFSA and MSs, taking into account the results of the Impact Assessment on the establishment of fees for EFSA.<sup>54</sup> Where significant, more recent data available has also been taken into account.<sup>55</sup>

In the context of the joint nature of the evaluation, the Commission was assisted in the two external studies and the internal intermediary EFSA report by the Expert Group on the General Food Law and the Working Group on RASFF, both composed of experts from the competent authorities of Member States. The HLG has also been invited to attend the meetings of the Expert Group on the General Food Law. A wide range of stakeholders has participated in the Fitness Check exercise through the special Working Group of the Advisory Group on the Food Chain and Animal and Plant Health. Participation in this Working Group was expanded to include stakeholders that are not formally members of the Advisory Group to ensure the broadest representation of the interests concerned possible.<sup>56</sup>

The overall approach to the evaluation was a multi-method analysis to identify quantitative and qualitative findings across the actions. Methodologies of each of the external studies were individually designed and summarised in the form of evaluation matrixes, setting out assessment criteria and indicators for each evaluation question laid down in the relevant Terms of References ('ToRs') and identifying the appropriate consultation tools and data sources per indicator (both primary and secondary sources).<sup>57</sup> Throughout the process, the methodology was continuously refined. The outcomes of the different consultation tools (opinions and evidence) were triangulated and validated with relevant stakeholders in regular phases throughout the process.

An inter-service Steering Group on this Fitness Check, composed of relevant services of the Commission, was also set up to steer, monitor and ensure the necessary quality of the two external studies and the overall process.<sup>58</sup>

Detailed procedural information and a summary of the data collection methods and consultations are provided in **Appendices 2, 3 and 4**.

### 3.1.1 Primary data collection

Primary data collection in the context of the two external studies included surveys, case studies and workshops as well as in-depth interviews.

#### Surveys

In the context of the **General GFL study**, three surveys were carried out: (1) a targeted survey of the EU28 Member State competent authorities (MS CAs) carried out between January and March 2015, to which a total of 25 MS CAs replied;<sup>59</sup> (2) a targeted survey of EU and national stakeholders (associations)<sup>60</sup> carried out between January and March 2015, to which complete replies have been provided by 67 stakeholders<sup>61</sup> (fourteen of those replies originated from associations of consumer groups and NGOs); and (3) a survey targeting individual companies and more specifically SMEs,<sup>62</sup> which took place between end of March and early June 2015 through the European Enterprise Network ('EEN') using the EU survey tool, to which 925 replies were received covering the entire food chain.<sup>63</sup> Nearly two thirds of the SME respondents were processors and manufacturers of food products. The overwhelming majority of the respondents were SMEs (94% of the respondents).<sup>64</sup> Of these, over a third were micro enterprises,<sup>65</sup> nearly another third were small-sized<sup>66</sup> and nearly a quarter were medium-sized.<sup>67</sup>

In the context of the **RASFF study**, two complementary surveys targeting (1) RASFF national contact points ('NCPs') and other stakeholders involved in RASFF and (2) relevant competent authorities in the field of food and feed crisis management and relevant stakeholders were carried out between 19 December 2014 and 27 February 2015. In addition, the Administrative Assistance and Cooperation contact points in the Member States, EU and international organisations, organisations of FBOs and consumer organisations in the EU were also consulted. In total, 75 national contact points and other stakeholders participated in the RASFF survey and 47 competent authorities and relevant stakeholders participated in the survey on crisis management.

#### Case Studies and Workshops

In the context of the General GFL study, four thematic case studies on traceability, allocation of responsibilities, risk analysis and transparency provisions were carried out in 10 MS in the 2<sup>nd</sup> quarter of 2015.<sup>68</sup> The specific thematic case study on risk analysis focused on four specific food sectors: food additives, feed additives, contaminants and food contact materials. In those MS, further interviews with stakeholders and the relevant MS CAs were also carried out. In addition, two 1-day workshops on the basis of detailed Working Documents on those four thematic case studies with stakeholders<sup>69</sup> and representatives of all MS CAs<sup>70</sup> were also held. These were followed by written submissions by both groups on the basis of Working Documents.<sup>71</sup> In the context of the RASFF study, three case studies were carried out focusing on the following serious food safety incidents: melamine (2008)<sup>72</sup>, glass fragments in instant coffee (2010)<sup>73</sup> and *E.coli* in sprouts (2011.)<sup>74</sup>

#### Interviews

Extensive interviews have been conducted with EU-level authorities (including Commission services), MS CAs, stakeholders, and with key non EU trading partners (*i.e.* US, Chile, Brazil, Canada and China).

### 3.1.2 Secondary data analysis

#### Desk Research

The evidence base of the external studies but also of the present Fitness Check was further complemented by literature and other external studies. For example, a recent external study on the competitive position of the European food and drink industry carried out on behalf of the Commission and published in 2016 ('Competitiveness study') has provided, amongst others, relevant and useful insight into the impact of the GFL Regulation on the competitiveness of the EU food chain *vis-à-vis* Non-EU Country trading partners. The geographical scope of the Competitiveness study was the EU and comparisons were made with the following EU's main trading partners: the U.S, Australia, Brazil and Canada. The time periods used for measurement purposes were two: 2003-2007 and 2008-2012. The most recent years could not be factored into the comparative competitiveness indicators, given the timing of data releases by the various benchmark countries and by some EU sub-industries at the time of the report.<sup>75</sup> Other complementary information included reports from the audit and inspection service of Commission's Directorate-General for Health and Food Safety ('DG SANTE'), formerly known as the 'Food and Veterinary Office' ('FVO'), Court of Auditors reports and the case-law of the Court of Justice of the European Union.

### 3.1.3 Public consultation

No public consultation took place in the context of this Fitness Check. This was because of the following reasons: (a) extensive consultations were carried out via surveys, workshops and interviews involving MS and stakeholders of a broad range of interests, (b) the draft general results from the consultants' work had been shared with MS and stakeholders and had received an overall positive feedback as being representative, (c) the dedicated SME consultation had received extensive feedback which was in line with the consultants' findings, and (d) the external studies were launched in September 2014 and the relevant consultations were finished by May-June 2015, which coincided with the transitional period of the Better Regulation package.<sup>76</sup> The relevant findings, nevertheless, of this Fitness Check will be part of the public consultations in the context of pending and future evaluations of other EU secondary food legislation.

## 3.2 Limitations

#### Limited data on national perspectives of the GFL Regulation

Despite this evaluation being a joint evaluation of the Commission and the MS, the latter did not carry out their own additional case-studies or consultations with FBOs and SMES in particular, to complement the evidence base. Therefore, the evaluation has been based **on the evidence gathered by the Commission solely**. This absence of complementary data had a direct impact on the analysis of the MS implementation of the GFL Regulation as such, as well as the incorporation of the GFL Regulation common definitions, main principles and requirements in national legislation in the limited number of non-harmonised areas of food law.

This limitation was addressed through extensive consultations with MS: for example, in the context of the study on the general part of the GFL Regulation, in addition to a targeted survey of MS and the four case-studies carried out in 10 MS, a 1-day workshop was carried out on detailed aspects of risk analysis and transparency provisions, which was followed by written submissions by sixteen MS CAs.<sup>77</sup> In addition, given that there are very few non-harmonised areas in the area of food law, the



impact of not having additional MS data on the actual incorporation of the GFL Regulation principles in national legislation is considered limited.

#### **Limited data on the situation prior to 2002 – lack of specific objectives and monitoring arrangements in the GFL Regulation**

The point of reference chosen in this Fitness Check is the situation prior to the GFL Regulation in order to assess progress over time.

There is limited data on the situation prior to 2002. The GFL Regulation was not preceded by a proper and detailed impact assessment as it was adopted at a time when *ex ante* impact assessment was not required.<sup>78</sup>

In addition, the two main objectives of the GFL Regulation (*i.e.* high level of protection of public health and the effective functioning of the internal market) are general and are not accompanied by specific objectives. Moreover, no appropriate monitoring arrangements were in place prior to the GFL Regulation, or laid down in the GFL Regulation (nor in other EU food secondary legislation that was adopted after the GFL Regulation).

As such, it has proven difficult to identify impact indicators to measure progress over time given the limited availability of centrally compiled data on the general implementation and enforcement at EU level or at MS level of the GFL Regulation.

To address these challenges, at a first stage, the baseline for the purpose of this exercise has been reconstructed mainly on the basis of information stemming from the Green Paper on the General Principles of Food Law in the European Union (1997) and the White Paper on Food Safety (2000) as well as on available literature of that time. At a second stage, the general objectives of the GFL Regulation have been broken down to more specific ones, where possible, *i.e.* food safety, protection of health other than food safety, protection of consumers' interest, internal market. Through a comprehensive desk research and consultation process, evidence was collected from the full range of relevant stakeholders and triangulated with several data sets made available through specific reporting and monitoring requirements laid down in some sectorial frameworks (*e.g.* pesticides, zoonoses<sup>79</sup>) to assess progress made compared to the situation prior to the GFL Regulation in terms of those more specific objectives. Within the framework of these specific assessments, a semi-quantitative approach was followed to identify particular cases causing concerns, as it is further analysed in the subsequent paragraphs.

#### **GFL implementation through other EU secondary food legislation**

The nature and role of the GFL Regulation is to set out a legislative framework with a set of common definitions, general principles and requirements rather than specific provisions. These general principles and requirements are further implemented through other EU secondary food legislation (horizontal or sector specific). Therefore, for the purposes of this Fitness Check, EU secondary food legislation has been reviewed in relation to **provisions that stem from the GFL Regulation**, to ascertain whether the former has been implemented consistently with the principles and requirements of the GFL Regulation and to unearth any systemic failures in the overall implementation.<sup>80</sup>

The interaction of the GFL Regulation and other EU secondary food legislation raised additional methodological challenges as regards the implementation at MS level and in the majority of the

cases resulted in difficulties in the attribution of impacts: (a) difficulty in establishing the causality of impacts attributed to the GFL Regulation, (b) difficulty of FBOs in distinguishing costs originating from EU food law in general and costs originating from national food law, private standards or contractual obligations, and (c) difficulty in identifying the impact of the GFL Regulation at aggregated level on trade, given its nature as a general framework.

These limitations have been addressed through a 'cascade' exercise: By carrying out a comprehensive consultation process, evidence was sought from the full range of relevant stakeholders to identify areas of GFL that still pose problems. Where stakeholders identified problems, on a systematic basis, the available evidence from the consultations was triangulated and balanced with evidence available from other sources taking into account, for example, the potential for a partial view or vested interest. Moreover, any evidence collected of problems in other EU secondary food legislation has been analysed and triangulated to further establish causality between the GFL Regulation and other EU secondary food legislation. In terms of the interface between legislation and private standards, evidence was triangulated with the outcome of interviews conducted with FBOs and different groups of stakeholders along the supply chain (*e.g.* evidence from food manufacturers on standards imposed by retailers vs. evidence from retailers).

### **Quantification of costs and benefits**

Data on quantification of costs and benefits has been collected as regards certain well-defined areas. For example, EFSA data collection activities have provided relevant information on the prevalence of zoonoses, zoonotic agents and food-borne outbreaks, on the surveillance of ruminants for the presence of transmissible spongiform encephalopathies ('TSEs'), on the presence of pesticide residues in food and on the monitoring of veterinary medicinal product residues and other substances in live animals and animal products. Similarly, information has been collected from the RASFF annual reports, the RASFF study as regards the costs of RASFF, the EFSA 2012 external evaluation report and Court of Auditors' reports as regards the operation of EFSA, as well as from reports of the audit and inspection service of DG SANTE (former FVO) and consultations carried out in the context of the GFL Regulation study.

Nevertheless, as stated earlier with respect to the lack of specific objectives and monitoring arrangements in the GFL Regulation, it has proven difficult to identify quantitative indicators to measure the overall impacts (costs and benefits) of the general principles and requirements laid down in the GFL Regulation. In addition, given the breadth of the food chain and the goal oriented provisions of the GFL Regulation, which imposes little direct costs and burden on businesses, a comprehensive analysis of regulatory burden could not be fully carried out, as the latter presupposes sectorial and company focus. Quantification of benefits for consumers and public health in economic terms also requires a case-by-case analysis.

The mitigating measures taken were to identify at least the categories of costs or benefits involved and their relative importance. In terms of analysis of costs, the focus was to explore whether FBOs, and particularly SMEs, raise any specific concerns on costs, to identify the most burdensome cost categories and to evaluate where they stem from, *i.e.* the GFL Regulation, other EU secondary food legislation, national legislation, contractual relationships or from private standards. In cases of absence of suitable data, a qualitative analysis was used on the basis of the extensive interviews and consultations. Throughout the entire analysis, collected information was verified and triangulated with other evidence, including studies on how the EU performs on food safety related matters

compared to other non EU countries. Finally, as regulatory costs and their quantification are more appropriately linked to the regulatory requirements of EU food law, as expressed by other EU secondary food legislation and not by the GFL Regulation itself, a series of evaluations of other EU secondary food legislation is planned or is currently being conducted to complement the present analysis with a more comprehensive quantification of costs (see section 1.1).

### **Food safety and protection of consumers' interests**

With respect to food safety and protection of consumers' interests, quantitative indicators cannot be fully used:

- The *trend in food safety incidents* reported through RASFF does not provide comprehensive information on the extent of the risk involved, as other factors may also influence the occurrence and the reporting of food safety incidents. An increase or a decrease in RASFF notifications does not necessarily prove decreased or increased food safety. As such, the trend in food safety incidents in RASFF does not provide any conclusive evidence on the improvement in food safety levels.
- As above-mentioned, surveillance data exist but is limited to certain aspects relating to food safety, such as the surveillance of zoonoses, TSEs, the presence of pesticide residues in food and veterinary medicinal product residues and other substances in live animals and animal products. In addition, official controls carried out in the MS on the enforcement of EU food law are risk-based. As such, comprehensive data on overall trends relating to food safety cannot be compiled.
- There is no systematic data collected with respect to *the trend in consumers' complaints* relating to the GFL provisions.
- The *latest data from Eurobarometer on consumers' trust* in food safety authorities and perceptions of food-related risks date back to 2010, while there are no systematic records at MS level.
- The *quantification of benefits for consumers and public health in economic terms* requires a case-by-case analysis. The difficulties of measuring non-economic impacts such as impacts on health, safety or specific consumer rights have also been highlighted by the European Consumers' Organisation (BEUC) in its response to the public consultation on the revision of the Commission's Impact Assessment Guidelines in 2014.<sup>81</sup>

In light of these limitations, the general GFL study followed a semi-quantitative approach in developing the various surveys and conducting detailed interviews with consumer organisations to identify particular cases causing concerns. This evidence-base is further complemented by other studies from which certain conclusions on the performance of the EU system vis-à-vis the system of other non EU countries are drawn.

### **Effectiveness and efficiency**

Certain limitations have also been identified as regards effectiveness and efficiency:

- A quantitative analysis of *the trend of reported non-compliance with the GFL Regulation* and other EU secondary food legislation is not possible and any data available could lead to misleading conclusions. Non-compliance data is not directly comparable between MS, given the lack of uniformity in the data collection.<sup>82</sup> For example, an increase in non-compliance may actually reflect more effective controls, and therefore overall better achievement of the GFL Regulation objectives.

- *The trend on complaints and infringements* (Article 258 of the Treaty on the Functioning of the European Union – 'TFEU') as far as the GFL Regulation is concerned is also not reliable. Infringement procedures are launched on the basis of complaints or on the Commission's own initiative. The number of complaints is not indicative of the functioning of the GFL Regulation as it largely depends on the level of consumers' awareness, on political and media trends, on whether there are active consumer and industry associations in a given field, on whether the examination of the complaint has revealed any irregularities *etc.* In addition, a number of complaints are addressed to national authorities and not directly to the Commission.
- Finally, there is no systematic collection of data at national or EU level as regards *withdrawals of unsafe food and feed*, although some cases are reported through RASFF when there is cross-border trade. Moreover, reporting through RASFF is also dependent on the seriousness of the risk involved.

To address these limitations, a semi-quantitative approach has been followed. For example, the survey questions focused on the overall impact of some provisions of the GFL Regulation, *e.g.* how benefits compare to costs. Although this approach does not provide an objective and quantified measure of effectiveness and efficiency, it allows a first level of analysis to address these criteria.

### **Analysis of regulatory burden**

The present Fitness Check has also addressed the regulatory burden resulting from the GFL Regulation and the implementation of its principles and requirements by other EU secondary food legislation to a certain extent. Given the general character of the GFL Regulation as framework legislation, which imposes little direct costs and burden on businesses, as well as the extensive supply chain involved (see Figure 4), such an analysis could be carried out to a certain extent only. Indeed, a comprehensive analysis of regulatory burden presupposes sectorial and company focus. Therefore, a lighter approach has been followed, on the basis of the Standard Cost Model ('SCM') method, so as to identify the overall extent of the burden in terms of specific Information Obligations that are the most burdensome. The aim of this approach was to identify the areas where further investigation of regulatory costs and burden is warranted and, where such costs were considered substantial, to consider the potential for their reduction. The resulting findings will provide the basis for a more in-depth analysis of administrative burden in pending and future evaluations of other EU secondary food legislation.

## **4 State of play**

### **4.1 Economic dimension of the food chain (2002-present)**

The EU **food supply chain**<sup>83</sup>, as depicted in Figure 3, comprises all actors and activities from primary agricultural production, food processing, distribution and retailing, and consumption. In 2013, there were 24 million people employed in the food supply chain comprising agriculture, food and drink industry, wholesale of agricultural and food products and food and drink retail. The total turnover of the food supply chain exceeded €3.9 trillion and the value added almost reached €700 billion.<sup>84</sup>

During the application of the GFL Regulation and the adoption of other EU secondary food legislation, the food and drink sector in particular **has maintained and strengthened its position as a leading sector in the EU economy**. In 2013, the EU food and drink industry comprised 288,000 companies, employed 4.25 million people for an annual turnover of €1090 billion.<sup>85</sup> It is the largest

manufacturing sector in the EU in terms of turnover, valued added and employment: it represents 15.6% of the total manufacturing turnover and 15% of total employment, ahead of other manufacturing sectors *e.g.* the automotive industry (12.4%) and fabricated metal products (11.7%) respectively (2013). In addition, in 2013 the EU food and drink industry generated a value added of €212 billion which represents 1.8% contribution to the EU gross value added.<sup>86</sup> At the same time, every household spends on average about 14% of its disposable income on food and drink, which represents the second largest household expenditure after 'housing, water and energy' (2014).<sup>87</sup> In 2015, the total intra-EU and extra EU trade of food and drink products amounted to €345.9 billion in 2015, 72% of which concerned intra-EU trade while 28% concerned extra EU trade.<sup>88</sup>

The food and drink industry maintains the characteristics of a stable, resilient and robust sector. Indicatively, between 2008 and 2012, and despite the global financial crisis that began in the US in 2008 and unravelled into a double dip recession in Europe, the **turnover** of the EU food and drink industry grew **by almost 7%**, while turnover decreased by 0.8% in the EU overall manufacturing sector. In the same period, the **number of companies** in the EU food and drink industry **grew by more than 7%**, while the number of companies increased by only 1.4% in the EU manufacturing sector<sup>89</sup>. In addition, **employment** in the EU food and drink industry marginally increased by **0.8%** between 2008 and 2012<sup>90</sup>.

The food and drink industry is relatively fragmented and dominated in numbers by SMEs, including micro-businesses; it accounts for more than 285,000 SMEs. They represent 99% of all food and drink enterprises, generate almost 50% of the total food and drink industry turnover (49.5%) and value added (48.1%) while provide two thirds of the employment of the sector (62.8%).<sup>91</sup>

The **value of EU internal trade** in the food and drink sector has also increased by **72%** over the past decade,<sup>92</sup> while in 2015 the volume of food and drink production was the highest since 2008.<sup>93</sup>

**Worldwide**, the EU food and drink industry continued to be the **leading worldwide producer and exporter**. It is the largest in turnover, enterprises and employment amongst US, Australia, Brazil and Canada: 1.5 times the size of the industry in the USA. The EU has also **improved its international competitive position**: it is the largest global trader and a net exporter of food and drinks. EU food and drink exports nearly doubled over the past decade to reach €98.1 billion in 2015 and a trade surplus of €25.2 billion.<sup>94</sup> In the period of 2008-2012 and despite the global financial crisis, **external trade grew by 6.3%**, far outweighing the growth of imports (0.5%), **resulting in a positive balance**: from **less than €3 billion negative in 2003 to over €10 billion positive in 2012**.<sup>95</sup> Nevertheless, EU share in global food and drink exports has decreased over the past decade, *i.e.* from 19.7% in 2005 to 17.8% in 2014, while emerging countries such as China, Indonesia, India and Malaysia have grown in importance.<sup>96</sup>

## 4.2 Implementation<sup>97</sup> of the GFL Regulation

### 4.2.1 Common definitions in other EU secondary food legislation

The common definitions of the GFL Regulation **have consistently been incorporated** in other EU secondary food legislation, adopted after the introduction of the GFL Regulation, where relevant, *i.e.* in 25 out of the 29 other legislative acts.<sup>98</sup> Where adapted definitions to the ones set out in the GFL Regulation have been introduced in other EU secondary food legislation, this was due to the fact that the scope of the latter is not exactly the same as that of the GFL Regulation, *e.g.* definitions of

'placing on the market' and 'traceability' in Regulation (EC) No 1935/2004 on food contact materials.<sup>99</sup>

Despite the overall positive feedback, parties consulted for the General GFL study have raised some concerns regarding the **enforcement of certain GFL definitions**. In particular, the broadness of the definitions, especially when they are further implemented in other EU secondary food legislation, is considered to have caused different interpretations by the MS competent authorities ('CAs').<sup>100</sup> In addition, the consulted parties have considered that some definitions are not explicitly included in the GFL Regulation, *e.g.* 'consumers' interests', 'local' or 'craft', 'ecommerce/distance selling'.

## 4.2.2 Implementation of the risk analysis principle

### 4.2.2.1 Risk assessment

#### 4.2.2.1.1 Risk assessment at EU level: EFSA<sup>101</sup>

EFSA started its operations in 2003. Specific provisions were adopted with respect to requests for scientific opinions and networking with MS.<sup>102</sup>

In the period 2003-2015, EFSA significantly grew both in terms of **budget and capacity**: with an overall EU budget of €12.6 million and 63 employees in total in 2003,<sup>103</sup> its budget increased to €78.8 million and to 434 persons in total in 2015<sup>104</sup> – an increase of 625% and 688% in budget and capacity respectively. The national experts contributing to EFSA represent a significant amount of expertise (215 panel members and around 1500 experts contributing) for EFSA. Experts from all countries and scientific organisations, can contribute to EFSA's work, if the relevant criteria on excellence and independence are met. The pooling of national experts, in particular, is considered as one of EFSA's strengths. The expert members of EFSA's Scientific Committee and Panels or those contributing to the Panel working groups or EFSA networks are employed by national scientific bodies.

**EFSA's own capacity of expertise is globally sufficient.** The progressive increase in EFSA's scientific capacity **matched the increased demand for scientific advice** following the systematic incorporation of the risk analysis principle in EU food law after the adoption of the GFL Regulation, with the Commission being the main requester: The requests varied from 229 in 2003 to 382 in 2016, with considerable peaks in 2008-2011: in 2008 EFSA received 5,522 requests (Table 1).

**Table 1:** Number of questions for scientific output received by EFSA 2007-2016

Year	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016
<b>Total (Commission/MS)</b>	568	5522	1036	1194	951	680	774	616	457	382

(Source: Updated Figure 4 of the EY 2012 external evaluation)

These peaks were the direct result of other EU secondary food legislation in the area of food law adopted after the GFL Regulation, *e.g.* food improvement agents, feed additives, GMOs, novel foods, health and nutrition claims, plant protection products including the setting of maximum limits for their residues ('MRLs'), which provided either for new areas of authorisation (*e.g.* health claims) or for review processes of existing authorisations.

**Nevertheless, as pointed out in the context of the EFSA 2012 external evaluation,** the frequent adoption of other EU secondary food legislation requiring EFSA to carry out risk assessment and the

limited consultation of EFSA during the EU legislative process have reduced EFSA's capacity to adequately plan its workload and, consequently, reallocate its resources. Indicatively, some stakeholders have considered that the EU legislators, while approving new EU food legislation, seem to hardly consider their impact on EFSA's work, without modifying the resources at their disposal.<sup>105</sup>

The progress made on the delivery of scientific outputs, namely scientific opinions (generic opinions on public health issues and opinions on authorisation dossiers submitted to EFSA for safety assessment), statements and guidance, scientific reports and, in the sector of plant protection products, reasoned opinions and conclusions on plant protection products' peer review, is reflected in Table 2. Since its creation, EFSA has delivered approximately 4,500 scientific opinions. In addition, in the period 2007-2014, it has delivered 60 self-tasking opinions.

**Table 2:** Number EFSA scientific outputs\* 2006-2016

Year	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016
<b>Total outputs delivered</b>	174	283	489	636	565	658	678	607	651	602	481
<b>Linked to authorisation dossiers</b>	130	180	292	492	399	472	434	380	340	306	321

\*A scientific output can reply to one or several questions.

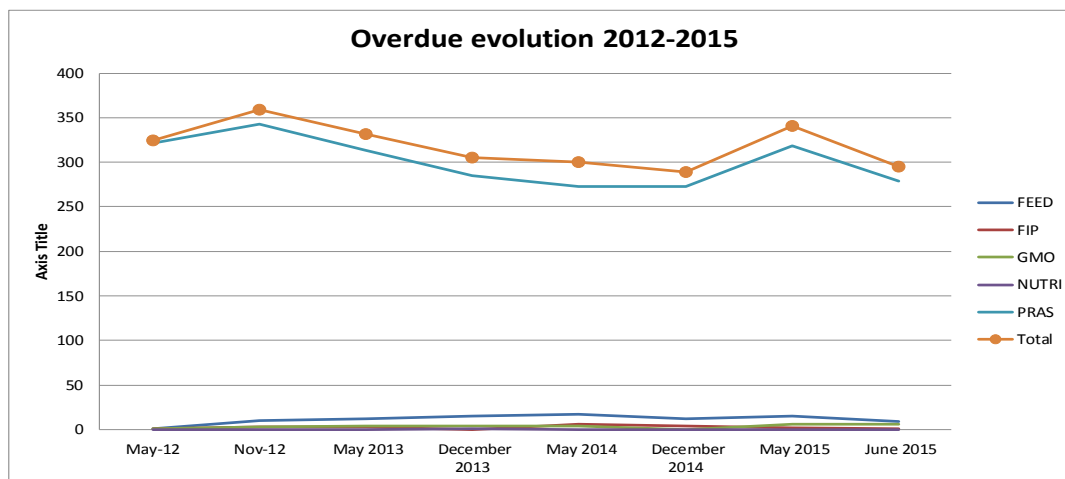
Overall, the **timeliness in the provision of scientific outputs** has improved over the years: from 59% in average in 2006 to 80% in 2014.<sup>106</sup> While the timeliness is satisfactory in the areas of general public health questions and data collection (98% and 85% respectively in 2014), it is **more problematic in the area of authorisations** (other EU secondary food legislation): 77% in 2014, with the area of MRLs on plant protection products scoring only 58% in the same period.

Those **delays** are linked to the **peaks of dossiers** mentioned earlier (*e.g.* MRLs on plant protection products, health claims, reviews of existing authorisations) and **long and frequent 'stop-the-clock' procedures**.<sup>107</sup> Indeed, the increasing workload of EFSA has determined a backlog, which at the time of the EFSA 2012 external evaluation corresponded to 1131 outputs in terms of questions classified as 'work in progress' (*i.e.* 11.5% of requests received in the period 2006-2011), while for 256 dossiers EFSA had 'stopped the clock', asking for additional data to be provided.<sup>108</sup>

EFSA has overtime reduced its number of backlogs and 'stop-the-clock' procedures in most sectors. Nevertheless, from May 2012 to June 2015, the number of overdue scientific opinions was still high in the area of plant protection products (PRAS) sector (see Table 3), while the number of 'stop-the-clock' procedures remained high in the feed additives sector (FEED) and significant in the area of GMOs and it has even increased for food improvement agents (FIP) (see Table 4).

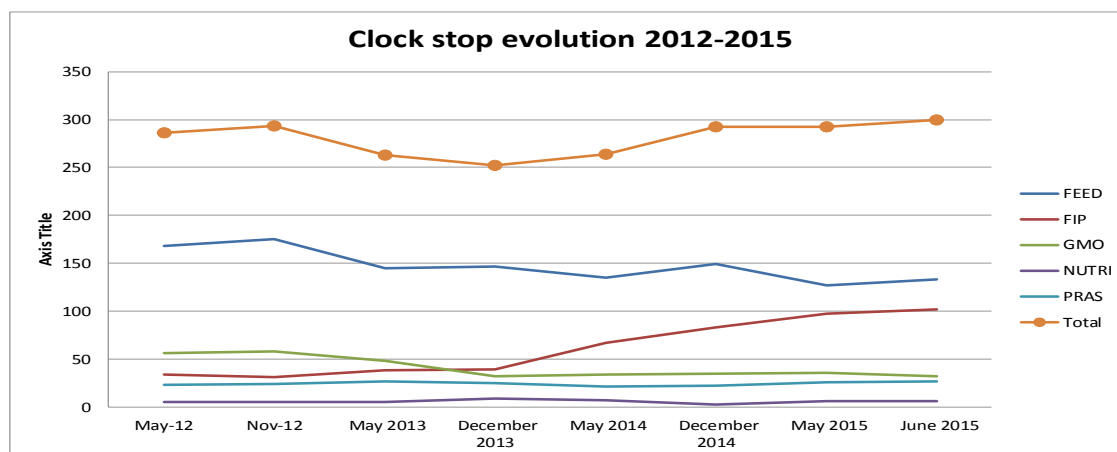
**Table 3: Evolution of overdue requests (May 2012- June 2015)**

	May-12	Nov-12	May 2013	December 2013	May 2014	December 2014	May 2015	June 2015
FEED	1	10	12	15	17	12	15	9
FIP	1	3	3	0	6	4	2	1
GMO	1	3	4	4	4	0	6	6
NUTRI	0	0	0	1	0	0	0	0
PRAS	322	343	313	285	273	273	318	279
<b>Total</b>	<b>325</b>	<b>359</b>	<b>332</b>	<b>305</b>	<b>300</b>	<b>289</b>	<b>341</b>	<b>295</b>



**Table 4: Evolution of 'stop-the-clock' procedures**

	May-12	Nov-12	May 2013	December 2013	May 2014	December 2014	May 2015	June 2015
FEED	168	175	145	147	135	149	127	133
FIP	34	31	38	39	67	83	97	102
GMO	56	58	48	32	34	35	36	32
NUTRI	5	5	5	9	7	3	6	6
PRAS	23	24	27	25	21	22	26	27
<b>Total</b>	<b>286</b>	<b>293</b>	<b>263</b>	<b>252</b>	<b>264</b>	<b>292</b>	<b>292</b>	<b>300</b>



The volume and context of the application dossiers to be processed as well as the fact that different regulatory procedures for these risk evaluations are defined in other EU secondary food legislation (and not in the GFL Regulation) with different requirements in terms of deadlines, flows and criteria<sup>109</sup> have challenged EFSA considerably in terms of processing the relevant requests.<sup>110</sup>

Long 'stop-the-clock' procedures on authorisation dossiers hamper quick access to the market for industry since they *de facto* extend the legal deadlines for the assessment of authorisations. This is the case in particular, in the period 2012-2014 for some categories of feed additives, where the average number of days for assessment was estimated at 542 days (stop-the-clock delays included) vs. 191 days (without stop-the-clock delays), for food contact materials where the average was



estimated at 583 days (delays included) vs. 399 days (without delays) and for nutrients sources (NUTRI) where the average was estimated at 502 days vs. 389 days (without delays). However, in other areas such as in food additives where an increase in the number of 'stop-the-clock' procedures has been observed, the delays attributed to 'stop-the-clock' procedures are more limited: 673 days (stop the clock delays included) vs. 644 days (without delays).<sup>111</sup> According to industry estimates, **the risk analysis process globally in the area of feed additives** takes around two years ideally, while for some innovative products it may take three to four years or more, due to 'stop-the-clock' procedures.<sup>112</sup>

Although the 'stop-the-clock' procedures are often justified and useful allowing the applicants to complete their dossiers and provide supplementary information, some of the resulting delays are partly attributed to lack of an early dialogue with the applicants.<sup>113</sup> Since 2012, EFSA has put corrective actions in place to improve communication with the applicants (*e.g.* application desk unit, catalogue of services to applicants, info sessions and work shop helping applicants for the submission of their dossiers, better involvement of stakeholders in the guidance on authorisations *etc.*); however, certain delays still persist.

EFSA has a **good track record** in responding **swiftly to demands in crisis or emergency situations**. In the period 2006-2013, there were 13 Commission requests for urgent scientific support. On average, EFSA provided its scientific assessment in 2-3 days in simple cases, 8-14 days in more complex cases while in three cases, it responded in 27-30 days with one specific case which took 46 days.

The quality of EFSA's scientific advice is highly dependent on the quality of its experts, of the evidence used and of the methodologies employed in its risk assessment. EFSA thus selects the members of its Scientific Committee and Panels and of the related working groups in a transparent way and on the basis of their excellence and independence. EFSA ensures multi-disciplinary expertise in the relevant Panels and working groups, given that scientific issues are often complex and therefore the input of different scientific disciplines is indispensable. EFSA has also created additional Panels<sup>114</sup> to reinforce its expertise and has now 70% of its staff devoted to scientific activities, resulting in an increased support for the work of the EFSA Panels (*e.g.* specific EFSA units focusing on risk assessment methodologies, data collection and analysis).

The evidence that EFSA uses in its scientific processes come from different sources, since it is important to take all relevant evidence into account. Amongst others, EFSA relies on data collected in collaboration with MS and stored in the EFSA data-warehouse.<sup>115</sup> For instance, EFSA collects EU quality data on food consumption habits and patterns from across the EU to assess how exposed people or specific population groups are to potential risks in the food chain. In a similar vein, it collects data concerning the level of microbiological contamination of the food chain, of chemical contaminants, of pesticides as well as of veterinary medicinal product residues. New data collection activities also include molecular typing of food-borne pathogens to support epidemiological investigations of food-borne outbreaks in collaboration with the European Centre for Disease Prevention and Control ('ECDC')<sup>116</sup> and data on food composition to support reference dietary values.<sup>117</sup> All these data collection activities have enhanced the robustness of EFSA's work and bolstered its scientific basis. Compared to the pre-2002 situation where in particular food consumption data were almost non-existent or where only available at national level, these were not harmonised at EU level, EFSA has made considerable progress.

Other sources of evidence are data from experimental studies submitted to EFSA by FBOs as part of the authorisation processes as well as data from external data holders (e.g. World Health Organisation ('WHO')). Literature reviews mapping all the available scientific studies on a given issue constitutes another important source of evidence for EFSA's work. Specific tools and methodologies, in line with international standards, are in place in the EFSA risk assessment process. Further methodologies are also applied by EFSA to weight evidence in a systematic, consistent and transparent way within its risk assessment processes.

EFSA continuously improves its Quality Management System ('QMS'), which includes a quality circle, an external review and a customer feedback system with the Commission and the MS. In 2014, all randomly selected EFSA opinions were found to be 'fit for purpose'.<sup>118</sup> In 2015, the External Review Working Group provided a positive opinion on the revised Quality Assurance System for Science developed by EFSA<sup>119</sup> and in 2016 EFSA obtained the ISO 9000:2015 certification<sup>120</sup> for its QMS.

Overall, EFSA's scientific outputs and especially scientific opinions have been accepted in a consensual way by both the mainstream scientific community and the national risk assessment bodies. This is facilitated by a high level of involvement of MS in EFSA. EFSA cooperates with the MS through its Advisory Forum, composed of all national risk assessment counterparts of EFSA and chaired by EFSA, and its 19 sectorial networks and working groups. In addition, a network of national scientific bodies ('Article 36 network') is established to support EFSA's scientific work. The cooperation is supported through the allocation of grants and procurements. The close cooperation with MS ensures the sharing of scientific data, methodologies and information concerning risks linked to food and feed, establishing a common information base for all risk assessors both at EU and national level. It thus promotes a mutual understanding on risks, minimises the risk of duplications and limits potential divergent views. Indeed, from a total of more than 4,500 scientific opinions, divergences of scientific opinions between EFSA and national assessment bodies have emerged only in 11 cases, seven of which were solved directly at the level of the Advisory Forum. **Scientific divergences have only been confirmed in four cases, two of which concerned the same substance.** Nevertheless, as those two concerned a politically sensitive matter, they attracted considerable public attention.<sup>121</sup> The finances dedicated to the outsourcing of EFSA's tasks to national risk assessors are considered by the MS<sup>122</sup> as relatively low (€10 million per year, 13% of EFSA's total budget).

The governance and structure of EFSA as laid down in the GFL provides for the separation of risk assessment from risk management as well as the separation between EFSA's scientific work and EFSA's strategic management. In contrast with other EU agencies, such as the European Medicines Agency ('EMA') and the European Chemicals Agency ('ECHA'), MS do not appoint members of its Scientific Panels. Membership in EFSA's Scientific Committee and Panels and their Working Groups is subject to a call for an expression of interests, to which experts including those employed by national scientific bodies, such as national risk assessment agencies, academia and public research bodies, reply on an individual and voluntary basis. If selected, those experts remain permanently employed by their national bodies, but contribute to EFSA's scientific work. This implies that the national scientific bodies employing them allow them to spend part of their work time in EFSA. Nevertheless, the current governance of EFSA is not in line with the Common Approach endorsed by the European Parliament, the Council and the European Commission on decentralised agencies in 2012.<sup>123</sup>

Members of EFSA's bodies as well as experts are required to make annually a declaration to act independently as well as to provide declarations of interest (annual, specific and oral) indicating the absence of any interest prejudicing their independence.

EFSA's independence is regularly scrutinised (Court of Auditors,<sup>124</sup> European Ombudsman,<sup>125</sup> European Parliament ('EP')<sup>126</sup>) and there is a good record of implementing the recommendations made. The special report No 15/2012 of the Court of Auditors on the management of conflicts of interest in selected agencies concluded that "*of the selected Agencies, [European Medicines Agency] and EFSA have developed the most advanced frameworks for declaring, assessing and managing conflict of interest dealing specifically with industry-related risks*".<sup>127</sup> EFSA regularly revises and refines its policy. In June 2017, EFSA adopted a revised independence policy to further strengthen its impartiality and protection against improper influence.<sup>128</sup>

**EFSA has been highly transparent** since its early days of operation: all EFSA scientific opinions and reports, agendas and minutes of meetings, declarations of interest, mandates and most of the scientific studies and data underpinning EFSA's opinions are published on EFSA's website. It is the only agency having public meetings of its Management Board. Additional progress on openness has been made: the plenaries of its Scientific Committee and Panels are open to the public, major draft scientific opinions are submitted to public consultation, and the hearings of experts by EFSA panels are more systematic. EFSA's policy of open data is making the scientific evidence used in the opinions accessible to the public, except for confidential data.

Despite **overall progress on the independence and transparency of EFSA's work, these remain sensitive issues** in terms of perception and the **stakeholders still have different points of view**. In particular:

NGOs (supported by some members of the European Parliament and some MS) still call for more stringent rules as they advocate that any link with industry must be considered as a conflict of interest. They advocate that EFSA experts should be excluded from any link with food industry funding, including private-public partnerships or food industry funding in areas different from the ones the experts contribute to. Nevertheless, other stakeholders (including some MS) consider that the rules on EFSA's independence are already too strict and that there is little room to implement more stringent rules without jeopardising EFSA's access to high quality expertise, in particular because of the trend for private/public partnership in science. EFSA has recently adopted a new independence policy providing for a two-year cooling off period on managerial, employment, consultancy activities, memberships in scientific advisory bodies undertaken by its experts with legal entities pursuing private or commercial interests, which partly addresses some of these concerns. A similar cooling off period is also applicable with respect to research funding from legal entities pursuing private or commercial interests.<sup>129</sup>

Certain NGOs also criticise the fact that EFSA bases its risk assessment of authorisation dossiers on industry studies. Under the current legislative framework and in line with the primary responsibility principle, **the burden is on the FBOs to prove that the products intended to be placed on the market comply with EU safety requirements**, given the scientific knowledge in their possession.<sup>130</sup> This is further elaborated in the EU secondary food legislation providing for the modalities of the different authorisation procedures. The same legislative approach is used regularly in all authorisation systems in the EU in other fields, e.g. EU chemical authorisations<sup>131</sup> and EU pharmaceutical authorisations,<sup>132</sup> but also in other jurisdictions, e.g. Canada. It is based on the

premise that public health is better protected when the burden is on the industry to prove that a particular food or feed is safe prior to its placing on the market, instead of the public authorities having to prove that it is unsafe.

Therefore, reversing altogether the burden of proof, *i.e.* to be imposed upon EFSA to carry all necessary studies to prove the safety of a food or feed, could jeopardise the high level of protection of consumer health achieved to date. Moreover, if the burden were to be reversed, EFSA – not being a laboratory – would not be able to carry out its own studies and would face considerable operational difficulties to commission studies in every authorisation dossier. It should be noted that the current system is accompanied by several guarantees to ensure that the industry studies provide sound scientific information. Indeed, other EU secondary food legislation and EFSA's scientific guidance in relation to authorisation procedures specify the types of studies to be provided as well as the international protocols and the principles of Good Laboratory Practices ('GLP')<sup>133</sup> that should underpin these studies, setting high quality standards for these underlying studies. Nowadays, only a small part of the studies supporting an authorisation dossier is carried out by the industry itself; the largest part is contracted out to specialised GLP accredited laboratories. Only a limited number of specialised laboratories are able to meet EFSA's high standard of risk assessment. Therefore, even if the burden of providing studies were to be transferred to EFSA at the expense of the applicant, as it has been suggested by some NGOs, EFSA would probably have to also subcontract the studies to the same laboratories, currently used by the industry to carry out the necessary work. Finally, EFSA assesses authorisation dossiers not only on the basis of the industry studies but also of other relevant public research scientific studies. Indeed, in several EU food legislations setting out authorisation procedures, industry must not only submit specific GLP studies but also a full literature review of all studies existing with respect to the subject matter at issue. For instance, in the case of the renewal of the approval of glyphosate as an active substance in plant protection products in 2016, EFSA assessed a totality of 700 studies, including but not limited to industry studies and to a literature review of scientific studies published in the last 10 years.

Furthermore, NGOs criticise EFSA that the above-mentioned industry studies are **partly confidential** (*e.g.* raw data are not made publicly available). In their view, the existing EU legal rules on confidentiality excessively restrict the access to industry studies. The general provision on confidentiality with respect to information received by EFSA laid down in the GFL Regulation (Article 38) combined with the strict confidentiality rules set out in other EU secondary food legislation providing for the modalities of authorisation procedures on one hand and the general EU rules on access to documents (*i.e.* Regulation (EC) No 1049/2001) create a rather complex system for the public release of documents.

The scientific cooperation between EFSA and the national scientific food safety organisations, which did not exist before 2002, is key to pool EU expertise and ensure an adequate scientific capacity of EFSA but there are a number of negative signals. Recent calls on the **membership of Panels** have shown **some negative trends in that respect**: the average age of experts participating to EFSA is increasing (from 53.6 years in 2012 to 55.3 years in 2015) and some Panels relating to authorisations have encountered **problems in attracting new members**. These are due to a number of disincentives: insufficient recognition for the scientists' career, modest financial compensation for the experts and their employers, amount of time required, strict rules on independence which do not take into account the increasing trend of public-private partnership in scientific research (indicatively, 34 candidates above the quality threshold were disqualified in the last selection

procedure on the basis of EFSA strict independence criteria). The recourse to external experts is considered by stakeholders both as strength (stronger expertise) and a potential weakness (EFSA expertise and independence partly dependent of external persons).

EFSA has concluded memoranda of understanding with other **EU scientific agencies**<sup>134</sup> to foster cooperation, especially when the expertise of more than one agency is needed in some cross-sectorial issues (*e.g.* antimicrobial resistance or food-borne diseases). EFSA has also an increased **international collaboration** on the sharing of data and methodologies with non EU countries and international bodies (*e.g.* Codex Alimentarius) and it contributes to several capacity building activities.

#### 4.2.2.1.2 Risk assessment at Member State level

Amongst MS, there are differences in the organisation of food safety structures,<sup>135</sup> some MS opting for national independent scientific bodies or for national independent bodies with mixed competences (*e.g.* risk assessment and enforcement activities). The establishment of scientific bodies able to carry out independent risk assessments in all the domains covered by EFSA, however, has been neither desirable nor feasible for all MS, given the high costs involved and the scarcity of high level expertise.<sup>136</sup> Moreover, because of the high level of harmonisation in the area of food law and the fact that the relevant risk assessment is carried out by EFSA, there has been a continuous decline in the necessity for national risk assessments for food law purposes which has led **to cost savings**.<sup>137</sup> The **main drivers that, however, continue to generate the need for national risk assessments are**:<sup>138</sup>

- a) the need to provide the scientific basis for national measures in the limited non-harmonized areas, such as processing aids used in the production of foods or partially harmonised areas such as food contact materials as well as the setting of maximum levels of substances in food supplements and in foods with added vitamins and minerals;
- b) exposure to hazards and risks, *e.g.* from contaminants, can vary at national level compared to the EU average, due to differences for example in consumption patterns or production systems;
- c) maintaining national scientific risk assessment capacity allows MS to supplement the expertise available to EFSA;<sup>139</sup> and,
- d) the need to support other activities where a scientifically-based approach is required to assess risks, *e.g.* in the context of official controls and of enforcement to identify whether a specific food or feed is safe and whether its withdrawal is required.<sup>140</sup>

#### 4.2.2.2 **Risk management**

##### 4.2.2.2.1 Risk management at EU level

Once the risk assessment is completed by EFSA, it is for the **EU risk managers** (mainly the Commission with the assistance of MS' representatives in the PAFF committee and depending on the applicable procedure the Council and the EP) **to take appropriate** EU measures.

##### Consideration of legitimate factors at EU level

Risk management at EU level is generally considered to **duly and consistently** take into account the results of **risk assessment** and in particular the opinions of EFSA, **as well as other legitimate factors**.<sup>141</sup> More specifically:

Science and in particular the scientific opinions of EFSA **systematically underpin the EU risk management decisions** in the area of food law, including authorisations of food improvement agents, feed additives, plant protection products, health claims, food contact materials and GMOs.

In a **very few cases**, the EU risk manager has not followed EFSA's opinion taking into account **other legitimate factors**. In the absence of an exhaustive list of legitimate factors in the GFL Regulation, the EU risk managers have considered as legitimate factors nutritional advantages and disadvantages, acceptability by the consumer, feasibility of controls, quality, tradition, environmental impact, societal factors, ethical considerations, impact on non-communicable diseases (e.g. obesity, cardiovascular diseases, metabolic diseases), lack of mitigation measures, animal welfare as well as economic factors. The use of legitimate factors in the EU decision-making process is not static; the exact range of factors and the weight attributed to them varies on a case-by-case basis depending on the subject matter and the measure concerned.<sup>142</sup>

Where the EU risk management decisions have departed from the scientific assessment, an explicit justification to that effect has systematically been included in the preamble to those decisions. For example, despite EFSA's favourable opinion, health claims on the effect of fats on the normal absorption of fat soluble vitamins, on the effect of sodium on the maintenance of normal muscle function<sup>143</sup> and on the effect of glucose to energy-yielding metabolism<sup>144</sup> were not included in the list of EU authorised claims, as they were found inconsistent with generally accepted nutrition and health principles.<sup>145</sup> As far as the application of legitimate factors in the area of food law is concerned, the Court has also recognised that "*[i]n some cases, scientific risk assessment alone cannot provide all the information on which a risk management decision should be based, and other legitimate factors relevant to the matter under consideration should therefore be taken into account. In the light of the foregoing, the Commission must be recognised as enjoying a broad discretion in an area which entails political, economic and social choices on its part, and in which it is called upon to undertake complex assessments.*"<sup>146</sup>

#### Use of precautionary principle at EU level

The precautionary principle is laid down in Article 191 TFEU and it has been recognised by the European Courts as a general principle of EU law.<sup>147</sup> Its implementation is therefore specified in the Commission Communication on the precautionary principle, adopted in 2000.<sup>148</sup> In the subsequent paragraphs, we therefore focus on the use of the precautionary principle by the risk managers.

The GFL Regulation explicitly refers to the use of the **precautionary principle** as **part of the risk management process**. As stated in Section 2.2, it allows the adoption of **provisional** risk management measures necessary to ensure a high level of health protection when, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists. It therefore requires a scientific evaluation as well as an evaluation and balancing of the risks involved, *i.e.* whether the potential risks identified exceed the threshold of what is acceptable for society as well as the consequences of non-action by the risk managers.

According to the jurisprudence of the European Courts, "*[i]n determining the level of risk deemed unacceptable for the society, the [EU risk managers] are bound by their obligation to ensure a high level of protection of public health, safety and the environment. That high level of protection does not necessarily [...] have to be the highest that is technically possible [...]. Moreover, [the EU risk managers] may not take a purely hypothetical approach to risk and may not base their decisions on a*

*'zero risk' [...]. The level of risk deemed unacceptable for society will depend on the assessment made by the competent public authority of the particular circumstances of each individual case. In that regard, [the EU risk managers] may take account, inter alia, of the severity of the impact on public health, safety and the environment were the risk to occur, including the extent of possible adverse effects, the persistency or reversibility of those effects and the possibility of delayed effects as well as of the more or less concrete perception of the risk based on available scientific knowledge.'*<sup>149</sup>

Therefore, the application of the **precautionary principle is not an alternative to a risk management approach**, or to the use of scientific risk assessment to underpin decision-making, but rather a particular form of risk management.

An example, where the EU risk managers took into account the precautionary principle in determining the appropriate measures to take for the society as a whole, while ensuring a high level of protection of public health are the measures taken regarding transmissible spongiform encephalopathies ('TSE') in 2008.<sup>150</sup> By that time, the EU managers considered that because the risk to public health was very low with respect to certain aspects of those measures, those had to be reassessed to ensure that they did not impose a burden on the MS and FBOs inappropriate to the level of risk involved and disproportionate to the objective pursued: as a result less restrictive measures of TSE surveillance and eradication than those earlier prescribed for sheep and goat herds were adopted. The Court of Justice later confirmed that this determination by the Commission had not breached the precautionary principle and the obligation to maintain a high level of protection of human health.<sup>151</sup>

EU managers have opted for the adoption of provisional measures on the basis of the **precautionary principle in very few cases**. Those measures have largely been reviewed depending on the availability of further scientific evidence. In particular:

In the area of food contact materials,<sup>152</sup> the precautionary principle has been used in relation to the use of azodicarbonamide in the manufacture of food contact materials<sup>153</sup> and Bisphenol A in plastic infant feeding bottles.<sup>154</sup> Similarly, certain Commission Decisions on non-authorized GMOs based on the precautionary principle<sup>155</sup> were later reviewed to take into account newer scientific evidence and eventually repealed.

In the context of EU emergency measures to avert or manage food crises (see also Section 4.2.10.1), the precautionary principle has been used only once. During the *E.coli* in sprouts outbreak in Germany in 2011, the EU temporarily banned the import of seeds and beans from Egypt by means of EU emergency measures, given the observed serious health risks from such seeds and beans and because at the time of the decision-making no precise information was available on the exact source of contamination in Egypt allowing for less restrictive measures.<sup>156</sup> This measure was reviewed within three and a half months and the temporary measures were prolonged for an additional period of 5 months.<sup>157</sup>

There are two cases, however, where the EU has invoked the precautionary principle and has adopted provisional measures that have been in place for a considerable period of time. The first case concerns the adequacy of acceptable daily intake values of pesticides and pesticide residues for the protection of the health of infants and young children in relation to infant formula and follow-on formula<sup>158</sup>, and processed cereal-based food and baby food for infants and young children<sup>159</sup>, for which provisional measures are in place since 1999. Rules for these products were reviewed in

several occasions, but in light of persisting scientific uncertainty on those occasions existing requirements on pesticides were maintained.<sup>160</sup> In the context of the implementation of Regulation (EU) No 609/2013 on food intended for infants and young children, food for special medical purposes and total diet replacement for weight control, existing rules on plant protection products have again been maintained but, at the same time, EFSA has been asked to provide an overview on the latest scientific evidence in preparation for a review of the rules.<sup>161</sup> The second case concerns EU measures banning the use of growth promoting hormones in stock-farming predating the GFL Regulation, which were reviewed in 2003 based on the precautionary principle.<sup>162</sup> In the latter review, the EU permanently banned one hormone, while provisionally banned the use of five others on the basis of the precautionary principle.

**No evidence** was provided in the context of the General GFL study **on concrete adverse impacts** of any of these measures **on innovation and trade**.<sup>163</sup> In recent years and with respect to politically sensitive issues, stakeholders and especially certain NGOs as well as certain MS have called for total bans notably for endocrine disruptors, plant protection products or GMOs in accordance with the precautionary principle. Nevertheless, these calls **do not fulfil the two conditions** for the application of the precautionary principle laid down in the GFL Regulation (identification of the possibility of harmful effects on health and persistence of scientific uncertainty), but they are also based on grounds other than science (*e.g.* political, ethical). As such, these requests seem to pertain to calls for considering other legitimate factors rather than the application of the precautionary principle.

**Delays at risk management phase** have also been noted with certain authorisation procedures (*e.g.* novel foods, health claims, food additives and other food improvement agents, feed additives). For example, in the area of novel foods, the comitology phase alone can last on average 14 months (434 days).<sup>164</sup> This is largely due to discussions in the PAFF committee concerning the appropriate risk management measures to take.

#### 4.2.2.2.2 Risk management at Member State level

National risk management measures in the area of food and feed are adopted in the following contexts:

- a) in the **few non harmonised areas**, such as processing aids in the production of foods or **partially harmonised areas**, such as food contact materials as well as the setting of maximum levels of substances in food supplements and in foods with added vitamins and minerals as regards; and,
- b) in the implementation and enforcement of the food and feed safety requirements of the GFL Regulation.

According to the General GFL survey, **for the most part national food law has been adopted on the basis of a risk analysis**.<sup>165</sup> Where this has not taken place, according to the consulted MS CAs, it is attributed to the challenges faced in the application of the risk analysis principle, such as restricted available resources and shortage of staff with the required specialist training, lack of sufficient data, insufficient scientific background, insufficient time available to complete all risk analysis steps, insufficient or outdated national legislation. The intensity of those challenges varies on a case-by-case basis. There is also some evidence that where national measures were not adopted on the basis of risk analysis,<sup>166</sup> they were subsequently amended or repealed.

#### Consideration of legitimate factors at MS level



Where national risk management measures have been adopted, the General GFL survey results have indicated that other legitimate factors have been taken into account mostly on a case-by-case basis. In particular, the majority of the MS CAs indicated that all legitimate factors mentioned indicatively in the GFL Regulation were taken into account on a case-by-case basis. Moreover, eight MS CAs indicated that economic factors are always taken into account, six MS CAs indicated the feasibility of controls and societal factors, 5 MS CAs indicated environmental impacts, while 4 MS CAs indicated tradition factors are always taken into account. It is noted that four MS CAs indicated that they never take into account ethical factors and two MS CAs never take into account economic, societal, environmental or tradition factors.<sup>167</sup>

#### Use of precautionary principle at MS level

Most MS have indicated they have taken provisional national risk management measures on the basis of the precautionary principle. Out of the 23 examples of national measures which were indicated by MS CAs to have been taken on the basis of the precautionary principle, the majority of those measures (61%) have had a duration of more than 1 year, while one third of these measures have lasted over 5 years. In addition, some of the indicated measures had been adopted soon after the General GFL survey was conducted (<1 year), therefore their final duration was not definite at that time. 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 uncertainty raised only for few (3) measures out of the total 23 examples**; other factors were raised for few (5) measures *e.g.* environmental reasons for the trade restrictions on transgenic maize adopted in two MS.

A closer examination of the examples of measures provided by the MS in the context of the General GFL study demonstrates that the rationale underpinning risk management measures is not always clear as to whether it is based on the precautionary principle or on other legitimate factors.<sup>168</sup>

#### **4.2.2.3 Risk communication**

Risk communication is a shared competence between risk assessors and risk managers both at EU and national level. As stated in Section 2.2, risk communication is defined as the interactive exchange of information about risks throughout the risk analysis decision-making process. In order to be effective, a global process integrating all actors must be in place (see also Figure 2 on the risk analysis principle). Nevertheless, a distinction has to be made at this stage between 'risk communication' and 'communication at times of crisis', and in particular when food crises erupt. This aspect is addressed more in detail under Sections 4.2.5 and 4.2.10.

EFSA, as the EU risk assessor, is entrusted with communicating food and feed safety scientific results to its principal partners, stakeholders, the media and the public at large, to help bridge the gap between science and consumers. To this end, EFSA devoted €7 million of its budget (9% of total EFSA budget) in 2015 as well as 36 staff (8% of total EFSA personnel) to risk communication activities.<sup>169</sup> In addition, it has created the Advisory Forum Working Group on Communication (2003)<sup>170</sup>; the Advisory Group on Risk Communications (2005)<sup>171</sup> and a Communication Directorate. Overall, the 2012 evaluation indicated that EFSA's risk communication has been effective and of good quality (*e.g.* relevant, timely and published on the website).

The stakeholders, although positive on EFSA's risk communication activities (79%), were nevertheless critical with respect to certain issues: *e.g.* the clarity is considered satisfactory mostly with respect to

the informed public; there are contradictory views on the appropriate target group of EFSA's communication (general public v. current strategy to target national risk assessors and national risk managers that can adapt the communication content provided by EFSA to their national needs); the perception of EFSA's communication by the media as too complex.<sup>172</sup> Since 2012, EFSA revamped its website to be a more user-friendly, customer-oriented platform. It has also introduced specific communications products designed for lay audiences. Furthermore, it has developed its presence on social media,<sup>173</sup> complemented by multimedia products (e.g. infographics).<sup>174</sup> Some more sophisticated elements of risk communication (**new openness policy**), such as public consultation on some of its draft scientific opinions, increased involvement of stakeholders on its self-tasking mandates and in particular on the ones on guidance as well as generalisation of early dialogue between risk managers and EFSA on mandates, have recently been put in place; however, their eventual impacts are not yet known.

Risk managers are to consult with stakeholders to determine the appropriate measures to be taken for preventing or containing a risk taking into account the scientific advice, legitimate factors and, where necessary, the precautionary principle and to communicate on which basis risk management measures were taken. As such, risk communication at EU level takes place through the justifications provided in the recitals of risk management measures (e.g. balancing of scientific opinions and legitimate factors), media communications, as well as minutes of the PAFF committee.<sup>175</sup>

According to available evidence, **risk communication is not always effective enough.**

- Several of the consulted parties (FBOs, NGOs and consumer groups) in the context of the General GFL study, have pointed to occasionally conflicting communications from EU vs. MS risk assessors, and also to divergences between EFSA, the Commission and national level communications. In their view, this has led in some cases to a lack of clarity as regards the final decision-making process with direct impact on consumer trust.<sup>176</sup> Indeed, on the very few occasions, where there were scientific divergences between EFSA's risk assessment and that of national assessors, national risk management measures were adopted, which differed or contradicted EU risk management decisions (e.g. French measure on Bisphenol A), creating confusion for the public. Divergences between different scientific bodies, however, do not *ipso facto* question the work of the different scientific bodies, as they could be explained by different legal frameworks, by different questions being asked by risk managers or by different methodologies followed. As regards the latter, divergences can in some cases be explained on the basis that one scientific opinion may have carried out a hazard assessment, while another may have carried out a risk assessment. Often incorrectly perceived to be synonyms, a hazard stems from the ability of an organism or substance to cause an adverse effect. Risk, by comparison, is the likelihood that such adverse effects will occur taking into account possible exposure to the hazard in question. In other words, a hazard is anything that can cause harm, whereas risk is the potential that a hazard will cause harm. This different approach can lead to different results, and hence has the potential of having an adverse impact on public perception. A recent example of this was the scientific controversy that emerged in 2016 with respect to the renewal of the approval of glyphosate as an active substance used in plant protection products. While EFSA following a full risk assessment, including the assessment of potential carcinogenicity and taking into account the intended use of glyphosate had delivered a favourable assessment for humans, animals

and the environment for the approval of glyphosate as an active substance, the International Agency for Research on Cancer ('IARC') had warned against glyphosate in general on the basis of a hazard identification which is the first step of a risk assessment. In addition, EFSA had focused on the pure active substance, whereas IARC had included in its assessment formulated products and had focused on possible hazard, without taking into account whether the dose necessary to provoke the observed effect is in any relation to exposure which can be realistically expected. EFSA's conclusions were backed by all MS pesticides' risk assessors but one expert of a national agency. Statements made by national political authorities – sometimes contradicting their own national scientific agencies – however, led to a heated public debate in which the public got confused by the different messages on this issue. In addition, the risk trade-offs in risk management decisions are not always communicated to the public. In that respect, consumer organisations have underscored the importance of understanding the underlying *rationale* where national measures differ from or even contradict EU legislation, *i.e.* whether it results from scientific diverging conclusions (*e.g.* French national assessor weighing the same data differently from EFSA on BPA), from apparent scientific divergences (different approach used such as hazard assessment instead of a risk assessment in the case of glyphosate) or from different political choices in risk management and possible trade-offs.<sup>177</sup>

- Effective risk communication should also take into account that humans tend to take decisions not based on statistical analyses, but often on the avoidance of certain risks which are considered as most relevant to them. For example, the above-mentioned IARC study on carcinogenic substances identified a high number of other possible carcinogenic substances at the same (red meat) as or even a higher ranking (processed meat) than glyphosate; however, this did not lead to similar concerns in the general public.
- Scientific divergences (real or perceived as such) related to food safety are high on the public agenda mostly when related to GMOs and active substances for the production of plant protection products where other societal choices are at stake, such as the protection of the environment *vs.* the productivity of agriculture, globalisation *vs.* preference for local production. However, the limited scope of the communication on science or on food safety leads to difficulty in addressing these wider problems. Indeed, EFSA risk communication activities under the GFL Regulation cannot address criticisms on issues other than science *e.g.* globalisation concerns. Science, although a key element of risk management, is not sufficient to establish trust in technological innovation (*e.g.* GMOs) when larger societal choices are at stake.
- The General GFL study has also identified that there is a perception amongst stakeholders that the risk analysis principle is not systematically applied.<sup>178</sup> The concrete cases provided by stakeholders showed that they considered that the risk analysis principle was not respected in cases where the EU risk managers had also taken into account other legitimate factors. Some stakeholders, including consumer groups have also raised the concern that the gap in timing between communication on risk assessment (EFSA opinion) and risk management decisions can also accentuate the perceived lack of clarity as regards the final decision making process. Therefore, risk communication activities should not be limited to specific scientific outputs. They should also address the entire risk analysis process on a regular basis. Indeed, the effectiveness of risk communication in general as well as the acceptability of the

risk management decisions would increase, should the general framework within which such decisions are taken and the different steps in the process be made clear in advance.

For communication in times of crisis, please refer to Sections 4.2.5.3 and 4.2.10.3.

#### *4.2.2.4 Analysis of the overall implementation of the risk analysis principle*

The rigorous implementation of the risk analysis principle throughout the EU food law has overall raised the level of protection from potential food safety risks in a number of ways.

First of all, the creation of EFSA has led to an increased scientific capacity globally meeting the increased demands for scientific advice in the EU. Nevertheless, the adoption of subsequent EU food legislation has had an impact on EFSA's activity in two ways. Firstly, it has influenced EFSA's flexibility, limiting sometimes rooms for action and imposing different processes and reducing standardisation, mainly in relation to the evaluation of regulated products. Secondly, the legislative framework had an impact on EFSA's capacity to adequately plan and allocate its resources because of poor exchanges with the EU institutions during the legislative process and the limited notice of official communications.<sup>179</sup> No extra budget or staff was foreseen in the financial fiches accompanying the new authorisation procedures, adopted following the establishment of EFSA.

To address the impact of the high workload of EFSA in the area of authorisations, the Commission undertook an impact assessment on the establishment of fees for EFSA in 2013.<sup>180</sup> Although it acknowledged the high workload of EFSA in the area of authorisations, the latter impact assessment concluded that the imposition of fees for EFSA was not workable because of the complexity of the legal framework, embracing 19 different pieces of EU legislation. An in-depth analysis of the options considered showed that none of those proposing the introduction of fees would ensure EFSA a satisfactory income, nor would they result in significant savings for the EU budget. In addition, the perception of EFSA's independence could be damaged.

Since 2015, 10 extra contractual posts were created to reduce the backlog experienced by EFSA.

Nevertheless, there are a number of negative signals on the capacity of EFSA to maintain a high level of scientific expertise:

- Recent calls on the membership of some panels have shown the difficulties encountered to attract new members due to a number of disincentives: insufficient recognition for the scientists' career, modest financial compensation for the experts and their employers considering the amount of time required for their EFSA's contribution, strict rules on independence which do not take into account the increasing trend of public-private partnership in scientific research (see also Section 4.2.2.1.1).
- The distribution of experts per MS in Scientific Committee/Panels show that 69% of experts originate from 6 MS, while 86% originate from 10 MS. A similar tendency had also been stated in the EFSA 2012 external evaluation: 59% of experts originating from 6 MS and 71% from 10 MS. This is linked to a different capacity of scientific expertise in the MS which EFSA only moderately alleviates by providing trainings on risk assessment.
- The current trend of diminishing public administration budget might also impact on the capacity of national bodies to send experts to EFSA or to contribute to its work.

- As stated in Section 4.2.2.1.1, the finances dedicated to the outsourcing of EFSA's tasks to national risk assessors are considered by the MS as relatively low (€10 million per year, 13% of EFSA's total budget).

These negative signals show the limitations of the current system to ensure in the long-term sufficient expertise and to fully engage all MS in scientific cooperation.

As stated in Section 2.2 (see Figure 2), the three components of the risk analysis principle are interconnected. Notwithstanding this interconnection, the **separation** of the risk assessment and risk management at EU level to guarantee the independence from political influences has been improved over time. According to the EFSA 2012 external evaluation report, EFSA is generally independent and it has one of the most advanced and robust systems in place for ensuring its independence.<sup>181</sup> As stated in Section 4.2.2.1.1, the current structure and governance of EFSA is not in line with the Common Approach endorsed by the European Parliament, the Council and the European Commission on decentralised agencies in 2012.<sup>182</sup> According to the latter, *"in order to improve the performance of agencies' boards and reinforce their capacity to supervise the administrative, operational and budgetary management of agencies, while guaranteeing full participation of the Member States and of the Commission"*, all Member States must be represented in the Management Board of decentralised agencies, amongst others.

As analysed in Section 4.2.2.1.1, despite **overall progress on the independence and transparency of EFSA's work, these remain sensitive issues in terms of perception**. EFSA has recently taken some steps to strengthen its rules on independence. In effect, there is a trade-off between increasingly stringent requirements to manage potential conflicts of interests and the availability and willingness of experts to make themselves available under these requirements. This risks the availability and quality of scientific advice to EFSA and calls into question the sustainability of the model of relying on outside expertise in contrast to other regulatory agencies which source their expertise from Member State nominations.

As regards the transparency of the risk assessment process and in the context of authorisation dossiers, EFSA is bound by **strict confidentiality rules** that are laid down in the GFL Regulation and in the multiple authorisation procedures in EU secondary food legislation. The application of the confidentiality rules **creates the perception of a certain lack of transparency**. This perception is further reinforced by the civil society's concerns over EFSA's independence from industrial interests, as EFSA bases its risk assessment on authorisation dossiers on studies conducted by the industry. These criticisms in turn can have a **negative impact on the acceptability of EFSA's scientific work by the general public**. There is therefore a need to address perceived issues with respect to the transparency as well as the reliability and independence of studies underpinning EFSA's assessments, while protecting legitimate confidential business information, in order to safeguard the reputation of EFSA's work. This can be achieved, for example, through measures to increase transparency of the supporting studies, an involvement of public authorities in the process of deciding which studies need to be conducted for an application dossier, enhanced auditing of studies conducted in accordance with the principles of GLP, and the possibility to exceptionally commission ad-hoc studies in case of serious doubts or conflicting results, for example, in case of widely used substances.

As stated in the EFSA 2012 external evaluation report, the increased number of requests for access to documents taken to the European Courts and the increasing number of access to documents that EFSA has subsequently granted show that EFSA should progressively adapt its way of working to the

new expected levels of transparency. The relevance of transparency to EFSA's work should further increase in the future in a way to protect reputation of its work.<sup>183</sup>

In addition, as detailed in Section 4.2.2.3, risk communication has not always been or perceived to have been effective and this has had a negative impact on consumers' trust **and on the acceptability of risk management decisions**.

All consulted parties have also recognised that the systematic implementation of the risk analysis principle in EU food law has raised the overall level of protection of human health,<sup>184</sup> and that the separation of the risk assessment and risk management at EU level generally functions well in practice.<sup>185</sup> In deciding the appropriate measures to be taken, EU risk managers have considered other legitimate factors in addition to the risk assessment by EFSA in a few cases. Where national risk management measures have been adopted, other legitimate factors have been taken into account mostly on a case-by-case basis.

At EU level, the precautionary principle has also been relied upon in limited cases and on the basis of the two criteria mentioned in the GFL to ensure the appropriate protection of public health. It has also been applied in a proportionate manner as demonstrated in the EU management of the BSE measures and confirmed by the relevant jurisprudence of the Court of Justice of the EU. Nevertheless, in two cases, despite the provisional character of this risk management tool, measures have been in place for considerable period of time. At national level, based on the General GFL study findings, the rationale underpinning risk management measures is not always clear as to whether it is based on the precautionary principle or on other legitimate factors.

Overall, no **systemic inconsistencies in the application of the risk analysis principle as such** have been identified at EU level. While the implementation of the risk analysis principle at EU level is fully achieved, **this is not always the case at MS level**, according to the available evidence and subject to the limitations mentioned in Section 3.2. Nevertheless, because of the high level of harmonisation in the area of food and feed safety, national measures are relatively limited.

The centralised approach of the risk analysis **has also increased efficiency and ensured the effective functioning of the internal market**, in terms of (a) cost savings and removal of barriers resulting from the centralised approach put in place, including the establishment of EFSA (b) benefits of pooling the scientific resources involved in EU and national assessment bodies, *e.g.* access to a larger pool of EU and national scientific expertise with the participation of national scientists in the work of EFSA, convergence of scientific views across the EU (see also Section 5.3.1).

Supply chain stakeholders have also generally acknowledged – in the context of the General GFL study - the **positive impact of harmonised risk analysis procedures** in supporting **trade and innovation** in the single market context. For example, the removal of plant protection products not meeting the safety criteria has provided an incentive to develop more innovative products that better protect public health and have equivalent or better efficacy.<sup>186</sup> This finding is further corroborated by the recent study on the competitiveness of the EU food and drink industry. In that context, a number of food industry manufacturers have considered the EU food safety requirements (including the risk analysis principle) laid down in the GFL Regulation as a comparative advantage for EU manufacturers.<sup>187</sup> For example, foods accompanied by a health claim approved on scientific grounds may provide a higher marketing value and create long term consumer trust on the food chain vis-à-vis other unsubstantiated claims on foods in other markets that do not require scientific grounds for their authorisation.<sup>188</sup>

Nevertheless, the **length of the risk analysis process in certain sectors relating to innovative products** (e.g. novel foods, health claims, feed additives, food improvement agents), due to long stop-the-clock procedures during the risk assessment phase and long deliberations with MS' representatives in the PAFF committee during the risk management phase (**comitology delays**) can **have a negative impact on innovation, in terms of expected return on investment**.

According to a recent study commissioned by the Federation of specialty food ingredients, in general, companies are looking for internal rates of their investment within a range of 15% to 25% and an expected payback basis of three to five years. This can be achieved where, for example, a novel food authorisation is completed within 12-18 months of an application. Since 2000, however, the average time taken for a novel food to complete the process of authorisation has been 36 months, within a range of 16-92 months. Similarly in the area of health claims, the average time for approving a health claim has been about 2.5 years, within a range of 15 months and four and a half years.<sup>189</sup> These delays can be compounded by successive authorisation procedures, where the authorisation under sectorial legislation cannot begin until authorisation under another one has taken place (e.g. novel ingredients accompanied by health claims). Where approval is delayed to three years, the internal rate of return falls to an average 10.6% and the payback takes seven years, while where approval is delayed to five years, the internal rate of return falls to an average of 5.8% and the payback is extended to 10 years.<sup>190</sup>

A comparison of the average time taken to approve novel foods in non-EU countries showed that the EU takes, on average, the longest time for a novel food to complete the authorisation process; however, it should be mentioned that due to the different criteria used and procedures operated in various countries to approve novel foods, the time taken to approve novel foods amongst countries are not necessarily directly comparable.<sup>191</sup>

As stated in Section 4.2.2.1.1, to remedy delays in the risk assessment phase, EFSA has initiated since 2012 a series of actions, e.g. introduction of a single entry point for applicants (application desk unit), dialogue with industry in particular through info sessions and work shop helping applicants for the submission of their dossiers and better involvement of stakeholders in the guidance on authorisations. In addition, a new Regulation on novel foods with simplified centralised authorisation procedure at EU level has also been recently adopted, which sets out specific deadlines for risk assessment and for the Commission to propose a draft risk management measure to the PAFF committee.<sup>192</sup>

Delays in the risk management phase are often linked with **risk communication issues**. For example, in the context of the General GFL study, several MS have raised the fact that they are not consulted on the mandate for a scientific opinion developed by the Commission, although they are called to vote on the final decision at the PAFF Committee.<sup>193</sup> The formulation of the mandate is important, because it determines the adequacy of the risk assessment outcome and its relevance to addressing the needs of the risk managers at the comitology phase. Some of the debates in the risk management phase (particularly the comitology phase) could be minimised, if the risk communication activities linked to the risk assessment phase, especially with respect to politically sensitive issues, were more interactive and ensured greater involvement of MS and stakeholders at an early stage. EFSA is already trying to ensure greater involvement of its stakeholders in the risk assessment phase in the context of the most important self-tasking mandates. The Heads of national

food agencies also produced two reports recommending an increased transparency of the risk management decisions at national, EU and Codex Alimentarius levels.<sup>194</sup>

In addition, the Commission has recently **adopted a proposal for amending Regulation (EU) No 182/2011<sup>195</sup> ('Comitology Regulation')** with a limited scope to, amongst others, reduce the risk of 'no opinion' being delivered at committee level and provide an incentive for Member State representatives to take a clear position. The objective of this proposal is to improve the functioning of the comitology procedures at the level of the appeal committee to ensure wider political accountability and ownership of politically sensitive implementing acts. This proposal could indirectly contribute to a shortening of delays in the risk management phase. Under the current Comitology Regulation, the Commission endeavours to find solutions which command the widest possible support within the committee.<sup>196</sup> To this end, the Commission holds preparatory discussions at committee level to ensure the widest support possible before a vote takes place. By facilitating wider political accountability and ownership of the risk management measures, the preparatory discussions at Committee level may be less time-consuming. Nevertheless, given the early stages of the negotiations with respect to the proposal, the final form and overall impact of this initiative in the risk management phase is yet unknown.

FBOs have also cited the cost of preparing authorisation dossiers (see also Figure 5 and Box 1)<sup>197</sup>, the uncertainty of the authorisation procedures as regards the consideration of other legitimate factors, the more stringent requirements applicable to feed additives as opposed to feed materials, as elements that can hamper innovation.<sup>198</sup> All these obstacles relating to innovation and trade, however, appear to be due to the **modalities** of the authorisation procedures, as laid down in other EU secondary food legislation, and will therefore be further analysed in pending and future evaluations of relevant EU secondary food legislation.

**Figure 5:** Average costs of preparing application dossiers and estimated market values (2011-2012)<sup>199</sup>

Substance/product/claim	Average cost per applicant (€)	Market value (€)
Active substances of plant protection products (PPP)	0.5-3.7 million	7-8 billion for PPP 250 million of microbial, semi-chemical and natural products based PPP
MRLs of PPP	0.2 million per new MRL (less for extension of use)	<i>[not available]</i>
Food additives (new authorisation)	0.25 million – 1.8 million	<i>[not available]</i>
Food flavourings	0.354 – 0.5 million	1.5 million
Smoke flavourings	0.35-0.385 million	[not available]
Enzymes	Feed: 0.3 million Food: 0.45 million	<i>[not available]</i>
Food contact materials	Up to 2 million	100 billion



Health claims	0.008/0.2 – 1 million	Approximately 8.6 billion
Nutrient sources	0.02-0.045 million	
Novel foods	0.02-0.045 million	

**Box 1:** Costs of preparing an application dossier in the area of feed additives (industry estimates)<sup>200</sup>

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

Direct costs:

Art. 4 full dossiers (authorisation of a new feed additive - 1 major species): 2 to 5 Mio € depending on the “novelty” and functional group (much higher for zootechnical additives);

Art. 13 dossiers (modifications of existing authorisations): 0.1 to 2 Mio €: depends widely on the type of modification requested;

Art. 14 dossiers (renewals of authorisations after 10 years): 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. Industry estimates 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 may 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 for 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.

*\* 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.*

In few sensitive areas where there are societal concerns, the necessary cooperation between the Commission, MS and EFSA to ensure the consistency of the risk analysis process is not always fully ensured. For example, there are a few cases where the national risk managers have requested a risk assessment by their national risk assessors, duplicating the EFSA risk assessment at EU level and leading to potential divergences in the risk analysis process, such as in the case of Bisphenol A.

Finally, a more **global risk communication** performed at **the different steps of the risk analysis process involving risk assessors and risk managers both at EU and MS level combined with open dialogue** may be more effective in addressing criticisms on politically sensitive issues and bolster consumer trust.

### 4.2.3 Allocation of responsibilities

#### 4.2.3.1 Primary responsibility of FBOs – general safety requirements – withdrawals

Pursuant to the GFL Regulation, FBOs are primarily responsible for (a) ensuring compliance with both EU and national food law (*e.g.* food and feed safety requirements, labelling requirements), which are relevant to their activities and (b) to verify (own controls) that such requirements are met.

As this is a **goal-oriented obligation**, FBOs have the **necessary flexibility** to design their own optimal procedures and own controls. Other EU secondary food legislation has built upon the principle of primary responsibility. First and foremost, EU secondary food legislation in the area of food and feed hygiene requires FBOs to put in place, implement and maintain a permanent procedure based on the Hazard Analysis and Critical Control Point (HACCP') approach.<sup>201</sup> The HACCP approach provides a means to FBOs to implement control measures that can eliminate, or reduce to an acceptable level, hazards along the production chain in a preventive manner, rather than relying mainly on end-product testing. The HACCP approach allows each FBO to make the necessary adaptations taking into account the specific level of risk, the specific nature of its activity and the size of the production. It is important to also note that the Food Hygiene Regulations allow for the application of 'good manufacturing practices' rather than fully-fledged HACCP systems (**flexibility**). For this purpose, two main criteria render a FBO eligible for flexibility: its nature and its size:<sup>202</sup> (a) the nature is the basis for a risk-based approach and depends on the activity of the FBO (*e.g.* processing, wrapping or just storage of prepacked food); and (b) the size of the business concerned (*e.g.* volume of production, throughput *etc.*), is linked to proportionality for small FBOs and is mainly reflected in a reduction of administrative burden (use of generic guides, extent of documentation, records *etc.*). Another example of EU food law that has built upon the primary responsibility principle is the Food Information to Consumers Regulation with respect to the responsibilities of FBOs in terms of food information.<sup>203</sup>

In this respect, the GFL Regulation **led to a more systematic application of procedures and measures that FBOs had in place before the GFL Regulation**. For the most part, FBOs – particularly larger companies – did not encounter any considerable constraints to comply therewith. FBOs have also considered the EU guidelines on the GFL Regulation<sup>204</sup> as a useful tool to ensure compliance with their primary responsibility obligations.<sup>205</sup>

According to both stakeholders and MS CAs, FBOs at all stages of production, processing and distribution are verifying (*e.g.* via their own internal controls) that the requirements of food law that are relevant to their activities are met. However, the General GFL survey 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.<sup>206</sup>

The General GFL study has also addressed the costs for FBOs of complying with the primary responsibility obligation as set out in the GFL Regulation. FBOs **were not** in a position to **quantify these costs**, *e.g.* as % of total production costs. This is largely due to the fact that the costs are **specific to each FBO** so that the form in which compliance is achieved is specific to each stage of the chain and to the profile and needs of each operator. The costs are also influenced by a combination and range of factors: business type or size, extent of cross-border trading or sector, product, supplier and customer range *etc.* Size is an important factor when all others are equal: in relative terms,

smaller FBOs 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 and customers.<sup>207</sup>

Compliance costs are often incorporated in **contractual obligations in place and/or private quality management and certification systems ('private standards')**, which build upon the GFL primary responsibility principle and the requirement to carry out own controls to ensure compliance with food law.<sup>208</sup> Indeed, over the last decade, several private standards put in place by retailer organisations relying, amongst others, on global benchmarks (*e.g.* the Global Food Safety Initiative 'GFSI') have developed,<sup>209</sup> which tend to provide for strict verification procedures. This trend has been particularly fostered by the globalisation of the food trade and the complex character of the food supply chain. **Adherence to private standards has now become common business practice.** In the cereals/oilseeds trade sector, for example, more than 80% of traders are certified with the industry standard, while in some MS, food processors are virtually excluded from selling to large retailers, unless they are certified according to recognised standards.<sup>210</sup> Large retailers tend to be a key driver in promoting their private standards to the rest of the food chain, motivated by the need to avoid costs associated with non-compliance, to ensure that controls by authorities do not lead to any problems and, to maintain the integrity of their reputation.

Nearly half of **SME respondents** considered that the verification (own controls) requirement is the hardest to meet. When asked about the most prevailing food law requirements in their contracts with suppliers and customers, half of the SME respondents are asked to comply with specific private standards, guidelines and codes of practice issued by industry associations and communicate results of own controls to their suppliers and customers. One third of the respondents have hired an external consultant to help them comply with EU food law.<sup>211</sup>

Where FBOs have determined that a food or feed is unsafe, they have for the most part proceeded to the necessary withdrawals from the market and informed accordingly the competent authorities.<sup>212</sup> Moreover, three quarters of the SME respondents have an internal system in place to withdraw unsafe food and feed, while it is still in their immediate control. Less than half of those have actually ever used it.<sup>213</sup>

Similarly, the cooperation between FBOs and authorities has been generally functioning well.

#### 4.2.3.2 *Official controls by MS*

The EU framework for the organisation and performance of official controls is set out in Regulation (EC) No 882/2004 (Official Controls Regulation).<sup>214</sup> According to the latter, official controls should be carried out regularly, on a risk basis<sup>215</sup> and with appropriate frequency taking into account, amongst others, the **reliability of the FBOs' own controls**. Where non-compliance is identified, MS CAs are required to take action to ensure that the operator remedies the situation. MS remain responsible for organising and performing official controls in accordance with the Official Controls Regulation. Therefore, the implementation of official controls varies not only between MS<sup>216</sup> but also within the same MS at regional or local level.

Problems reported include the fact that MS CAs **do not consistently take into account FBOs' own controls** in their risk assessment and, as a consequence, in their control plans, irrespective of whether third party certification is performed. FBOs perceive this as a major limitation to the

optimisation of the costs related to own controls, while a level playing field as regards compliance costs is not ensured across the EU (*i.e.* FBOs face different costs depending on the approach followed by national authorities). This variable approach of the MS CAs can, however, also reflect to some extent differences in the **reliability of own controls**.<sup>217</sup>

'**Distance selling**' has gained importance, since the adoption of the GFL Regulation, as a way of supplying food to consumers. According to a report from the audit and inspection service of DG SANTE,<sup>218</sup> an increasing share of the trade in food supplements is developing on internet. E-commerce is less transparent and more difficult to control.

The recently adopted Regulation (EU) 2017/625 on Official Controls and other Official Activities<sup>219</sup>, which will repeal and replace the existing Official Controls Regulation as of December 2019, modernises the current system and provides a single framework for all official controls along the agri-food chain (including plant health, plant reproductive material and animal by-products). Businesses and MS CAs are expected to benefit from reduced administrative burdens, more efficient processes and strengthened controls. At the same time, consumers are expected to benefit from more transparency on how controls are carried out and their outcome to ensure food safety and quality, high standards for plant health, animal health and welfare and to prevent fraud. Currently, under the existing legal framework, MS transmit data on the implementation of official controls on an annual basis; however, this data is not comparable and cannot be relied upon for drawing conclusions on the implementation and enforcement of EU food law. The new Regulation on Official Controls empowers the Commission to establish standard model forms for these annual reports. This is expected to facilitate the collection and transmission of comparable data, its subsequent compilation into EU-wide statistics and the preparation of reports by the Commission on the operation of official controls across the EU. In the future, such Commission reports can provide considerable evidence for undertaking in-depth evaluations of EU secondary food legislation. In addition, the new Regulation also provides for different control tools which can address more effectively 'distance selling'.<sup>220</sup>

In addition, to enhance a harmonised understanding and application of a wide range of EU secondary legislation, including food law, the Commission has in place the *Better Training for Safer Food programme* ('BTSF')<sup>221</sup> providing training primarily to official control staff of MS and to officials from non EU countries. From the launch of training activities in 2006 until 2016, BTSF has organised approximately 1500 training events attended by approximately 61,000 people, with an overall budget of around €140 million. In 2016, the Commission launched a study titled "**Analysis of the impact of Better Training for Safer Food (BTSF) Programme**", comprising two tasks:

- establishment of an evaluation model based on the Kirkpatrick/Return-on-investment ('ROI') model to estimate the effectiveness of BTSF training and its return on investment;
- A SWOT (strengths-weaknesses-opportunities-threats) analysis of the possible alternative training models in order to see how best the objectives of BTSF can be achieved by which model, or combination of models.

In 2016, the Commission launched a cost-effectiveness study on the BTSF with two main objectives: (a) to ensure an estimation of the cost-effectiveness of the current training model using key performance indicators and a robust cost-benefit model and (b) to perform a SWOT analysis of the different training strategies to determine the model best suited to respond to the growing demand for training. This is due to be completed in the course of 2017.

The vast majority of MS have in place a system of effective, proportionate and dissuasive **measures and penalties** for violations of food law; between 20 and 24 of the 25 responding MS indicated measures and/or penalties in place specifically for violations of food law. The form, specificity and severity of the measures and penalties currently in place **tend to vary** considerably between MS, as this is a matter of national competence. No compiled data is, however, available on the trend of penalties and other measures actually applied at national level specifically for violations of food law during the period 2003-2013, or an explanation of any observed trends.<sup>222</sup>

MS have also considered the **EU guidelines** on the GFL Regulation as a useful tool to ensure compliance with their enforcement obligations.<sup>223</sup>

To ensure that national authorities fulfil their legal obligations with respect to EU food law amongst others, the audit and inspection service of DG SANTE carries out audits or inspections in EU MS and non EU countries on the basis of a multi-annual programme taking into account risk and trade factors as well as the status of the legislation. This initiative bolsters the effectiveness and efficiency of official controls. If deficiencies are identified, recommendations are made to assist the competent authorities in taking corrective actions. The actions taken are followed up either administratively, in general follow-up audits in MS, or by on-the-spot audits. If non-compliance is sufficiently serious, stronger actions may be taken by the Commission, such as legal action, restrictions or even bans on the movement of goods, as well as infringements proceedings.<sup>224</sup>

#### **4.2.3.3 Analysis of the distribution of responsibilities between FBOs and competent authorities**

According to **consulted consumers**, the obligation of FBOs to perform own controls to verify compliance has contributed to a high level of protection of human health and consumers' interests with respect to food/feed products placed on the market, as such controls at every level of the chain allow a number of check points to ensure continuous compliance with food law until a food or a feed reaches the final consumer.<sup>225</sup>

**Consulted FBOs and MS** have acknowledged the following outcomes:

- The primary responsibility principle **has facilitated** the placing on the market of food products and contributed to the effective functioning of the internal market, strengthened 'trust' along the 'farm to fork' supply chain, and ensured a consistent implementation of the 'farm to fork' policy. It has also raised operator awareness of the responsibility to comply with the legal requirements at each level of the chain and across the EU.<sup>226</sup>
- Several MS CAs have noted that the primary responsibility principle established a '**chain responsibility**' which is defined as the collective responsibility of all FBOs at all stages of production, manufacturing and marketing. This was considered a major novelty of EU food law, compared to the pre-GFL fragmented approach.
- The GFL Regulation has ensured an **efficient allocation of responsibilities**: the distribution of responsibilities amongst FBOs along the food chain as well as between FBOs and MS CAs has become clear ensuring an overall level playing field for all FBOs in the EU, reducing administrative burden (e.g. by avoiding unnecessary repetition of own controls along the 'farm to fork' supply chain), and, freeing up resources at MS CA level to focus on the enforcement of food law.<sup>227</sup> In addition, FBOs have generally appreciated the **goal-oriented character** of the GFL Regulation, given its flexibility to design optimal, fit for purpose own control systems.

Primary responsibility, however, has certain limitations, as the GFL Regulation **does not regulate the allocation of liability** amongst the different links of the food chain. Liability (criminal and/or civil) is **determined by national law** (e.g. sanctions), in combination with the specific provisions of (EU or national) food law that were violated.<sup>228</sup> Some national systems also take into account the fact that appropriate own controls have been performed by the operator to assess liability issues (due diligence). Since liability is determined at national level, considerable differences amongst MS exist.<sup>229</sup>

The own controls systems in place by FBOs also address the HACCP approach set out in the EU Food and Feed Hygiene Regulations with respect to the general safety requirements. According to a recent overview report on the state of implementation of HACCP in the EU of DG SANTE,<sup>230</sup> there is **general agreement on the importance and the resulting benefits** of implementing food and feed safety management systems based on **HACCP principles**. The experience of FBOs with HACCP has been generally positive. **Nevertheless, certain difficulties have been identified that stem from a lack of understanding of core concepts, particularly by small FBOs, or inconsistencies in their implementation by MS CAs.** Flexibility is the least understood HACCP concept, which results, amongst others, in small FBOs maintaining unnecessary documentation, which increases their administrative burden. To provide more clarity, the Commission has recently published a notice on the implementation of food safety management systems covering prerequisite programs and procedures based on the HACCP principles, including the facilitation of the implementation in certain food businesses.<sup>231</sup> Moreover, many small food retailers have difficulty complying with the requirements of existing food safety management systems; in particular applying complex HACCP plans can be beyond the capacity of establishments that may employ only a handful of staff. In that respect, EFSA, at the request of the Commission, has recently proposed a simplified approach to food safety management to assist small retail businesses such as grocery shops, butchers and bakeries.<sup>232</sup>

The General GFL study found that the **benefits** of the primary responsibility principle **have overall outweighed** the costs of meeting this requirement (e.g. via own controls) **for more than half of the FBOs consulted** (52%). The benefits were mostly felt by those FBOs trading within the internal market as they can benefit from harmonisation. Nonetheless, a quarter of stakeholders indicated that benefits have not for the most part outweighed costs. Those FBOs tended to be smaller and craft enterprises that are more active in national markets. They do not, therefore, benefit from the harmonised requirements of the internal market, but have, nevertheless, to cope with the administrative burden stemming from other EU secondary food legislation. Given the diversity of the sector, however, it cannot be concluded that harmonisation benefits larger enterprises more than smaller ones, as in practice a large range of operational contexts can prevail.<sup>233</sup>

Smaller FBOs often commented that they have difficulties in complying with food-related requirements. However, those FBOs, particularly micro and small operators, do not distinguish between **regulatory** and **non-regulatory requirements**. **Private standards**, which have now become common business practice, serve as the basis for integrating regulatory requirements, as they build upon existing EU food law requirements. But at the same time, they may add to the burden of FBOs, as they often lay down additional non-regulatory requirements. For example, large retailers, cautious to avoid any potential risks and driven to accommodate what consumers are interested in, often require from their suppliers voluntary 'marketing' requirements (e.g. origin indications), which also need to be part of the verification systems in place. Smaller FBOs, which tend to be mostly in direct

and long-standing contracts with retailers, may therefore commit to non-regulatory requirements to ensure customer loyalty through contractual obligations or adherence to private standards.<sup>234</sup> The Commission is currently considering whether EU-level action is needed to address anti-competitive practices caused by the weaker position of farmers and SMEs in the food supply chain with respect to foods of agricultural origin vis-à-vis other levels of the chain.<sup>235</sup>

According to MS CAs, the distribution of responsibilities between FBOs and CAs with the former being primary responsible for compliance with food law and the latter responsible for carrying out official controls, allowed competent authorities to develop a more harmonised and better targeted, risk-based approach to official controls, and ensure efficiency gains.<sup>236</sup>

The overall implementation of the general safety requirements and of the relevant provisions on withdrawals of unsafe products has been positive.<sup>237</sup> However, stakeholders have identified as an issue of concern the **variable level of implementation of withdrawals** amongst the MS, both in terms of how the provisions relating to the withdrawals of products are implemented by the FBOs and in terms of the withdrawals ordered by the authorities themselves.<sup>238</sup> This is **mainly** attributed to differences of implementation on the part of MS CAs in determining the safety of feed and food. According to several FBOs, MS CAs can take different courses of action when applying the general safety requirements. For example, when a particular food is found to be non-compliant with a legal provision linked to safety, some MS CAs might consider such non-compliance as justifying a withdrawal of the relevant food on the basis of the evaluation of risk but also on the basis of other factors (such as intentional adulteration of a food). However, others might take a different approach and consider that after an assessment of the safety parameters of the food in question that a withdrawal might be disproportionate and opt for a different course of action (*e.g.* imposition of penalties, adaptation of labelling *etc.*).

#### 4.2.4 Traceability of feed and food

##### 4.2.4.1 Implementation of traceability by FBOs

The general traceability requirement provided in the GFL Regulation for safety purposes for both food and feed consists of 'one step back – one step forward' traceability. The 'one step back' part of the traceability requirement allows the identification of the source of risk, while the 'one step forward' part allows the identification of the unsafe batches, lots or consignments. This general requirement has been complemented by more specific requirements for two particular sectors: for foods of animal origin<sup>239</sup> and, in response to the 2011 *E.coli* crisis, for sprouts and sprout seeds.<sup>240</sup>

According to the General GFL study,<sup>241</sup> the 'one step back – one step forward' traceability was already applied to some extent on a voluntary basis prior to the GFL Regulation; however, its application across the food supply chain tended to be fragmented. Following the GFL Regulation, the "one step back – one step forward" traceability has been implemented across the entire food chain both in quantitative (from partial to complete implementation of traceability by all FBOs) and qualitative terms (from fragmented to full application along the chain).<sup>242</sup> Traceability information transmitted through RASFF in case of cross border risk occurrences has also become more readily available, complete and reliable, compared to the situation prior to the GFL Regulation. Nevertheless, it still occurs that the traceability chain is interrupted because of errors or incomplete documentation at a particular stage.

Given the **goal-oriented** character of traceability and the diversity of operational contexts and systems available<sup>243</sup>, **considerable variations in the implementation of this requirement have been noted**, *e.g.* in the recording medium which may range from paper copies to sophisticated IT tools holding an extensive range of data. These depend on a range of factors such as size and type of company, business model, sector of activity, product portfolio, range of suppliers and customers, sourcing patterns and length of the supply chain, allowing FBOs to choose the appropriate solutions for their individual business model.

In the context of the General GFL study, FBOs **were not** in a position to **quantify** the traceability costs, *e.g.* as % of total production costs. Generally, however, for a considerable (although not precisely known) part of the supply chain, the mandatory traceability requirement **had a neutral impact** on the operational structure of FBOs, given that it was on a voluntary basis prior to the GFL Regulation. Even where systems already existed but were outdated, the introduction of the new rules has acted as an incentive for FBOs to update their systems and IT software solutions used, also aligning with technological/IT innovations, or to move from paper-based to electronic systems. No correlation between the impact of traceability and the size of operators has been established. According to supply chain representatives, as a general rule, **smaller FBOs with a large range of products and suppliers, using paper-based traceability would have been the most impacted**. At the other end of the spectrum, local FBOs with a limited range of products and suppliers or FBOs of any size with well-established systems prior to the GFL Regulation, certainly would have had an advantage compared to other operators.

As far as **SMEs** are concerned, the **majority of respondents have not found it hard to meet** the traceability requirement, although 42% of respondents have faced some difficulties.<sup>244</sup> SME respondents also ranked the **cost of traceability compliance** (together with labelling, authorisations, registration and certification) as **one of the most costly** of all EU food law requirements. In the absence of data on the quantification of costs of the traceability, an effort was made to evaluate whether the burden involved stems from the GFL Regulation itself or not. Nearly half of the SME respondents implement the one step back-one step forward traceability as going beyond a normal book-keeping exercise, *i.e.* **beyond the minimum information required by the GFL Regulation**.<sup>245</sup> This is confirmed by the fact that 73% of the SME respondents have internal traceability systems in place, nearly two thirds of which were set up at businesses' own initiative.

The fact that SMEs have in place **more extensive traceability systems** than what is required by the GFL Regulation, with direct impact on increased administrative burden, may be due to non-regulatory requirements (*e.g.* private standards, codes of practices, contractual obligations or own initiative traceability systems) or additional requirements posed by other EU secondary food legislation for purposes other than food safety (*e.g.* origin traceability for food information purposes).<sup>246</sup>

Generally, **no systematic cases of failures** have been identified: traceability stands out as the area where the least differences in the interpretation and enforcement by national authorities are identified. Any constraints in applying traceability generally stem from (a) other EU secondary food legislation for purposes other than safety, (b) private standards, and (c) diversity in implementation/enforcement approach at MS level as regards internal traceability: while internal traceability is not required by the GFL Regulation and it is ultimately a business decision (which allows even more targeted and accurate withdrawals), FBOs have reported instances where national



control authorities had requested them to provide records of internal traceability. This approach varies between MS but also within the same MS.<sup>247</sup>

Consulted FBOs and MS have considered the **EU guidelines** on the traceability requirement largely useful in assisting them with their respective obligations.<sup>248</sup>

#### 4.2.4.2 Analysis of traceability implementation

Both stakeholders (including consumers) and MS CAs consider that the general traceability requirement has improved the tracing of feed and food for safety purposes compared to the situation prior to the GFL Regulation,<sup>249</sup> especially as regards feed.<sup>250</sup> The improved tracing of feed and food has further led to the following positive outcomes: identifying and containing food safety problems; ensuring effective and rapid tracing along the supply chain; ensured targeted withdrawals of unsafe products in a **speedier and less costly manner than before**, taking into account the risk involved; and maintaining consumer trust in food safety. Various incidents have demonstrated these outcomes, even when it concerns imported goods (*e.g.* melamine crisis). A comparison between the dioxin crisis in Belgium in 1999 and a 2016 incident of dioxin contamination in yeast compound feed from Italy with raw material from India is indicative of the improvements resulting from the traceability requirement, set out in the GFL Regulation. In the former case, a complete picture regarding supply and distribution was only available after almost two months without the possibility to identify precisely the products affected. Although the contamination was traced to a particular supplier, the repercussions were enormous as it resulted in vast withdrawals of numerous products and relevant bans. As stated in Section 2.1, the losses for the Belgian economy were estimated at €1.5-2 billion. In the latter case, on the other hand, it took less than a month to identify the source of the problem and the production of derived products affected, which resulted in a great number of targeted withdrawals of dozens of feed formulations distributed worldwide in as many as 34 countries, through information exchanged in RASFF. Because of the prompt response and the targeted withdrawals of affected products, the disruption of the market was limited and did not have an adverse effect on consumers' trust.

According to the General GFL study, more than half of consulted FBOs (57%) have indicated that overall the **benefits** of traceability **have outweighed the relevant costs**. Nonetheless, 23% of FBOs indicated that benefits have not for the most part outweighed costs, while 21% did not provide an answer because they were not in a position to know.<sup>251</sup>

Traceability, however, in the current set-up has **certain limitations**, as it does not always result in targeted withdrawals, when the risk involved with suspected products is considerable. This was the case with respect to **pork meat contaminated with dioxin through feed in Ireland in 2008**, where a large withdrawal operation in the EU and non EU countries involving as many as 54 countries, amongst them 27 RASFF member countries, took place within less than two weeks.

As internal traceability is not required, it was not possible to identify exactly which pork carcass from a particular farm went into each batch of finished pork product. Given the considerable public health risk relating to the exposure to dioxins over a significant period and the wide extent of cross-border and international trade involved, the Irish authorities decided within days to withdraw from the market all pig meat and pig meat products produced from pigs slaughtered the preceding three months in Ireland, even if not more than 6-7% of the Irish pig meat production was affected by the contamination incident.<sup>252</sup> Despite this, **EU-wide traceability** - in combination with effective risk communication and other crisis management tools available at EU level, *e.g.* RASFF and EFSA's

scientific advice on this issue, which was delivered in two days – **enabled a quick response to effectively contain the risk and avoid a spill-over effect to the beef sector**, which is a particularly important sector in Ireland, while **preserving overall consumer trust**.

In addition, traceability **has also contributed to containing other non-risk related incidents**, such as the case of food products adulterated with horse meat in 2013, despite the inherent difficulties that fraudulent practices present.

These findings are also confirmed by the **SME panel**. Indeed, a vast majority of the SME respondents has acknowledged the **following benefits of the traceability system**: it makes it easier to manage risk in food safety incidents (85% of respondents); helps identify which products need to be withdrawn from the market (83%); and, 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). Small and micro enterprises are less convinced<sup>253</sup> of the benefits of a traceability system, except for the contribution of the traceability system to consumer trust.

Given the extent of the cross-border trade in the internal market, these positive impacts are directly the result of **EU-wide traceability**. Indeed, if there were no EU-wide system, the traceability system would have limited value given the extent of the internal trade within the EU. An EU-wide system is more uniform, allows a level playing field across the EU for all FBOs, facilitates the exchange of information between MS so as to identify more rapidly the sources of incidents and affected products in cross-border trade and limits unnecessary disruptions of trade and costs through targeted corrective actions (*e.g.* withdrawals).<sup>254</sup> Without such an EU-wide system, MS would probably close their borders as soon as an incident is identified causing trade disruptions.

#### **4.2.5 Principles of transparency: Public consultation and public information**

Although, transparency is an underlying concept that supports different provisions of the GFL Regulation, and especially the risk analysis principle as analysed in Section 4.2.2 (*e.g.* transparency of EFSA's operation, risk management, risk communication), it is specifically enshrined as a principle with respect to (a) the open and transparent development of food law both at EU and national level through public consultation (Article 9), and (b) the obligation imposed on MS CAs to take the appropriate steps to inform the public (public information) where there are reasonable grounds to suspect that a food may present a risk to health (Article 10).

##### **4.2.5.1 Public consultation at EU level**

To implement the public consultation principle and to ensure the active consultation of stakeholders in EU decision-making relating to food chain matters, the Commission reorganised the various advisory committees and standing committees and created a new **Advisory Group on the Food Chain and Animal and Plant health** in 2004.<sup>255</sup> The Advisory Group is composed of 45 members selected on the basis of established criteria and drawn from representative European bodies, including consumer associations. To ensure that the Advisory Group works efficiently and transparently, there is also the possibility of organising working group meetings which are open to other interested parties, where necessary. The Commission has been consulting the Advisory Group on all issues of food legislation<sup>256</sup>

on a regular basis. Nevertheless, the Commission can always decide to hold direct public consultations, where it is necessary.

All consulted parties have noted **considerable progress towards an improved public consultation** at EU level, with the frequency of public consultation being perceived to be generally higher in the case of EU legislation than in the case of national legislation.<sup>257</sup> The most important improvements include a more systematic application of public consultation throughout the decision making cycle (*e.g.* impact assessments, evaluations, revisions *etc.*) involving the complete spectrum of stakeholders across the various legislative fields, including SMEs and also through the Advisory Group, and the increase in the consultation of the general public (online open public consultations). Public consultation is further fostered by Commission's "Better Regulation" agenda.<sup>258</sup>

#### **4.2.5.2 Public consultation and public information at MS level**

MS have progressively introduced or adapted public consultation in the national legislative process of food law in line with the GFL Regulation.<sup>259</sup> These adjustments run concurrent with the considerable reorganisation of MS CAs' competences on food safety, in the aftermath of the food crises in mid-90s and prompted by developments in the communication and media sector, in particular the increase in speed of, and access to online information by the public. The main difficulties encountered by national authorities during this process have been the cost and the workload resulting from the effort to develop systems enabling enhanced transparency: the extent of the difficulty depended on the level of transparency prior to the GFL Regulation (which, as indicated, was highly variable between MS).<sup>260</sup>

Similar to the EU level, the most important improvements brought about by national public consultation was a more systematic application of this principle in the development of food law, the involvement of a wider spectrum of stakeholders and the increase in general public consultation. However, the frequency of public consultation is generally perceived as lower in the case of national food law than EU food law.<sup>261</sup>

Stakeholders (including consumers) have identified certain cases of continuing **failures in public consultation at MS level**: impact assessments supporting the preparation and the revision of legal provisions are not systematically carried out; not all relevant stakeholders are consulted or given access to relevant information; and the impact on SMEs, particularly micro- and small-sized enterprises, is not systematically investigated, in the preparation, evaluation or revision of national law. Moreover, stakeholders and MS CAs have different views on the comprehensiveness of the national consultation process. This is largely due to remaining differences in the consultation process, and transparency more generally, between MS.

Similar to public consultation requirement, MS had also to adjust their administrative structures to comply with **their obligation to inform the public** where there are reasonable grounds to suspect that a food may present a risk to health.<sup>262</sup> MS CAs communicate to the general public **mostly in the event of recalls** of specific products, 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 products'.<sup>263</sup> The parallel development of social media required MS to set out communication strategies in case of food safety incidents; according to them, this involved

considerable costs and workload for MS CAs, although **no quantification of costs** was provided on their part.

According to both MS and stakeholders, the process of **informing the public** that a feed or food may present a risk has **improved** over time (although more so according to MS than stakeholders),<sup>264</sup> taking into account lessons learnt from poor communication and its impact during previous food crises. Compared to the situation prevailing prior to the GFL Regulation, the provision of information to the general public has become more systematic and harmonised across the EU, such as the type of information provided. Public authorities tend to inform the general public in an order of priority that is generally defined and is proportionate to the level of potential food safety risk and the type of information provided (in the case of recalls) is generally considered adequate/appropriate.

#### **4.2.5.3 Analysis of public consultation and public information principles**

According to the General GFL study, **despite persisting national differences**, these are progressively narrowing, leading to an overall higher standard of transparency throughout the EU. Generally, **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 Regulation.<sup>265</sup>

Several MS CAs have indicated that the improvement of public consultation has led to an **increase in stakeholders' confidence in the work of the public authorities**, as documented by the results of public satisfaction surveys where these exist. For example, in Belgium, the latest public satisfaction survey, indicates that 85% of participants have favourably evaluated the activities and services provided by the national agency AFSCA, including on transparency and communication aspects.<sup>266</sup>

Although, even in best practice cases, there are continuous stakeholder requests for more information dissemination and more direct involvement, which to some extent also reflects the increase in the volume and complexity of food 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, the views of stakeholders contribute to improving 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 of 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.<sup>267</sup>

The **impact of communicating** to the public that a feed or food product may present a risk for human or animal health, in the case of withdrawals that have occurred in the last five years, has generally been **positive in managing food crises** for both **MS CAs and stakeholders for the most part**. A majority of MS indicated that such communication has limited unnecessary disruption of trade and financial damage, while it has sustained consumer trust. For FBOs, however, informing the public, while it provides beneficial reassurance in the short term, also carries the risk of lasting adverse impacts on business reputation and consumer trust. This is because of the high volatility of consumer trust: it takes years to build up reputation in the food sector and only one poorly managed and/or communicated incident can destroy it. All consulted parties (including consumers) agree that where

communication to the public is coordinated, balanced, targeted, science-based and timely, it helps in more effectively managing food and feed safety emergencies and preventing fully blown crises from occurring, thereby limiting loss of consumer trust, unnecessary disruption of trade as well as financial damage.<sup>268</sup>

**Despite progress, both consumers and FBOs have indicated that there are considerable and persisting national differences as regards communication to the public.** Authorities have emphasized that there are no fixed rules on the best approach to take, particularly in balancing the need to provide additional information vs. confidentiality requirements, which also depends on the specific circumstances of each case. National differences also persist in relation to the understanding and implementation of the rules by MS CAs, *e.g.* on what type of information should be provided and how to address professional secrecy, particularly when additional information may play an important role in addressing public health risks.

Such **differences** can have considerable impact on the effectiveness and efficiency of addressing a food crisis. For example, in the **2008 dioxin crisis involving pork meat in Ireland**, the public authorities proceeded with a timely and appropriate communication to the public. Within days, the news about the dioxin incident was released publicly at a press conference. The message for consumers from the Irish authorities was clear: they should not consume Irish pork and bacon products and they should not be unduly concerned as short term peak exposure to dioxins does not result in adverse health effects. This communication contributed to containing the crisis and avoided the spill-over effect to the beef sector, as analysed already in Section 4.2.4.2. Nevertheless, the communication to the public in the 2011 ***E.coli* in sprouts outbreak was not effective enough**. Extensive media coverage of the events contributed to the alarm among the public and increased the pressure on the regional authorities to quickly identify and contain the risk. This pressure combined with the public health risks involved from this novel strain of the *E.coli* bacteria resulted in the premature and erroneous identification of cucumbers, amongst others, as the source of the outbreak by the local authorities with consequences for the entire EU, despite coordination efforts between EU and MS levels. Although the two cases are not comparable as they involved different types of risks and products, a more effective communication strategy could have minimised the impact on public health and on trade, as further described in Section 4.2.10.3.

#### **4.2.6 Protection of consumers' health beyond food safety at EU level**

##### **4.2.6.1 Implementation of the protection of consumers' health beyond food safety**

The GFL Regulation aims to achieve a high level of protection of human health in general. As such, it is not limited to food safety, but **it also comprises human nutrition**. This broader view of protection of human health is reflected in EFSA's mission to provide, amongst others, scientific opinions on nutrition issues.

This objective has been further built upon with the adoption of other EU secondary food legislation. For example, the Food Information to Consumers Regulation<sup>269</sup> has addressed nutritional aspects by introducing mandatory nutrition information on prepacked foods sold to the final consumer, including explicitly certain nutritional elements of importance to public health. In the context of the latter Regulation, the Commission adopted recently a report on trans fats which advocated setting an EU-wide legal limit for industrially produced trans fats.<sup>270</sup> In addition, specific provisions concerning the use of voluntary nutrition and health claims on foods are set out in the Nutrition and Health Claims Regulation.<sup>271</sup> The Food Supplements Directive<sup>272</sup> also lays down specific provisions for the use

of vitamins and minerals in the manufacture of food supplements so as to ensure a high level of protection of public health. Similarly, Regulation (EC) No 1925/2006 on the addition of vitamins, minerals and other substances to foods<sup>273</sup> ensures a high level of consumer protection by regulating the voluntary addition by FBOs of vitamins and minerals to foods, the addition of which is done for different purposes, such as the potential to improve the nutritional status of the population or specific population groups.

To complement legislative action, voluntary initiatives have also been taken in the context of the Strategy on Nutrition, Overweight, and Obesity-related Health Issues, that aim to reduce the risks associated with poor nutrition and limited physical activity in the EU.<sup>274</sup> Two important fora of the Strategy are the High Level Group on Nutrition and Physical Activity<sup>275</sup> and the EU Platform on Diet, Physical Activity and Health<sup>276</sup>. Reformulation aims at removing excess sugars, salt and fat from products marketed in the EU, helping EU citizens to have healthier diets, while supporting the most innovative FBOs. The Commission has been actively working to support MS' action in this area, through a EU Framework for national action on selected nutrients, and especially, for salt, saturated fat and added sugars.<sup>277</sup> Voluntary targets and methodologies have been agreed and a general monitoring process of nutritional information at product level for the entire EU will be launched during 2017, making it clear for public authorities, consumers and FBOs that there is still plenty of scope to improve products in many food categories, while supporting national reformulation plans. Indicatively, as a result of these initiatives the average salt content in bread in many MS has been gradually lowered in recent year, as salt has been the first ingredient of concern being addressed by the EU Framework. In addition, given that the public procurement of food is worth about €80 billion per year, the Commission has prepared a voluntary tool to help public authorities to draft food and catering contracts that promote healthier diets.<sup>278</sup>

#### **4.2.6.2 Analysis of the protection of consumers' health beyond food safety**

**Consumer organisations**<sup>279</sup> consider that no particular progress has been made on nutrition-related issues. This was attributed to a number of factors. First, lack of full implementation of other EU secondary food legislation on nutritional aspects: for example, the nutrient profiles – legally due by January 2009 – are yet to be established under the Nutrition and Health Claims Regulation. 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.<sup>280</sup> In addition, consumer organisations are of the view that certain opportunities for legislative action on the nutrition front at EU level have been missed: for example, no EU compulsory front-of-pack nutrition labelling to facilitate healthier food choices, no legal restriction at EU level on the use of trans fats to date. Finally, in their view, soft measures, such as the initiatives in the context of the EU platform for diet, physical activity and health, do not always work well,<sup>281</sup> given their voluntary character.

The Commission has recently launched a REFIT evaluation of the Nutrition and Health Claims Regulation with respect to, amongst others, nutrient profiles. Taking into account the failure of the EU institutions to set them, this evaluation aims at assessing whether nutrient profiles are still fit for purpose, without jeopardising the high level of protection of human health and the effective functioning of the internal market. This assessment should also consider that situations where nutrition or health claims mask the overall nutritional quality of a food should be avoided, as it would jeopardise the high level of protection of consumers' interests. It is expected to be completed in the course of 2018. At the same time, the Commission is preparing an impact assessment on trans fats,

which is also expected to be finalised in the course of 2018, and will constitute the basis for an informed policy decision in this area.

#### 4.2.7 Protection of consumers' interests

##### 4.2.7.1 Protection of consumers' interests at EU level

The GFL Regulation aims to achieve not only a high level of protection of human health but also of **consumers' interests** in general. To reaffirm this commitment, the GFL Regulation establishes this as a general principle: EU and national food law must aim at the protection of consumers' interests and provide a basis for consumers to make informed choices in relation to food they consume and to prevent practices which may mislead the consumer.<sup>282</sup>

The Food Information to Consumers Regulation<sup>283</sup> is the main EU legislation that further implements this principle in relation to food: it harmonises the mandatory food information particulars, including nutrition information, of foods sold to the final consumer. Specific provisions aimed at protecting consumers' interests in general are also laid down in other EU secondary food legislation, such as in Food Supplements Directive,<sup>284</sup> the Nutrition and Health Claims Regulation,<sup>285</sup> and Regulation (EC) No 1925/2006 on the addition of vitamins, minerals and other substances to foods.<sup>286</sup>

Despite the limitations inherent in **tackling food fraud**, given that there is no EU-wide definition of 'food fraud' and that certain parameters fall within national competence (liability and sanctions, as further set out in Section 4.2.7.2), a number of specific initiatives have been taken at EU level. In 2013, in the aftermath of the horse-meat incident (which concerned the mislabelling of horse meat), the Commission activated a dedicated network of administrative assistance liaison bodies that would handle specific requests for cross-border cooperation in cases of fraudulent practices in the food chain (Food Fraud Network – 'FFN'). The objective of this network is to improve the capability of MS CAs to detect and prevent violation of the food chain rules, including across borders and in relation to fraudulent practices, but also to collect the information needed in accordance with the applicable national rules to further refer a case for investigation. In November 2015, to support the network, the Commission launched a dedicated IT system (Administrative Assistance and Cooperation – 'AAC') that allows MS and the Commission to exchange data in a structured manner on non-compliances with food and feed legislation.

Since its creation in 2013, details of approximately 300 cases have been exchanged through the network. In 2015, in particular, alleged violations were mostly related to labelling non-compliance (36%), suspicion of illegal exports (18%), and prohibited treatments and/or processes applied to certain foods (13%). However, these figures do not provide a complete statistical overview, as MS also had exchanges on a number of cross-border non-compliances bilaterally, while cases without a cross-border dimension, are not exchanged within the FFN.<sup>287</sup>

##### 4.2.7.2 Protection of consumers' interests at MS level

Under the GFL Regulation, food law must 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.

According to the General GFL study,<sup>288</sup> MS have for the most part taken national measures to prevent (a) fraudulent practices, (b) food adulteration and (c) any other misleading practices. Nevertheless, these national measures, where in place, are diverse both in coverage (*e.g.* food specific provisions

vs. general legal provisions covering all or some of the measures preventing any of the three above-mentioned practices (*i.e.* (a) to (c)) and in severity of penalties (*i.e.* whether administrative and/or criminal).

Legal provisions on liability and sanctions **fall within national competence**, and **there are considerable differences in approach between MS**. Criminal charges are not always applicable with respect to fraud in the food chain. The variation in MS implementation and enforcement has implications in terms of potential effectiveness to address the protection of consumers' interests, in particular as regards the prevention of fraud. Indeed, there is some concern that the applicable national regulatory framework, **which extends beyond GFL as such however**, is not sufficiently equipped to prevent, detect and sanction fraud in the food chain. Beyond the legislation as such, there are also indications that some MS try to address fraudulent or deceptive activities with controls taking place at different levels, while some representatives of the supply chain are considering the integration of food fraud prevention mechanisms in existing private standards (for example, retailer schemes have integrated requirements, such as unannounced controls to address fraud issues).

#### **4.2.7.3 Analysis of protection of consumers' interests**

According to the General GFL study,<sup>289</sup> there is overall positive feedback on the contribution of the GFL Regulation in increasing the protection of consumers' interests in general both from MS and stakeholders including consumer organisations; while amongst stakeholders, this objective received the second highest (4.0 out of 5.0), amongst MS CAs it received the lowest average rating (3.80 out of 5).<sup>290</sup> Despite the overall positive feedback, consumer organisations and some MS CAs have nonetheless expressed concerns that, in practice, this objective is less well achieved than the protection of consumers' health (especially in terms of food safety), as they consider that there is ongoing potential for fraudulent and misleading practices. Nevertheless, consumer organisations have positively noted the implementation of the principle on the protection of consumers' interests by means of the Food Information to Consumers Regulation, as it has extended the concept of consumers' interests.

To further strengthen the existing EU rules to tackle possible intentional violations of the agri-food legislation perpetrated through fraudulent or deceptive practices, the new Regulation (EU) 2017/625 on Official Controls and other Official Activities<sup>291</sup> requires MS CAs to carry out regular, unannounced risk-based official controls aimed at specifically detecting such practices.<sup>292</sup> In planning controls, MS CAs will need to take account also of the likelihood that consumers might be misled as to the nature, identity, properties, composition, quantity, durability, country of origin or place of provenance, method of manufacture or production of the food they buy.<sup>293</sup> Furthermore, the new Regulation will apply where checks, carried out under rules for marketing standards of agricultural products,<sup>294</sup> identify possible fraudulent and deceptive practices. Financial penalties for violations perpetrated through fraudulent or deceptive practices will need to reflect at least either the economic advantage for the operator or, as appropriate, a percentage of its turnover.<sup>295</sup> Furthermore,, the Commission may establish EU Reference centres for the authenticity and integrity of the agri-food chain. They would provide the Commission and MSs with, specialised knowledge, specific analyses, up-to-date reliable technical data and research findings, which would improve the effective performance of control tasks by competent authorities.<sup>296</sup> However, any impact resulting from these new rules will only materialise once the new Regulation enters into application (December 2019).



## 4.2.8 Trade and international aspects

### 4.2.8.1 Trade and international aspects of GFL at EU level

To enable and facilitate international trade in food products, a system of global governance is necessary. Pertinent in that respect is the role of the Codex Alimentarius Commission, which coordinates the harmonisation of food standards and requirements. Although voluntary, the Codex Alimentarius standards not only serve in many cases as the basis for national legislation worldwide, but they are also relied on by the World Trade Organisation ('WTO') as an international reference standard when resolving trade disputes, under the Agreement on Sanitary and Phytosanitary measures ('SPS Agreement'). Similarly, the OIE develops normative documents relating to rules that Member Countries can use to protect themselves from the introduction of diseases and pathogens, without setting up unjustified sanitary barriers. Through the SPS agreement, the OIE is recognised by the WTO as a reference for standards related to animal health and zoonoses.

The GFL Regulation and all other EU secondary food legislation in the area of food and feed **have made a positive contribution to international food safety governance** and in the quality/safety of agri-food trade globally in the following ways:<sup>297</sup>

Following the introduction of the GFL Regulation, a **vital cross-fertilisation** between the development of EU food law and international standards has taken place, which has been particularly facilitated by EU membership in Codex Alimentarius since 2003.<sup>298</sup> On one hand, the EU has made considerable efforts to **ensure alignment of EU food law with international standards**, especially those adopted at the level of Codex Alimentarius. This is reflected in other EU secondary food legislation, where specific reference to international standards in the development of food law is made; as a consequence, adaptation of EU law takes place in line with international standards.<sup>299</sup> On the other hand, as a major global trader of food and feed, the **EU has on many occasions significantly contributed to the development of international standards** (especially at Codex level) on the basis of EU standards. For instance, the Nutrition and Health Claims Regulation was mainly based on Codex standards but in some areas it went beyond Codex standards.<sup>300</sup> The fact that the EU standards are considered as being amongst the highest in the world is largely **due to the strong and sound science-based risk assessments, delivered by EFSA**.

There are cases, however, where the harmonised EU standards are stricter than those established at international level. Where this happens, the EU communicates its position in a transparent manner (for example, by making reservations regarding some Codex standards). This allows potential exporters to the EU to prepare accordingly to meet the EU standards. In certain respects, some of the consulted parties in the context of the General GFL study have also noted **the beneficial impact of those stricter EU standards**. For example, a consulted non-EU country reported that, following a large number of rejections of imports of a certain product due to the presence of a certain toxin, the non-EU country in question implemented a more robust control system for the toxin, hence contributing to an increase in the safety of the exported product.<sup>301</sup>

Other EU secondary food legislation has also further implemented the principle that food and feed **imported** into the EU must comply with the relevant requirements of EU legislation or with conditions recognised by the EU to be at least equivalent thereto.<sup>302</sup>

#### 4.2.8.2 National restrictions on imports/exports of feed and food

The GFL Regulation enables MS to implement certain restrictions on trade, *i.e.* imports of only feed and food compliant with food law and specific provisions relating to exports of food injurious to health or unsafe feed. The available evidence indicates that for the most part such restrictions are applied and that the application of restrictions is generally transparent.

In the context of the General GFL study, 23 out of 25 responding MS CAs have indicated that they had implemented restrictions on imports.<sup>303</sup> Key reasons for such restrictions are non-compliance issues with EU food law, identified during controls at border inspection posts. In the event of non-compliance with EU food law, the measures provided for by Regulation (EC) No 882/2004 on official controls apply, *e.g.* destruction or re-dispatch of food and feed in question, imposition of appropriate special treatments *etc.*

As regards exports, 18 of 25 responding MS CAs have indicated that they had imposed restrictions on exports of food injurious to health or unsafe feed.<sup>304</sup> Restrictions on exports are usually implemented by measures taken under 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 as such. This has achieved the intended objective of the GFL Regulation of avoiding the export to non EU countries of food injurious to health or unsafe feed; indeed, no such incidents have been reported by the consulted non EU countries.<sup>305</sup>

#### 4.2.8.3 Analysis of trade and international aspects

The consultations, including with selected non EU country authorities in the context of the General GFL study, have concluded that the GFL Regulation has overall facilitated food trade with non EU countries. In particular, it has **influenced rather positively both imports** of food into the EU from non EU countries **and EU exports** to non EU countries.<sup>306</sup> The positive impact of the GFL Regulation lies particularly in setting the same requirements for both imported and EU food products, by mainly aligning with international definitions and standards, which has led to harmonisation and setting a level playing field. Nonetheless, the impacts that can be attributed to the GFL Regulation are mostly in qualitative terms, including enhanced business and consumer trust as well as 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 economic factors, rather than the GFL Regulation *per se*, although harmonisation more generally both across the EU and in alignment to international standards exerts a positive role on international trade.

The **economic data also corroborate this finding**. The GFL Regulation requirements, including on food safety, have supported the production of high quality EU products, which allowed the EU to achieve a more globally competitive position since 2003 vis-à-vis the main trading partners, as detailed in Section 4.1. According to the recent Competitiveness study, the **increase in competitiveness** of the EU food and drink industry on the international market as far as relative trade advantage and world market share are concerned, although other indicators like value added and labour productivity have weakened, is due to the ability of the sector to differentiate itself from other trading partners **by offering higher quality next to differentiated products**. The focus on the high quality products has been supported, amongst others, by the food safety requirements imposed by the **GFL Regulation**.<sup>307</sup>

The General GFL study **has not identified any systemic failures of the GFL Regulation** as regards trade in food and feed. Regarding imports, RASFF ensures the notification of any rejection related to risk to human health of a batch container or cargo of food or feed by MS CAS at EU border posts so as to ensure that a rejected product at one border post will not enter the EU via another point. **Regarding EU exports** to non EU countries of food more generally, EU FBOs and MS CAs have expressed some concerns over the lack of balance between the principles that the EU applies to its imports of feed and food from non EU 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 non EU countries to 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. As a consequence, the level playing field that the GFL Regulation and other subsequent EU food law generally ensure for non EU country suppliers to the EU market is not always ensured in non EU country markets for EU products.<sup>308</sup>

#### **4.2.9 Strengthening of RASFF**

##### **4.2.9.1 Strengthening of RASFF at EU level**

Currently, RASFF comprises 32 members: 28 MS, the Commission (as manager and coordinator), EFSA, EEA states (Iceland, Liechtenstein, Norway), EFTA Secretariat (responsible for the coordination of the input from the EEA countries) and Switzerland (partial member of RASFF for products of animal origin since 2009).

The scope of RASFF under the GFL Regulation covering a direct or indirect risk to human health deriving from both food and feed was further extended in 2006 under the Feed Hygiene Regulation,<sup>309</sup> to also include serious risks to animal health and to the environment resulting from feed.

The **iRASFF** is the direct online notification system for RASFF members. According to the latest data, the 32 members of the network have transmitted a total of 3,049 original notifications in 2015 (approximately more than 8 notifications per day); of these, 1,387 concerned products originating in non EU countries, covering food, feed and food contact materials.<sup>310</sup> All these notifications were further followed up by the MS and have given rise to 6,204 follow-up<sup>311</sup> notifications. The information transmitted between users of RASFF **has allowed for numerous products presenting a risk to be removed from, or denied access to the EU market.**

In 2011, the Commission adopted **implementing measures for RASFF** setting out the formal procedures to be followed in case of notifications.<sup>312</sup> In addition, the Commission adopted Standard operating procedures for RASFF (RASFF SOPs), which provide guidance and best practices for its operation. These SOPs are further supported by working instructions (WI) with practical details on how certain parts of the SOPs are to be implemented.<sup>313</sup>

**EFSA's role in the context of RASFF** is most relevant in the context of major and serious food safety incidents concerning emerging risks for which no prior full risk assessment by EFSA is available. According to the RASFF study, EFSA has largely fulfilled that role. Consulted MS CAs, industry associations and consumer organisations have recognised EFSA's contribution in managing complex issues linked to crisis management, *e.g.* melamine crisis (2008) and *E.coli* in sprouts (2011).<sup>314</sup> In addition, EFSA coordinated the Hepatitis A outbreak investigations between MS in 2013-2014 and published scientific reports on the outbreak and its potential sources.<sup>315</sup> Although EFSA's role in the

above-mentioned major incidents was significant, EFSA's input to supplement RASFF alert notifications that are not related to such incidents appears to be less prevalent.<sup>316</sup> In many cases, such input is simply not needed: alerts often relate to well-known risks where there are clear guidelines or precedents, which allow a rapid and consistent consideration of the risk involved. It appears, however, that on some occasions more involvement of EFSA could be helpful, specifically when the risk involved is less well known or as a way to harmonise diverging national approaches to assess risk. In that respect, a key challenge for any input by EFSA into a RASFF notification is the difference in the timeframes within which EFSA and RASFF are working due to their different remits. While RASFF is expected to verify an alert notification and to transmit it to its members in 24 hours, EFSA's scientific risk assessment procedures typically entail a more time-consuming process with the involvement of external expertise. On average, EFSA provided its scientific assessment in 2 to 3 days in simple cases, 8 to 14 days in more complex cases while only in two cases, it responded in 30 and 46 days respectively (see also Section 4.2.2.1.1). Because of varying levels of scientific support and interpretations of risk between MS, a need for more guidance on risk evaluation has been identified. Hence, the Commission has asked EFSA to provide scientific and technical assistance on **methodologies relating to risk evaluation of RASFF notifications**. In that respect, EFSA supported the issuing of RASFF guidelines for the evaluation of risks for MRLs in plant protection products. In addition, EFSA was recently requested to provide the same type of technical support in the area of contaminants.

To increase transparency, the Commission has - **on its own initiative** - set up two parallel IT platforms for interested parties other than the RASFF members, **going beyond the GFL Regulation**: the RASFF Window and the RASFF Portal and Consumers' Portal. Given the globalised context of the food chain, the **RASFF Window** provides non-members (*e.g.* non EU countries) limited access to notifications. Currently, 113 countries outside the EU/EFTA have access to RASFF notifications that relate to their country.<sup>317</sup> According to certain non EU countries that participated in the RASFF survey, information from RASFF is mainly used to prevent affected consignments from being exported to the EU, to prevent affected consignments from being imported into those countries or remove affected consignments from their market, and to improve compliance with EU rules of products to be exported. The **RASFF Portal and Consumers' Portal** serves to inform industry and consumer stakeholders about notified products, subject to professional secrecy requirements. According to the RASFF study, there is no consensus regarding the extent to which the RASFF Portal sufficiently informs FBOs and other stakeholders.<sup>318</sup> The main issue appears to be the lack of detail regarding products concerned by RASFF notifications, preventing some FBOs from being able to quickly assess whether or not action should be undertaken on their side. The **RASFF Consumers' Portal** does not directly address consumers; it is rather a gateway between RASFF notifications and advice given to consumers by the MS CAs or FBOs in the context of a recall or public information released about products that have been notified through RASFF. Regarding specific incidents, it has the added value of combining available public information released in various countries by different authorities.

Parallel to RASFF, the Commission operates the Early Warning and Response System (EWRS) pursuant to which the Commission and competent public health authorities in Member States (EU and European Economic Area) are in permanent communication for the purposes of alerting, assessing public health risks and determining the measures that may be required to protect public health.<sup>319</sup> Pursuant to the RASFF study, the RASFF works well together, amongst others, with EWRS.

While the RASFF is generally not considered to duplicate any of these systems, some instances of potential duplications have been noted. They are partly unavoidable and may be necessary when a product concerns two or more networks covering distinct scopes. For instance, alerts on serious cross-border human health threats deriving from both food and feed must be posted on both RASFF and EWRS.<sup>320</sup> As the EWRS system is currently being updated, there is an ongoing reflection on how to improve the coordination of the two systems to avoid duplications.

In addition, RASFF **cooperates with INFOSAN**,<sup>321</sup> a joint programme of the WHO and the Food and Agriculture Organisation of the United Nations ('FAO') and the main international partner system of RASFF. The information flow is most relevant in times of large international food safety incidents, such as the 2008 melamine crisis, in which INFOSAN was a key source of information for RASFF and acted as an intermediary between the EU and China.<sup>322</sup>

#### 4.2.9.2 *Involvement of MS in RASFF*

The GFL Regulation provided additional impetus for member countries to create the essential structures for running RASFF at the national level. According to the RASFF study, half of the respondent MS (14 out of 26 MS that provided information) have adopted national legislation to implement RASFF, while 12 of those have implemented RASFF without legislative changes. No correlation has been detected between the presence of national legislation and the effectiveness of RASFF at national level.

Overall, the MS as members of RASFF generally fulfil their relevant obligations, according to their peers and self-assessments, as well as the assessment of the Commission Contact Point. This finding is also supported by the evidence collected in the relevant case studies of the three serious food safety incidents in the context of the RASFF study (*e.g.* melamine, glass fragments in instant coffee and *E.coli* in sprouts). Nevertheless, the extent to which member countries submit notifications through RASFF varies significantly, ranging from three to over 500 original notifications in 2013. Even when population size and trade activity of the notifying country are considered, differences between countries in notification numbers remain. Other factors that influence the number of notifications MS transmit through RASFF include particular national approaches concerning certain risks deriving from food and feed, specific national legislation that causes certain MS to carry out controls in addition to those required by EU food law, differences in enforcement of food law or frequency of official controls in the MS, and MS-specific administrative structures and procedures as well as the political organisation of a MS (*e.g.* federal vs. a centralised structure).<sup>323</sup>

#### 4.2.9.3 *Analysis of RASFF*

The main achievements of RASFF in terms of enhanced protection of health and containment of risks linked to food and feed can be summarised as follows:<sup>324</sup>

- Overall, RASFF has **functioned effectively throughout the evaluation period**. RASFF has achieved its core objectives of informing the members of the RASFF network on direct and indirect risks related to food and feed and to exchange information on the follow up actions, in particular on the measures taken to contain the identified risks. This is reflected in the large number of original notifications and follow-up notifications handled by the system: in total 3,137 original notifications and 5,158 follow-up notifications in 2013 including the information to non EU countries. Partly, the effectiveness of RASFF can be attributed to the role of the Commission as manager of the network. The Commission was found to have

largely fulfilled its duties deriving from the GFL Regulation and other implementing legislation with respect to organisational aspects, and, most importantly, the verification and transmission of notifications. Its contribution to the coordination of the members of RASFF and to the development of good and common notification practices is also viewed very positively by its addressees – National Contact Points ('NCPs'). The Working Groups of the RASFF NCPs have contributed to the better functioning of RASFF, and the RASFF SOPs have been considered to be helpful, clear and consistent with needs and expectations.

- The system is much appreciated by NCPs – and a large quantity of actionable information is transmitted through the system, allowing MS and international partner countries to react swiftly to risks detected in food and feed. Indeed, the information exchange through RASFF during serious food safety incidents constitutes a significant crisis management tool in containing incidents which have the potential to develop to full-blown crises. For example, in the melamine crisis, RASFF was used by the RASFF members to confirm the presence of melamine in composite products containing milk ingredients and to notify the illegal import of milk and milk products from China. As member countries were requested to report unfavourable results of controls through RASFF, the resulting notifications were instrumental in reassessing and adapting the emergency measures in place, by extending them to other food products that were found to contain melamine. RASFF was also used to transmit data compiled by INFOSAN of findings received from competent authorities around the world.
- Since its conception in 1979, **RASFF remains highly relevant**. The increasingly globalised trade in food and feed, as well as the deepening of the European Single Market reinforce the need for an effective means of transmitting information on risks detected and measures taken by individual MS. In addition, RASFF is **largely coherent** with a number of other notification systems, both at EU level and with its main international partner system INFOSAN. Where **overlaps do occur**, certain measures have been planned or have already been taken to **minimise duplications**, as set out in the RASFF SOPs and WI.<sup>325</sup>
- In terms of **efficiency**, the costs of **RASFF appear to be reasonable**, although they cannot be directly compared with the benefits of the system. This is because the information exchange through the system is not a benefit in itself, but rather contributes to benefits that accrue as a result of measures taken on the basis of RASFF notifications. Key benefits<sup>326</sup> would relate to: (a) rapid information of network members of the risks identified, allowing rapid action to be taken where appropriate; (b) comprehensive exchange of information on the follow-up to notified direct or indirect risks and on measures to contain risk, allowing for coordinated approaches so as to contain the relevant risks; and (c) information flow to non-EU countries on risks detected to human health deriving from food and feed, allowing the latter to take prompt measures to improve the safety of the exported goods.<sup>327</sup> Nevertheless, comparing total costs to the quantity of information transmitted provides some insight into the efficiency of RASFF: for the reference year 2013, the costs amounted to €690 per item of information transmitted to RASFF members. Considering that most notifications concern multiple countries, the cost per notified country is substantially lower. Nonetheless, there is some scope for improving its efficiency in the future, specifically by upgrading the iRASFF application, moving certain tasks to other notification systems, further improving linkages between RASFF and other relevant notification systems, and allowing for a degree of de-centralisation of the system in specific cases.

- There is nearly unanimous consensus that **RASFF provides added value** compared to what could be achieved without it, by MS acting at the national level, given that the total intra-EU and extra EU trade of food and drink products amounted to €345.9 billion in 2015, 72% of which concerned intra-EU trade while 28% concerned extra EU trade.<sup>328</sup> Therefore, RASFF benefits may only accrue, if it is operated at EU level.

#### 4.2.10 Emergency measures and crisis management

##### 4.2.10.1 Emergency measures and crisis management at EU level

Emergency interim measures adopted at EU level have been regularly used to ensure a harmonised approach of the EU in terms of containing risks related to food and feed and avoid unjustified barriers to the free movement of goods. In the period 2002-2014, the Commission adopted 40 EU emergency measures in order to contain and manage an equivalent number of serious food safety incidents.<sup>329</sup> These measures are regularly reviewed given the impact that they may have on the effective functioning of the internal market given their restrictive character. The majority of those measures (25) have been repealed or have expired without being extended, suggesting that these measures are no longer needed because the risk is contained or is otherwise no longer relevant. Those that are still in force indicate the continued relevance of the measures, although some of them have been substantially amended.

National interim protective measures have been used on an exceptional basis in two instances. In 2003, France adopted interim protective measures following an incident in which Sudan dye 1 was found in imported hot chilli products in France. In the latter case, the Commission extended the emergency measures to the remainder of the Union. Similarly, in 2009, France adopted emergency measures prohibiting the marketing of milk and milk products from herds affected by scrapie. Nevertheless, in this case, the Commission suspended the national interim protective measures.<sup>330</sup>

In the context of EU emergency measures, the precautionary principle has been used only once during the *E.coli* in sprouts outbreak in Germany in 2011 (see Section 4.2.2.2.1).

The general plan for crisis management, referred to in the GFL Regulation, was established by means of Commission Decision 2004/478/EC.<sup>331</sup> It provides two layers of actions: a first layer of action related to potential serious risk, where a crisis unit is not required and a second involving the setting up of a crisis unit. To date, the second layer has never been activated. Furthermore, the general plan includes a communication strategy and principles of transparency.

Crisis management may include a number of actions. For example, in the context of the melamine crisis, crisis management resulted in a request for urgent advice to EFSA, teleconferences with concerned MS, EU emergency measures that were adapted overtime, use of RASFF to inform MS and to exchange data on the results of controls, withdrawals of unsafe products at national level and press releases to inform consumers. In addition to the actions mentioned for the melamine crisis, the *E.coli* in sprouts outbreak in Germany involved regular teleconferences amongst EU authorities and bodies (Commission, EFSA, ECDC), MS and other relevant bodies, such as WHO, the dispatch of a task force to Germany composed of Commission experts as well as experts from ECDC and EFSA, daily press releases to the public, as well as a request to EFSA to perform a tracing exercise to identify the source of the outbreak.

#### 4.2.10.2 Implementation of national crisis management plans

To implement the general plan for crisis management at national level, MS are required to draw up an operational contingency plan under the Official Controls Regulation.<sup>332</sup> According to a recent overview report of the audit and inspection service of DG SANTE, on the basis of fact-finding missions in five MS carried out in 2013 and 2014,<sup>333</sup> the emergency preparedness arrangements in the MS visited varied; some of them had advanced arrangements already in place while others were in the process of finalising contingency planning for food and feed. In most MS visited, administrative re-organisations had taken place recently and contingency planning was ongoing, not only to adapt to new organisational structures but also to ensure continuous improvement. Nevertheless, in all these MS, the existing crisis management tools were found to be sufficient to manage food or feed incidents, according to past experiences.

#### 4.2.10.3 Analysis of emergency measures and crisis management

According to the RASFF study, **EU interim emergency measures have proven effective**, as confirmed by the results of the survey of competent authorities and stakeholders, with nine in ten respondents assessing emergency measures as having been moderately to very effective for the management of serious food safety incidents. Similarly, a nearly as large majority of competent authorities and stakeholders assessed that the mechanisms in the GFL Regulation as regards emergency measures have contributed moderately to very much to avoiding disparities between measures taken by different MS and to ensuring a consistent approach in previous serious food safety incidents.

MS CAs in the field of food crisis management – and to a lesser degree also other stakeholders – have also considered the two layers of actions, set out in the **general plan**, to be **relevant and still appropriate** for crisis management. This is despite the fact that a crisis unit has never been set up, as the second layer of action has not been used during serious food safety incidents experienced during the last decade.<sup>334</sup> Overall, CAs and other stakeholders agree that existing crisis management arrangements have achieved consumer health protection, the efficient management of food safety incidents and coordinated implementation of the most effective measures to contain the risk in past serious food safety incidents. According to respondents, consumers' trust in food safety and limited disruption of internal market and trade were achieved to a lesser degree, although the average rating was still positive.<sup>335</sup>

Taking into account the wide extent of the cross-border and international trade involved, the 2008 dioxin crisis in pork in Ireland demonstrated that the combination of the **EU-wide traceability** with effective risk communication and **other crisis management tools available at EU level**, such as RASFF and the delivery of EFSA's scientific advice within two days **enabled a quick response to effectively contain the risk at issue**, while **preserving overall consumer trust. It also avoided a spill-over effect to the beef sector**, which is a particularly important sector in Ireland. In a survey that was conducted in Ireland with respect to the latter crisis, the majority of respondents (70.5%) accepted that the way in which the authorities managed the crisis was 'adequate' or 'very efficient' and that those they trusted the most to inform them about the latter crisis were scientists (32%) and public authorities (21%) while media being preferred by 13% of the respondents (see Sections 4.2.4.2 and 4.2.5.3).<sup>336</sup>

Nevertheless, the **2011 E.coli in sprouts outbreak** in Germany has high-lightened **the need to continuously re-evaluate** the management of food crises at EU and national level. This was the most serious food safety outbreak in the EU after the adoption of the GFL Regulation legislative



framework, given the human casualties involved (55 casualties reported) and roughly 900 cases of the life-threatening post-diarrhoeal sequel of haemolytic uremic syndrome. In the context of the RASFF study, the effectiveness of crisis management in the latter *E.coli* outbreak was rated the lowest. Apart from public health impact, it also caused **considerable disruption in the internal market**. It is estimated to have resulted in a loss of more than €812 million to European farmers in the first 2 weeks of the crisis and a temporary ban on the export of vegetables to Russia (which have an annual value of €600 million), while EU interventions to the value of €277 million were also needed to restore trust in the EU market of fruit and vegetables.<sup>337</sup>

According to the RASFF study, the **key factors for the negative outcomes** identified above were the difficulty in locating the source of the outbreak, the premature and erroneous communication to the public, and the extent of cooperation between the public health and food safety authorities at MS and EU level. Indeed, in the *E.coli* outbreak, the complex nature of the pathogen combined with the unexpected source of the outbreak (sprouts) led to a significant delay in identification of the source, which in turn caused confusion and panic among the public as well as a significant disruption to the internal market and trade. In the context of the RASFF study, several interviewees criticized the cooperation by public health and food safety authorities between the EU and the MS level, during the outbreak. According to them, better sharing of information and coordination between the two sides would have been helpful in managing more effectively and efficiently this crisis. A more coordinated strategy for communicating to the public could have mitigated the effect of the media pressure and ensured the transmission of coherent messages to consumers by the different authorities involved.<sup>338</sup> Although audio-conferences were held on a daily basis between the EU food safety and public health authorities and agencies (DG SANTE, ECDC, EFSA) as well as national food safety and public health authorities and national agencies, when EFSA tried to align its communication efforts with other organisations and MS, it became clear that some of the MS were better informed about ongoing events than others, and that a common understanding of the situation had not been achieved.<sup>339</sup> This also created confusion for the public as regards the risks involved, though it must be stressed that the events were unfolding rapidly.

The *E.coli* outbreak **also had a negative impact on consumers' trust on the implicated products, which actually were not the source; however, that was limited in time**. Once the source of the outbreak was confirmed (sprouts), consumption of the wrongly implicated products recovered relatively quickly. In the weeks following this incident, consumption increased, at times reaching a higher level than in 2010. By the end of 2011, consumption of cucumbers followed the pattern of the previous years, meaning that the *E.coli* outbreak had no impact on cucumber purchases in 2012 and 2013.<sup>340</sup>

In the context of the RASFF study, several of the consulted stakeholders including MS criticised the fact that no crisis unit was established in the *E-coli* outbreak. One consideration why a crisis unit was not established was the need to formally declare a crisis for this purpose. This was considered to be not opportune as it might have increased the level of public concern. In consequence, the standard procedures of the crisis plan relating to potential serious risk, including information exchange through RASFF and procedures for involving MS in decision-making regarding relevant EC measures (mainly through the PAFF committee) were complemented by ad-hoc crisis management arrangements to handle the incident at EU level. Thus, while crisis management at EU level has been assessed on average positively and has worked well in the context of limited crises, during more complex crisis situations such as the *E.coli* outbreak the provisions in the general plan foreseen for

this type of situations appeared not to be a completely appropriate tool. According to MS CAs and other stakeholders there seems to be a need to review the general plan and to develop more workable arrangements that can be applied during incidents, such as *E.coli*, possibly including a greater role of the Commission in communication and general coordination of MS, as well as providing a step-wise approach for escalating measures of crisis management and related criteria for escalation.<sup>341</sup>

Nevertheless, the lessons learnt from the *E.coli* outbreak have been analysed further by the Commission,<sup>342</sup> and have led to the introduction of a number of measures to improve existing arrangements, including cross border crisis simulation exercises, collaboration between EFSA and ECDC on molecular typing<sup>343</sup>, training courses on food-borne outbreak investigations in the framework of the BTSF programme and fact-finding inspection missions carried out by the audit and inspection service of DG SANTE to identify best practices in emergency preparedness of MS.<sup>344</sup> As regards the latter action, the fact-finding report on national emergency preparedness arrangements has identified certain good practices and provides a summary of lessons learned drawn from real cases.<sup>345</sup> Overall, elements commonly identified by the visited MS as being important for emergency preparedness included: clear allocation of responsibilities, specific organisational structures, e.g. "Alert Units" or operational groups, sharing of relevant information and its effective communication to the public, use of peacetime structures and procedures also for dealing with incidents, use of rapid alert systems for monitoring and early detection as well as managing an incident/crisis, availability of comparable data and their successful interpretation, availability of risk assessment by independent expert services, a clear definition of alert levels and criteria for their escalation as well as continuous improvement on contingency planning based on simulation exercises and on lessons learned from real cases. In developing an effective communication strategy, the ever-growing role of social media, which can easily spread false alarms and raise consumers' concerns, should be given due consideration. Finally, in light of the experience gained over the years and especially in the aftermath of the *E.coli* in sprouts outbreak in 2011, the Commission intends to revisit the 2004 general plan on crisis management so as to ensure a stronger focus on prevention and preparedness.

## 5 Answers to the evaluation questions

This Fitness Check aims at evaluating the relevance, effectiveness, efficiency, coherence and EU added value of the GFL Regulation, as the foundation of the food law both at EU and national level, against the 'baseline'.

As analysed in detail in Section 2.1, **the baseline** was mainly characterised by the following elements:

- Lack of a framework providing for a one common and consistent basis, composed of common objectives and common definitions, general principles and requirements (a) for the entire agri-food chain, including feed, (b) at all stages of the agri-food chain, (c) whatever the type and origin of the food and feed, and (d) both at EU and national level;
- EU measures were not systematically underpinned by scientific advice, and where that was the case, the scientific advice was not accompanied by sufficient guarantees concerning independence and transparency:
  - The risk analysis principle was not applied in all cases in the agri-food chain involving risks;

- Scientific advice was still dependent on risk management and had not always considered to be of the highest standard both within the EU and internationally while it lacked capacity to address scientific needs;
- Access to scientific data and knowledge needed for a high-quality risk assessment and to better identify emerging risks was not ensured;
- Impact on international trade, especially where EU measures had to be scientifically justified with respect to divergences from international standards;
- Lack of crisis management tools at EU level covering the entire agri-food chain, such as EU-wide traceability, RASFF, EU emergency measures and established crisis management procedures.

All these elements did not guarantee a high level of protection of public health and consumers' interests at all times. Moreover, they would also raise obstacles to the free movement of goods, jeopardising the internal market.

## 5.1 Relevance

### 5.1.1 To what extent is the legislative framework introduced by the GFL Regulation still relevant to address current needs and trends? To what extent are the objectives of the GFL Regulation still relevant and valid? Are there any other objectives that should be considered?

Pursuant to the GFL Regulation study, the original core objectives of the GFL Regulation legislative framework, *i.e.* protection of public health and consumers' interests and the effective functioning of the internal market, are still relevant; they continue not only to correspond to current needs and trends, but also to be the most relevant objectives for a general legislative framework covering the food chain, such as the GFL Regulation.<sup>346</sup> More specifically:

The original needs that prompted the adoption of the GFL Regulation in 2002 were the following: priority to consumers' health and interests at all times, consumers' trust in food, prevention and containment of food crises and limitation of unnecessary disruptions of trade, an integrated approach to food law covering the entire food chain at EU and national level, transparency in the decision-making and a robust science-based legislation. Given the paramount importance of the production and consumption of food to the EU and its citizens, including in economic and social terms, the original needs that prompted the adoption of the GFL Regulation in 2002 **are still pertinent today.**

The negative impacts of all food-related incidents cannot be underestimated. Safety and non-safety food incidents can impact directly public health and consumers' interests, ranging from human casualties (*e.g.* 2011 *E.coli* in sprouts) to loss of consumer trust, costs and losses for the industry including trade disruptions (*e.g.* 2011 *E.coli* in sprouts, 2013 horsemeat fraud scandal). These negative impacts can be considerable taking into account the economic dimension of the EU food chain, as set out in Section 4.1.

**These original needs** have been further reinforced by certain **current trends** within the Union and more globally. In particular:

- Trends affecting consumer trust: Consumers' trust is based on consumers' perceptions rather than facts. It is, therefore volatile and highly dependable on many factors.<sup>347</sup> The volatility of the consumers' trust in relation to food has been accentuated by certain recent trends, such as the varied and increasing number of sources of information available to consumers, including information provided by NGOs with single-issue agendas, the emergence and increasing use of

social media, the rising level of affluence and education of consumers, the increasingly complex character of new technologies and scientific methods<sup>348</sup> as well as the increased awareness of food fraud. According to the General GFL consultation,<sup>349</sup> the GFL Regulation had **on average positively impacted consumers' trust in food.**<sup>350</sup>

- *Consuming healthier food:* At the time of the GFL Regulation adoption, health problems linked to foods in the EU were related to food safety or nutrient deficiencies. This has changed considerably. Nowadays, consumers show an increasing interest in the nutritional value of the food they purchase. Today, most of the biggest risk factors for premature death relate to unhealthy diets and to over-nutrition, such as overconsumption of energy, saturated fats and salt. Cardio vascular diseases account for 37% of all deaths in the EU and dietary factors make the largest contribution to the risk of cardio vascular death of all behavioural risk factors. Therefore, protection of public health also addresses the intake of essential nutrients, while limiting intake of other elements in order to avoid adverse health effects, including anti-nutritional effects. Scientific information has shown that an adequate and varied diet is key factor in maintaining good health and overall well-being.

Weight problems and obesity are increasing at a rapid rate in most of the MS, with estimates suggesting that more than half of the EU population was overweight or obese in 2008. According to the WHO, Europe had the second highest proportion of overweight or obese people in 2008, behind the Americas. Globally, the share of adults (aged 20 years and over) who were thought to be overweight or obese was estimated at 35%.

Nutrition is embedded in the core objectives of the GFL Regulation under the pursuit of a high level of protection of human health, although not explicitly spelt out. According to the GFL Regulation study, views were divided as to the merit of explicitly mentioning nutrition in the GFL Regulation objectives. For example, consumer organisations have put forward a proposal for including in the GFL Regulation a wider objective related to the "wholesomeness" of food,<sup>351</sup> although both consulted consumers and industry organisations view nutrition as an objective of other EU secondary food legislation in the first place.

Against this background, the original core objectives of the GFL Regulation are still relevant today and also in line also with the TFEU. Article 26 TFEU provides that the Union shall adopt measures with the aim of establishing or ensuring the functioning of the internal market, ensuring amongst others the free movement of goods. In addition, a high level of human health protection must be ensured in the definition and implementation of all Union policies and activities (Article 168 TFEU). Moreover, in order to promote the interests of consumers and to ensure a high level of consumer protection, the Union must contribute to protecting the health, safety and economic interests of consumers as well as to promoting their right to information, amongst others, to safeguard their interests (Article 169 TFEU).

Given the pertinence of the original needs still today as reinforced by current needs, the **original core objectives** of the GFL Regulation **are still relevant today.**

The General GFL study has also looked into whether the legislative framework of the GFL Regulation is **adequate** to also address **other trends** than those mentioned above, which have emerged **after the adoption of the GFL Regulation.** This evaluation has identified a number of such external and internal trends relevant to the GFL Regulation framework:<sup>352</sup>

### Increased globalisation

The challenges posed by **increased globalisation** are **adequately addressed** by the current provisions of the GFL Regulation and its implementation, as already analysed in Sections 4.2.8 and 4.2.9.

In summary, the GFL Regulation ensures a level playing field for all EU and non-EU food and feed products placed on the market, as they are subject to the same general requirements. The GFL Regulation also provides specific rules governing the export of EU products. The general principle to take into account international standards in the development of EU food law but also the development of EU standards on sound science have also paved the way to meet the objective of high level of consumers' health in relation to food in a global context. Indicators of the positive impact of the GFL Regulation in the international context include the **EU's leading role in Codex Alimentarius** with, amongst others, EFSA opinions providing the basis for the adoption of international standards, the fact that certain trading partners have either adopted or are considering the adoption of provisions, similar to those of the GFL Regulation, such as on traceability, the recent call from both US and EU consumer groups for the application of the EU standards in the context of the TTIP negotiations in most food areas as well as the international cooperation of RASFF through its network of single contact points in non-RASFF member countries and its close cooperation with the INFOSAN. This positive contribution of the GFL Regulation 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.

### Growth and competitiveness

In the context of the economic downturn that has affected Europe since 2008, the need to ensure **growth and competitiveness** has taken centre-stage in EU policies. The promotion of innovation has, hence, been signposted as a key driver and reflected in a number of EU initiatives.<sup>353</sup>

As analysed in Sections 4.1 and 4.2.2.4, the GFL Regulation **has generally been found adequate to address competitiveness and innovation**, by means of its framework covering the entire food chain ('farm to fork' approach) and the high degree of harmonisation in EU food law. In the context of the General GFL study, supply chain organisations have noted that the GFL Regulation ensures the overall **competitiveness potential** of the EU food chain. For example, it provides goal-oriented principles and general requirements, which can be tailor-made to fit the operational context of individual businesses, rather than prescriptive provisions.<sup>354</sup> The high degree of harmonisation in the area of food law based on the GFL Regulation framework removes obstacles to the free movement of foods. In addition, the systematic application of the risk analysis principle in other EU secondary food legislation by means of authorisation procedures has reinforced the comparative advantage of EU manufacturers vis-à-vis their competitors: **the stricter requirements** for the marketing of feed and food by means of authorisation procedures provide a **higher marketing value**, since authorisations are underpinned by science.<sup>355</sup> Similarly, food and feed supply chain stakeholders have noted that **innovation** is not hampered by the GFL Regulation as such.<sup>356</sup> Any negative impacts on competitiveness and innovation mainly stem: (a) from the fact that few areas of the food chain are not yet fully harmonised, such as food contact materials other than plastics and the setting of maximum levels of vitamins and minerals in food supplements and in foods to which vitamin and

minerals are added; and (b) from delays in certain specific authorisation procedures foreseen in other EU secondary food legislation.

This is reflected in the increased internal trade and international competitiveness of the EU food and drink industry. The value of the EU internal trade in the food and drink sector has increased by **72% in the last decade**.<sup>357</sup> In addition, and despite the 2008 global financial crisis, the EU food and drink industry managed to increase its workforce by 0.8% and achieve a **more competitive position globally vis-à-vis the main trading partners** as far as relative trade advantage and world market share are concerned, although other indicators like value added and labour productivity have weakened in the period 2008-2012. This increase in international competitiveness of the EU food and drink industry can be explained by its ability to differentiate itself from other trading partners, by offering higher quality next to differentiated products. In that respect, the GFL Regulation is **credited for supporting EU industry's reputation for high quality products**.<sup>358</sup>

### Food sustainability

**Food sustainability** is an emerging trend in response to a growing world population, limited natural resources and the pressure of climate change. Indeed, with the simultaneous rise in global demands for food, feed, fuel and fibre and limited natural resources, it is important to decouple EU growth from resource use and significant environmental impacts, in particular in view of climate change impacts. This has to be done against a backdrop of increasing urbanisation and an ageing EU population. Providing a health and balanced diet, in an equitable and sustainable manner to a growing world population will be one of the major development challenges of the next decade. Moreover food, water and energy security are inextricably linked and actions to improve only one of them might impact on the others. These interrelated challenges could impact the sustainability of food systems in years to come. As such, the Stakeholder Dialogue Group on Food Sustainability has underlined the urgent need for a holistic approach to ensure the sustainability of food systems for future generations.<sup>359</sup>

In this context, the EU and the MS committed in 2015 to the 2030 Sustainable Development Agenda, which includes several food-related targets designed to shift EU food systems towards greater sustainability, health, security and equity. These include a specific target to halve food waste by 2030, a commitment reaffirmed in the Commission's new Circular Economy Package<sup>360</sup> which singles out food waste prevention as a priority area for action.

The GFL Regulation has been found **largely inadequate to address food sustainability in general, and food waste in particular**, as not all parameters of food sustainability are considered in the GFL Regulation framework. Since GFL's conception, the food value chain has changed with the emergence of new actors (*e.g.* food banks) and activities (*e.g.* food redistribution). **Innovation in the food supply** chain can contribute to food sustainability by increasing yields and reducing use of water, energy and chemicals (*e.g.* enzymes applied in UHT processing of milk can reduce energy and water use with 15%), by extending the shelf-life of food products and keeping organoleptic properties for a longer time (helping to reduce food waste), or by innovating in food packaging and product conservation. Nevertheless, **the core objectives of the GFL Regulation as such are not necessarily convergent with a global approach to food sustainability**, which goes beyond them.

This finding is also confirmed by the General GFL study, pursuant to which MS CAs and stakeholders consider that the GFL Regulation is **largely inadequate to address food availability and food waste**<sup>361</sup>

given certain legal and operational barriers for donors and receivers to the redistribution of food in the EU<sup>362</sup>, while underlying the importance of distributing only safe and edible food. For example, supply chain stakeholders have noted that differences in the implementation of the food safety requirements can result in unnecessary food waste in the case of withdrawals,<sup>363</sup> although globally traceability limits the extent of such unnecessary withdrawals. In addition, the application of GFL to food donors and food redistribution partners, given the broad definition of 'food business' and the fact that food banks and charity organisations are subject to the requirements of traceability and of primary responsibility can create barriers for food redistribution. Both food donors (*e.g.* industry) and receivers of surplus food have pointed to difficulties in knowing how to best ensure compliance with EU food law and meet obligations concerning food safety in particular and the related issue of liability<sup>364</sup>, the latter essentially being governed by national rules. In the area of food hygiene, for instance, retailers which redistribute food of animal origin to food banks or other charity organisations must be approved by national CAs for this activity, which is not the case when they provide such foods directly to consumers<sup>365</sup>, thereby creating an additional hurdle for an activity which may only be occasional. In order to assist in lifting barriers to food redistribution, the Commission has recently adopted EU guidelines on food donation, in close cooperation with the EU Platform on Food Losses and Food Waste.<sup>366</sup> Nevertheless, stakeholders (including FBOs and NGOs) as well as MS CAs have commented in the context of the General GFL study that food sustainability and food waste should best be addressed by dedicated policies and legislation.<sup>367</sup>

#### Digitalisation of the market – Distance selling

**Digitalisation of the market** also in the area of food, has considerably impacted the way the retail sector operates and interacts with consumers in recent years, increasing opportunities for both the FBOs and consumers as regards the way food and feed are produced and traded (*e.g.* by means of distance selling). At the same time, it has influenced the tools which are at the disposal of competent authorities to follow the activities of FBOs and if necessary to intervene.

The GFL Regulation does not specifically address the provision of food and feed by way of online or distance selling, unlike other more recent EU secondary food legislation.<sup>368</sup> This has prompted consulted MS CAs and stakeholders in the context of the General GFL study to question the adequacy of the GFL Regulation to address distance selling.<sup>369</sup>

Nevertheless, the **common definitions and general obligations** laid down in the GFL Regulation are also relevant for, and applicable to **distance selling** activities. For example, the definition of 'food business' is broad enough to also cover distribution of food and feed by distance selling. Feed and food sold through digital means must also be traceable. E-commerce FBOs are also primarily responsible for compliance with food law requirements and must carry out own controls. **Shortcomings** identified do not relate to the relevance of the GFL Regulation as such, but rather to its implementation and enforcement as this trade is less transparent and more difficult to control (see also Section 4.2.3.2).

#### Food quality

As regards **food quality**, on balance most stakeholders agree that the GFL Regulation framework is **currently adequate**. In their view, safe food ultimately leads to higher quality. By setting high standards of food safety the GFL Regulation has enhanced the quality of EU food and its reputation as safe, both within the Union and in non EU countries.

In recent years, the issue of 'dual quality' of foodstuffs, *i.e.* foods marketed in different EU MS under the same brand and packaging, but with differences in composition, has recently spurred interventions by a few MS and by some Members of the European Parliament. Some MS have conducted studies and laboratory testing on the issue, comparing the composition of a limited number of branded products on different EU markets. Although there is agreement that this issue does not relate to food safety and that the GFL Regulation is currently adequate in terms of food safety requirements, the issue still remains that consumers' perceptions in certain MS are that they are being treated unfairly and do not receive the same quality of food from certain brands.

As long as products comply with EU legal requirements (*e.g.* food safety criteria under the GFL Regulation, not misleading food information as to the main characteristics of the products concerned under the Food Information to Consumers Regulation), companies are not prevented from differentiating products under the same brand according to markets in line with the taste, preferences or purchasing power of consumers and other considerations, such as local sourcing of raw materials. There is no legal basis in the EU food law to challenge differences in foods' composition in individual MS, as long as they are safe and the relevant food information is truthful. Nevertheless, under the existing EU consumer protection rules, MS have the necessary tools to prevent unfair trading practices when a food is advertised as being identical in different parts of the Internal Market, in spite of differences in composition; such practice could be considered as unfair under Directive 2005/29/EC concerning unfair business-to-consumer commercial practices.<sup>370</sup> On 26 September 2017, the Commission issued a set of guidelines on the application of the relevant EU legislative framework to assist national authorities in the application of the latter.<sup>371</sup> This issue continues to be discussed in the context of the High level Forum for a Better Functioning Food Supply Chain, with a view to identifying possible action, including by producers and retailers. The Joint Research Centre ('JRC') is also currently developing guidelines for a robust harmonised testing approach, including sampling, to establish the dimension of the phenomenon. MS will also be provided financial support for studies or enforcement actions.

The GFL Regulation is adequate **to address** the following current trends that have emerged more prominently after its adoption: **growth and competitiveness, increased globalisation and food quality**. As regards the **digitalisation of the market**, while the GFL Regulation is adequate to address the challenges that emerge, there are implementation and enforcement issues to be looked at, as this trade is less transparent and more difficult to control. The GFL Regulation, however, is a **less adequate framework to address food sustainability in general and food waste** in particular. This trend, however, may be best addressed by dedicated horizontal policies and legislation.

## 5.2 Effectiveness

### 5.2.1 What progress has been made over time towards achieving the objectives of the legislative framework introduced by the GFL Regulation? Is this progress in line with the initial expectations?

#### **Overall findings**

The overall evidence set out in Section 4.2 with respect to the implementation of the GFL Regulation demonstrates that the GFL Regulation has **for the most part achieved its two core objectives**.



## **A. High level of protection of human health and consumers' interests**

### **Human health**

Overall, the GFL Regulation has **contributed to achieve a high level of protection of human health**, as evidenced by the following:

*a. Rate of application of the risk analysis principle in the EU decision-making in the agri-food chain - performance of EFSA in delivering quality work*

Considerable progress as regards food safety has taken place through the systematic implementation of the risk analysis principle in other EU secondary food legislation. Following the creation of EFSA, all EU food legislation that predated the GFL Regulation was aligned to, or reviewed in line with the risk analysis principle. Indeed, where pre-existing legislation referred to scientific opinions by the previous Scientific Committees, the GFL Regulation made provision for the automatic alignment to the new regulatory system of scientific assessment (EFSA) by means of Article 62 thereof (automatic alignment).<sup>372</sup> Where, however, pre-existing legislation did not refer to scientific assessment, adaptations were made to ensure compliance with the GFL risk analysis principle.<sup>373</sup> In addition, all subsequent EU legislation which, inter alia, manages microbiological, chemical and physical risks linked to food/feed has consistently incorporated the risk analysis principle.<sup>374</sup> As such, any amendments or measures supplementing EU food legislation are systematically based on scientific assessment, except where this is not appropriate to the circumstances or the nature of the measure. The risk analysis principle is therefore applied consistently in the various sectors of EU food law.<sup>375</sup>

Furthermore, as detailed in Sections 4.2.2.1.1 and 4.2.2.4, the creation of EFSA has improved the scientific basis and transparency of EU measures through:<sup>376</sup>

- the broad scientific remit of EFSA covering all risks linked to the food chain;
- strict policies on independence, transparency and openness, which are regularly reviewed;
- major improvements in the collection of data required to carry out evidence-based risk assessments (particularly, EU occurrence data and food consumption data);
- higher resources and staff in EFSA supporting the Scientific Panels and advancements in the scientific knowledge and understanding of risks linked to food and feed, *e.g.* cumulative exposure to risk;
- sharing of scientific data and cooperation with national scientific bodies ensuring a common scientific understanding of risks linked to food across the EU and minimising scientific divergences and development of international cooperation;
- the development and harmonisation of risk assessment methodologies in collaboration with national and international risk assessors;
- internal quality control on the development of scientific opinions in EFSA;
- increased involvement of stakeholders in the risk assessment process; and,
- the development of a culture of information exchange between MS, the Commission and EFSA and strengthened cooperation with national and international scientific bodies.

The overall functioning of EFSA has promoted a mutual understanding on risks, minimised the risk of duplications and limited the number of scientific divergences between EFSA and risk assessment bodies. As stated in Section 4.2.2.1.1, from a total of more than 4,500 scientific opinions, divergences of scientific opinions between EFSA and national risk assessment bodies have emerged only in 11

cases. Seven of those were solved directly at the level of the Advisory Forum, while scientific divergences have only been confirmed in four cases, two of which concerned the same substance.

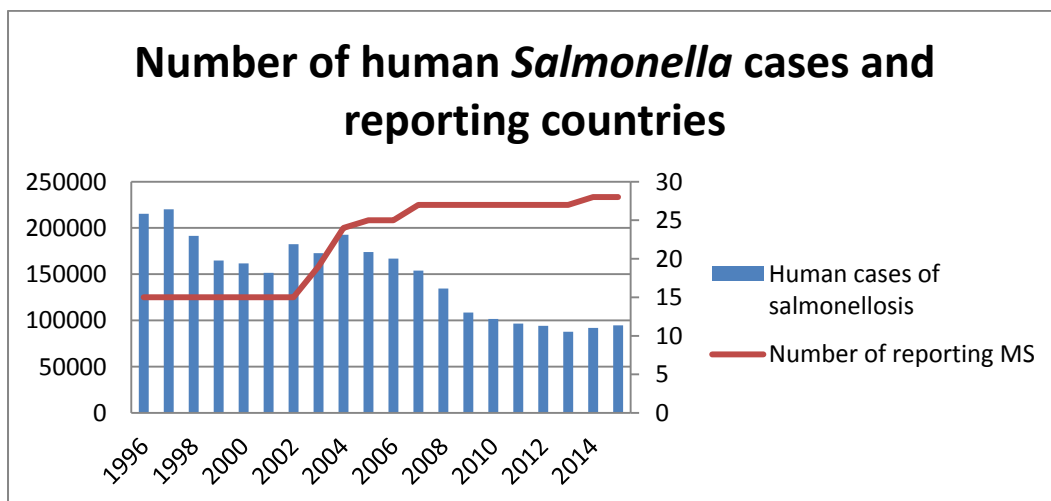
EFSA's opinions have gained international recognition as they are often referenced by food safety agencies in non EU countries and international bodies.<sup>377</sup> The **citations of EFSA's opinions** in scientific journals have increased from only 13 in 2006 to 487 in 2011<sup>378</sup> and to **2.126 in 2014**.<sup>379</sup>

As a result, all EU risk management measures are based on a high quality risk assessment and thus more proportionate to the effective risk to be controlled.

*b. Overall safer food on the market*

Appropriate risk management measures based on EFSA opinions and the setting of harmonized monitoring systems established the reference to measure trends in a more accountable system. Accordingly, it was possible to record that the number of BSE cases in cattle reported each year has dropped from 2200 in 2001-2002 to 6 in 2015<sup>380</sup> and classical BSE is almost completely eradicated. In addition, *salmonella*, being the most reported food-borne zoonosis before 2002, dropped from 150,000-220,000 cases per year in 15 MS before 2002 to about 90,000 cases in 28 MS in 2012-2015. The number of *Salmonella* outbreaks has fallen by 41% since 2010.<sup>381</sup>

**Figure 6:** Human *Salmonella* cases and reporting countries based on the EFSA EU summary report on trends and sources of zoonoses, zoonotic agents and food-bourne outbreaks (2015)<sup>382</sup>



At the same time, the results of monitoring and reporting on contamination with pesticides, veterinary medicines and other contaminants ensure that food consumed in the EU is now largely free of residues or contains residues that fall within the EU legal limits.

Indeed, with regard to pesticide residues in food, the annual EFSA reports demonstrate a stable compliance rate with pesticide maximum legal limits, notwithstanding the ongoing establishment of new (lower) legal limits and the availability of more sensitive laboratory equipment. According to the 2015 EU report on pesticide residues in food,<sup>383</sup> more than 97% of more than 84,000 food samples collected across the EU, Iceland and Norway in 2015 were within legal limits, with just over 53% free of quantifiable residues of 774 pesticides. Legal limits were exceeded in 5.6% of the samples from non EU countries, down from 6.5% in 2014. For products from EU, Iceland and Norway, legal limits were exceeded in a very small part of the samples, *i.e.* 1.7% of samples, which represented a slight

year-on-year increase. from 1.6% in 2014. Of the samples of foods intended for infants and young children, 96.5% were free of residues, or residues fell within the legal limits.

Furthermore, the annual EFSA reports on the results from the monitoring of veterinary medicinal product residues and other substances in live animals and animal products suggest high rates of compliance overall and demonstrate the strengths of the EU monitoring system and its contribution to consumer protection. More specifically, according to the 2014 annual report on this issue<sup>384</sup> out of 730,000 samples reported in 2014 from the 28 MS, the level of non-compliance in in targeted samples (*i.e.* samples taken to detect illegal use or check non-compliance with the maximum levels) rose slightly to 0.37%, compared to 0.25%-0.34% over the previous seven years. There was slightly higher non-compliance for resorcylic acid lactones (hormonally active compounds produced by fungi or man-made) and contaminants such as metals and mycotoxins.

Food contaminants are substances that have not been intentionally added to food. Since contaminants are naturally present in food because of the contamination of the environment, climate conditions and processing of food, this is to a certain extent unavoidable. It is therefore not possible to impose a total ban on these substances. Given, however, the public health risks, other EU secondary food legislation has set maximum levels for the contaminants of greatest concern to EU consumers, either due to their toxicity or their potential prevalence in the food chain, following a scientific assessment by EFSA. These include aflatoxins, heavy metals, such as lead and mercury, dioxins and nitrates. The continued surveillance of food contaminants has also contributed to a high level of protection of human health. EU MS monitor levels of contaminants found in food and feed. These data are used to assess exposure of people and animals to contaminants. Since 2010, most EU MS submit the collected data to EFSA through a standardised reporting format. This system has improved the quality of data that are used to: understand how often foods are contaminated and by how much; estimate consumer exposure and identify the most exposed populations; protect public health by limiting contaminants in food; and, evaluate prevention, reduction and monitoring programmes. As a result of official controls, a high number of RASFF notifications concern the presence of various contaminants in food originating from the EU and non EU countries: for example, mycotoxins in nut and oilseed products and cereals or heavy metals in fish products have been amongst the most frequently notified contaminants. The setting of maximum levels which can be achieved by applying good practices according to the 'As Low As reasonable Achievable (ALARA)' principle, obliges FBOs along the food chain in the EU and in non EU countries to put in place good practices to prevent and reduce contamination as much as possible, so as to ensure compliance with the maximum levels. In addition, the EU promotes best practices amongst all those involved in the production, storage and distribution of food to ensure that contaminant levels are kept to a minimum, such as patulin in apple juice,<sup>385</sup> and fusarium toxins in cereals and cereal products.<sup>386</sup>

A number of EU sectorial food legislation have introduced re-evaluation programmes of existing authorised substances to ensure their safety and conditions of use according to the latest scientific knowledge. In the context of plant protection products, the number of approved active substances in such products has been cut down by more than 60%, following an EU review involving the Commission, EFSA and the MS in the past 25 years. Of some 1,000 active substances on the market in at least one MS before 1993 (start of the EU review programme), only 26%, corresponding to about 250 substances, have passed the harmonised EU safety assessment. Many active substances used in plant protection products which were routinely used by farmers 25 years ago are no longer authorised and have been replaced by other safe substances or non-chemical methods. In the

meantime, new active substances have been approved in addition to those available before 1993, so as of today 488 active substances are approved. In the area of food additives and flavourings, a re-evaluation programme has also been launched with respect to food additives and flavourings authorised prior to 2008. As far as food additives are concerned, out of 112 re-evaluated substances to date, the authorisation for 4 food additives has been withdrawn, while the conditions of use for 5 additives has been amended. In addition, out of 106 flavourings evaluated since 2012, 36 have been withdrawn from the Union list of authorised flavourings.

RASFF had also an indirect positive impact on raising the level of food safety in many occasions. For example, prior to the GFL Regulation the issue of veterinary drug residues in seafood from Asia was already a known problem. Through RASFF, every finding provided an incentive to RASFF members to increase sampling for similar products and unearth more non-compliances. These findings led to several emergency measures against these products compelling the exporting non EU countries to take corrective action. A similar impact of RASFF notifications could be seen in the context of sudan dyes in spices.

*c. International recognition of EU food safety framework and of the traceability requirement*

The food safety framework set up by the GFL Regulation has also served, in some cases as a **source of inspiration for non EU countries** developing their national legislation. Such examples include the modernisation of feed legislation in Japan and Canada on the basis of the EU model and the modernisation of food legislation in the US and Canada.<sup>387</sup> Similarly, the EU standards are often looked upon by consumers as the desired standard of international governance in the food chain. For example, pursuant to the 2013 Transatlantic Consumer Dialogue ('TACD') resolution on food issues in **TTIP**, which was jointly drafted by US and EU consumer groups, the EU standards are demanded by consumer groups on both sides of the Atlantic in most food law areas.<sup>388</sup>

The **superiority of the EU traceability system vis-à-vis other non EU countries** has also been acknowledged in a recent review of the existing food traceability regulations of 21 OECD countries.<sup>389</sup> The latter countries were evaluated based on responses to a series of questions that were developed to allow assessment of their traceability programs. Countries were ranked based on the nature and scope of their mandatory traceability regulations (as opposed to industry-led requirements) and on the comprehensiveness of the regulations in question. More specifically, the questions sought background information 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. **EU MS** (along with Norway and Switzerland) **received an overall world ranking of 'superior'**, above other OECD countries (for example, Australia, Canada, Japan, Brazil, New Zealand) while the US and China received an overall world ranking of 'average' and 'poor' respectively.<sup>390</sup>

This review led the authors to note the **importance of harmonisation of traceability requirements** and regulations to minimise the potential for misunderstandings, inefficiencies and delays in times of crises. According to the review, the comprehensive mandatory EU-wide traceability system covering the full range of feed and food products as well as the entire supply chain both for domestic and imported foods, set out by the GFL Regulation, is considered to have established the EU **as a strong**

**leader in global food traceability.** Only some non-EU countries have mandatory traceability regulations, and where they exist, regulations are restricted to specific commodities. That review concluded that *"it would be **very beneficial for global markets** if countries would move toward the development of an interoperable and uniform global traceability system **by following the example of the EU [...]**".*

*d. EU-wide food crises affecting consumption patterns are better contained*

The GFL Regulation was the direct response to a food crisis which had a pan-European dimension affecting consumer patterns. Such crises have not emerged since the GFL Regulation, with the exception of the *E.coli* in sprouts incident in 2011. But even in the context of the *E.coli* outbreak, which was a food crisis of pan-European dimensions affecting consumer patterns, the existing arrangements allowed relatively quick recovery of consumer patterns. As analysed in Section 4.2.10.3, once the source of the outbreak was confirmed (sprouts), consumption of the wrongly implicated products increased quickly at times reaching higher levels than the previous year. This demonstrates that such crises are now better contained.

The better containment of crises has been mainly achieved through the possibility to obtain rapid scientific advice from EFSA on emerging risks, the application of EU-wide traceability, better exchange of information through RASFF covering the entire food chain and better coordination amongst the risk managers in the context of the PAFF committee accompanied by emergency measures at EU level where appropriate. The near absence of unilateral actions taken by MS against food products from other EU MS through national interim protective measures (see Section 4.2.10.1) serves to illustrate the confidence MS have in the existing tools set out in the GFL Regulation with respect to crisis management.

*e. Consumers' perceptions of food-related risks*

Set against the baseline preceding the GFL Regulation, and in particular the BSE crisis, the goal of restoring and maintaining **consumer trust** in the food chain in general has been achieved. According to a 2010 Special Eurobarometer on perceptions of food-related risks, EU citizens broadly agree that public authorities do a 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, although some results pointed to areas where trust can be further improved.<sup>391</sup> Overall, consumer trust in the EU food safety regime has been restored compared to the baseline and maintained in the long term as evidenced in the 2008 dioxin incident in pork meat in Ireland and the 2011 *E.coli* in sprouts outbreak.

*f. Safety tools at the level of operators further strengthened in EU secondary food legislation and applied across the agri-food chain*

The GFL has set up a number of safety tools at the level of operators that bolster food safety, namely the food and feed safety criteria, the primary responsibility of FBOs to ensure compliance with food law requirements and to carry out own controls to that effect and the obligation to withdraw unsafe food and feed from the market. As described in Section 4.2.3, the 'own controls' obligation has been further strengthened in the EU Food and Feed Hygiene Regulations with respect to the general safety requirements by setting out a HACCP approach to be applied by all FBOs. A further incentive for FBOs

to comply with the 'own controls obligation' is laid down in the Official Controls Regulation, which links the frequency of official controls with the reliability of the FBOs' own controls.

These findings are also confirmed by the survey results in the context of the General GFL study. According to the latter, the objective of a high level of protection of public health received the highest average rating of the GFL Regulation objectives by both to MS CAs and stakeholders, including consumer organisations.<sup>392</sup> More specifically, the framework structure of the GFL Regulation setting out general principles, general obligations and the tools for the management of crises (see Figure 1) and its implementation at EU and national level have largely ensured a high level of protection of consumer health, especially in terms of **food safety**. More specifically, the general requirements imposed on the FBOs have ensured that risks to food and feed safety are minimised throughout the food chain at the level of each operator (own controls). If a risk still occurs, corrective actions, e.g. withdrawals of unsafe food and feed, can be taken by the operators efficiently on the basis of EU-wide traceability, as it was the case in the incident involving glass fragments in instant coffee.<sup>393</sup> Official controls carried out by MS CAs complement the general requirements established for FBOs. Even if food incidents emerge, the operation of RASFF in combination with emergency measures and crisis management tools can ensure the containment of crises and consumers' trust in the long term as well as avoid unnecessary disruptions to trade. According to the EU consumers organisation (BEUC) and environmental NGOs, “[g]enerally speaking and especially when comparing the EU food regulatory framework with that of non EU countries, the GFL Regulation established fundamental principles that have contributed to ensuring Europeans have access to food that is safe”.<sup>394</sup>

Protection of human health, however, is not limited to ensuring food safety; it also includes **human nutrition**. This broader concept of protection of human health is reflected in EFSA's mission to provide opinions on nutrition issues, set out in the GFL Regulation, as well as in other EU legislation addressing nutritional aspects and it is complemented by voluntary initiatives in the context of the EU platform for diet, physical activity and health and the High Level Group on nutrition and physical activity. As analysed in Section 4.2.6, although progress has been made, **nutrition-related issues have not developed as much as food safety**, despite a rising obesity trend which makes their consideration in developing food policy pertinent.

### **Consumers' interests**

The GFL Regulation also aims at a **high level of consumers' interests**. This objective has been achieved through the existence of a comprehensive legislative framework.

The protection of the consumers' interests is reflected in certain GFL provisions: e.g. in the consideration of legitimate factors and the use of the precautionary principle in the context of the risk analysis process, the food and feed safety requirements as well as the primary responsibility of FBOs to comply with food law requirements and to carry out own checks. All consulted parties, including consumer associations and NGOs, acknowledged the contribution of those provisions to a high level of protection of consumers' interests in the EU.<sup>395</sup>

As far as other EU legislation is concerned, this objective has been mainly achieved by the Food Information to Consumers Regulation, which entered into full application in 2016. This Regulation recognised the right of consumers to make informed choices and to make safe use of food with particular regard to health, economic, environmental, social and ethical considerations.

It is also complemented by the Nutrition and Health Claims Regulation, where the application of risk analysis (scientific assessment and application of legitimate factors, where relevant) has bolstered the protection of consumers' interests as the authorised claims on foods placed on the market ensure consumers that they have a scientific basis. In the past, many not evidence-based nutrition and health claims were used on labels and in marketing of foods. Indeed, more than 44,000 health claims, which were consolidated to approximately 4,600 claims have been submitted to EFSA for efficacy assessment. Up to March 2017, 267 health claims have been authorised, while 2,051 have not been authorised. In addition, 2,145 health claims are under consideration, including some 2,078 claims, which are subject to the ongoing REFIT evaluation on health claims made on botanicals and the general regulatory framework of the use of botanicals in foods.<sup>396</sup>

**Despite the overall positive feedback on the contribution of the GFL Regulation to increasing the protection of consumers' interests by all stakeholders,** consumer organisations and some MS CAs have nonetheless expressed some concern that, in practice, **this objective is not as well achieved** as the protection of consumer safety as such, because of the **persisting potential for fraud and misleading practices** (see also Section 5.2.2 below).

The synergies between the GFL Regulation tools and procedures and the implementation of the GFL Regulation principles in other EU secondary food legislation aiming at preventing and managing crises have ensured a **high level of protection of human health in terms of food safety** in the Union. **Consumer trust** in food is considered to have been overall **restored and maintained**. Nevertheless, **human nutrition** related issues **have not progressed as much as food safety**, although improvements have been made, as far as other EU secondary food legislation is concerned, compared with the situation prior to the GFL Regulation.

The GFL provisions as well as other EU secondary food legislation **have contributed to an increased level of protection of consumers' interests** compared to the situation prior to the GFL Regulation. This objective, however, is less well achieved than the protection of food safety.

## ***B. Effective functioning of internal market***

The general horizontal framework introduced by the GFL Regulation and its implementation and application has **largely contributed** to achieving the objective of the **effective functioning of the internal market**.

### *a. Evolution of internal trade*

During the application of the GFL Regulation and the adoption of other EU secondary food legislation, the food and drink sector in particular **maintained and strengthened its position as a leading sector in the EU economy**. In 2013, the EU food and drink industry comprised 288,000 companies (99% of which are SMEs) and employed 4.25 million people for an annual turnover of €1090 billion<sup>397</sup> compared to 2.6 million employees for an annual turnover of over €600 billion in 2000.<sup>398</sup> As stated in Section 4.1., the EU food and drink industry, is the largest manufacturing sector in the EU in terms of turnover, valued added and employment: it represents 15.6% of the total manufacturing turnover and 15% of total employment, ahead of other manufacturing sectors e.g. the automotive industry (12.4%) and fabricated metal products (11.7%) respectively. In addition, in 2013 the EU food and drink industry generated a value added of €212 billion which represents 1.8% contribution to the EU gross value added.<sup>399</sup> The EU is the world's largest exporter of food and drink

products. Finally, in 2015, the total intra-EU and extra EU trade of food and drink products amounted to €345.9 billion in 2015, 72% of which concerned intra-EU trade while 28% concerned extra EU trade.<sup>400</sup> The **value of EU internal trade** in the food and drink sector has also increased by **72%** over the past decade,<sup>401</sup> while in 2015 the volume of food and drink production was the highest since 2008.<sup>402</sup>

*b. Occurrence of obstacles to the free movement of goods within the EU*

The contribution of the GFL framework to the removal of obstacles to the free movement of goods within the EU has also been recognised by all consulted parties, including supply chain stakeholders and MS CAs, in the context of the General GFL study.

- The systematic application of the **risk analysis principle**, especially at EU level, has contributed to the effective functioning of the internal market. EU and national food measures on risk analysis have avoided unjustified barriers to the free movement of such products.<sup>403</sup> Stakeholders, including 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, allowing free movement within the internal market and innovation. Positive examples of a harmonised risk based approach at EU level include the management of biological, chemical and physical risks, as well as authorisation procedures for regulated products, although certain shortcomings have been identified as regards the latter, as analysed below under Section 5.2.2.
- Overall, the **food and feed safety requirements** and the relevant criteria have also contributed to the effective functioning of the internal market.<sup>404</sup> Certain shortcomings, however, have been identified with respect to the appreciation of a level of risk leading to withdrawals, as detailed below under Section 5.2.2.
- Overall, the **allocation of responsibilities** throughout the food chain, namely the primary responsibility of FBOs and the performance of official controls by MS CAs accompanied, where necessary, by the imposition of effective, proportionate and dissuasive measures and penalties, **achieved the internal market objective**.<sup>405</sup> It has facilitated the placing on the market of products and it has created a level playing field for all FBOs in the EU, including imports<sup>406</sup> (see Section 4.2.3.3). Nonetheless, some questions were raised on the consistency of **national liability systems** in place (national competence), which may have a negative impact on the internal market objective, as elaborated below under Section 5.2.2.
- The **EU-wide traceability** in combination with systems in place to provide relevant information to MS CAs has for the most part contributed to ensuring a level playing field and to avoid unnecessary disruptions of trade (see Section 4.2.4.2).<sup>407</sup>
- For the most part, the combined application of the provisions on determining the safety of feed and food, both in terms of traceability and withdrawals, have contributed to limit disruptions of trade, although again this was more appreciated amongst MS CAs than amongst stakeholders.<sup>408</sup>
- EU emergency measures, which by definition give rise to barriers to the free movement of food and feed, have only been taken where justified and they are regularly reviewed with a view to restore the effective functioning of the internal market where the risk is contained or is no longer relevant (see Section 4.2.10.1).



The structure of the GFL Regulation as framework legislation providing a common and consistent basis both at EU and national level for the entire food chain including feed, combined with a great degree of harmonisation in other EU secondary food legislation have **contributed to the effective functioning of the internal market** by creating a level playing field for all FBOs in the EU market while limiting trade impacts, where problems have occurred. No systemic market failures were observed.

### 5.2.2 Which main factors have contributed to or stood in the way of achieving these objectives?

Based on the analysis of the available evidence in Section 4.2, the factors that have contributed to achieving the objectives of the GFL Regulation can be summarised as follows:

- The structure of GFL as a common framework for the development of EU and national food law achieved an integrated approach to food law (see also section 5.4.1 below);
- The **alignment** of the common definitions and the development and adaptation of food law to **international definitions and standards** enhancing the international orientation of the GFL Regulation (see also section 5.2.3 below).<sup>409</sup>
- The **general character of the GFL Regulation** and particularly, the **goal-oriented general requirements** imposed on FBOs have also facilitated the effective implementation of the GFL Regulation by prescribing the result to be achieved, and not the means. This approach has been acknowledged by all consulted parties as a major strength of the GFL Regulation, which confers two important and inter-linked advantages: (a) it allows for adaptability of the provisions to fit all operational contexts and specific cases; and (b) it acts as an important mitigating factor against unnecessary burden, by allowing FBOs to devise the most optimum structures that ensure compliance with the goal-oriented provisions of the GFL Regulation. These two advantages also contribute to the competitiveness and the innovation potential of the EU food industry.
- FBOs have also combined compliance of the GFL Regulation general requirements **with other complementary tools, such as private standards**, for example in the context of traceability and primary responsibility (see Sections 4.2.3.3, 4.2.4.2 and 5.3.1). This has allowed FBOs to meet their legal obligations under the GFL Regulation and other EU secondary food legislation more effectively. FBOs have considered EU guidelines to be the most helpful to meet their legal obligations under the GFL Regulation and other EU secondary food legislation (85%), followed by national guidelines (64%), private codes of good practice (62%), private guidelines (59%) and private standards (57%).<sup>410</sup> As regards the EU guidelines on the GFL Regulation in particular, both FBOs and MS CAs have acknowledged their important role in assisting them to comply with their respective obligations.<sup>411</sup>
- Following the 2011 *E.coli* outbreak, a number of initiatives that have taken place have strengthened the implementation of **crisis management**. These initiatives include crisis simulation exercises and fact-finding inspection missions carried out by the Commission to identify best practices in emergency preparedness of MS and training courses on food-borne outbreak investigations in the framework of the BTSF programme.

By contrast, available evidence has identified certain **factors that have not always ensured the full potential of the GFL Regulation** to achieve its core objectives, as follows:

The structure of the GFL Regulation as a framework has allowed in some instances for **national differences**.

**Differences in the implementation of the risk analysis principle** have been identified with respect to the following instances:

- Stakeholders have identified as an important issue of concern the **variable level of implementation of withdrawals** amongst the MS, both in terms of how the provisions relating to the withdrawal of products by FBOs themselves and in terms of the withdrawals ordered by the MS CAs in the context of official controls.<sup>412</sup> According to them, the **determination of food safety** (especially of food unfit for human consumption, which is not injurious to health) can vary in the different Ms and result in disproportionate withdrawals from the market. As a result, the implementation of feed and food safety requirements does not always yield the same proportionate results in all MS in terms of withdrawals. An effort has been made to alleviate such differences through the issuing of guidelines. For example, to address national disparities concerning the potential withdrawal of products that exceed the legal limits for pesticide residues and which are ordered by the MS CAs, the Commission has adopted the RASFF SOPs. The latter documents ensure, amongst others, a more uniform scientific appreciation by MS of the risk posed by exceeding MRLs in those substances for the purposes of notifying RASFF.<sup>413</sup> This is expected to reduce national disparities with respect to withdrawals of food and feed linked to the existence of pesticide residues.
- **A very few remaining partially harmonised areas in the area of food law**, such as food contact materials other than plastics, food supplements and foods with added vitamins and minerals as regards the setting of maximum levels of substances as well as lack of full implementation at EU level with respect to health and nutrition claims as regards botanicals: This aspect **goes beyond the GFL Regulation** and concerns the EU sectorial food legislation in place. In the absence of full harmonisation in this area, the risk analysis is carried out at national level resulting in disparities. Such national disparities are likely to give rise to obstacles to the effective functioning of the internal market. Nevertheless, given the limited number of non harmonised aspects in the area of food law, the impact on the effective functioning of the internal market of the EU food law as a whole is limited and it is currently addressed in a number of sectorial evaluations in more detail. More specifically, as regards food contact materials, the Commission is carrying out an evaluation to assess whether the current legislative framework is fit for purpose and delivers as intended. No evaluation has ever been conducted in this area. Evidence gathered so far on the non-harmonised food contact materials, however, indicates that there may be some fundamental deficiencies in the existing approach to regulating food contact materials and that the absence of EU harmonised rules negatively affects the functioning of the internal market and possibly the safety of food contact materials.<sup>414</sup> Similarly, a REFIT evaluation of Regulation (EC) No 1924/2006 addressing, amongst others, the health claims made on botanicals, the implementation of which is not complete at EU level, is also taking place. These evaluations are expected to shed more light into the extent of bottlenecks created in the effective functioning of the internal market attributed to the lack of a full harmonised framework in place.

The broadness of the **common definitions**, despite the overall positive feedback as mentioned earlier, especially when they are further implemented in other EU secondary food legislation, has been considered to have led to **different interpretations** by the MS CAs. In the context of the General GFL study, stakeholders have cited the application of the definition of 'food' and its distinction from medicinal products or medical devices in the context of the Food Supplements Directive, as well as the definition of 'retail' especially in the context of other EU secondary food legislation, *e.g.* food hygiene rules.<sup>415</sup> Again, these different interpretations are not of systematic nature but they occur on a case-by-case basis. Despite progress made compared to the baseline, **national differences** also persist in relation to the **information to the public on food safety incidents**. Such differences are inherent in this type of situations given that the circumstances of each food safety incident are different. Taking that point into account and as analysed in Sections 4.2.5.3 and 4.2.10.3, a good example where information to the public was timely and pertinent and therefore contributed in containing a food crisis was the 2008 dioxin crisis on pork meat in Ireland. In the 2011 *E. coli* in sprouts outbreak, however, certain communication at regional level to the public led to the erroneous identification of the problem at issue in the early weeks, resulting in disruptions of trade and impacting negatively on consumers' trust, albeit in the short term. Although the two situations are not directly comparable, MS CAs have identified difficulties in identifying the type of information to be provided to the public when public health risks are involved, while taking into account professional secrecy.<sup>416</sup> Moreover, given the reluctance to formally declare a crisis and establish a crisis unit in the context of the general plan in the context of the *E.coli* outbreak, there seems to be a need to revisit the 2004 general plan on crisis management to develop more workable arrangements that can be applied during such incidents, including in terms of communication.

As analysed in Section 4.2.3.3, **national approaches** to the implementation of **official controls** by MS CAs are variable. This variable approach of the MS CAs can, however, depend also on differences in the **reliability of FBO's own controls**. Again, no problems of systematic nature have been identified.

The evidence detailed in Sections 4.2.3 and 4.2.7 has also demonstrated that the form, specificity and severity of the **measures and penalties** currently in place to address compliance with food law **tend to vary** considerably between MS, as **this is a matter of national competence going beyond the GFL Regulation**. The variation in MS enforcement in terms of measures and penalties has implications on the effectiveness to especially address the prevention of fraud and protect consumers' interests. The new Regulation on Official Controls and other Official Activities addresses this issue to an important extent, by reinforcing the rules on financial penalties for fraudulent or deceptive practice and providing for the establishment of EU Reference centres for the authenticity and integrity of the agri-food chain.

As a general conclusion, although not systematic, the persistence of all above-mentioned national differences can have a certain negative impact on the high level of protection of human health and consumers' interests and on the effective functioning of the internal market.<sup>417</sup> This impact, however, is on a case-by-case basis and it does not jeopardise the overall effectiveness of the GFL Regulation. The Commission endeavours to alleviate these national differences through discussions within the Working Groups composed of MS' representatives, through the work of the audit and inspection service of DG SANTE and last but not least, through the issuing/updating of general guidelines.

Although it has been acknowledged that **transparency of the risk analysis process** has been improved compared to the baseline and that it is applied in a more harmonised way across the EU,

the General GFL study has also noted certain concerns especially with respect to **risk assessment and risk communication** (Sections 4.2.2.1.1 and 4.2.2.4).

As far as the risk assessment is concerned, in the context of authorisation dossiers, EFSA is bound by **strict confidentiality rules** that are laid down in the GFL Regulation and in the multiple authorisation procedures in EU secondary food legislation. This **creates a perception of a certain lack of transparency**, which is further reinforced by the civil society's concerns over EFSA's independence from industrial interests, as EFSA bases its risk assessment on authorisation dossiers on studies conducted by the industry. These criticisms **can have a negative impact on the acceptability of EFSA's scientific work by the general public**. As stated in Section 4.2.2.4, there is therefore a need to address perceived issues with respect to the transparency as well as the reliability and independence of studies underpinning EFSA's assessments, while protecting legitimate confidential business information, in order to safeguard the reputation of EFSA's work. This can be achieved, for example, through measures to increase transparency of the supporting studies, an involvement of public authorities in the process of deciding which studies need to be conducted for an application dossier, enhanced auditing of studies conducted in accordance with the principles of GLP, and the possibility to exceptionally commission ad-hoc studies in case of serious doubts or conflicting results, for example, in case of widely used substances (see Sections 4.2.2.1.1 and 4.2.2.4).

Furthermore, **risk communication** is, overall, considered **not to be effective enough**, especially given the growing challenges that it has to face in current times, such as the increasing complexity of scientific findings, including the time it can take to reach conclusions, and the difficulty to translate in simple words, the perception of risk often being emotional, cultural and disconnected from rational thinking, as well as the pluralism of news sources in combination with the increasing use of social media and the social amplification of risk (see Section 4.2.2.3). Consumer organisations, for example, have complained that there is not always sufficient information on the way risk management decisions are reached especially with respect to the weight that has been attributed to risk assessment vis-à-vis other legitimate factors and the application of the precautionary principle.<sup>418</sup> This has a negative impact on **consumer trust and on the acceptability of risk management decisions**.

EFSA, national risk assessors as well as EU and national risk managers must therefore do more to ensure **effective risk communication**, especially of risk management decisions. This has become more apparent in the very few cases where divergences have been noted at risk assessment level between EFSA and national risk assessors<sup>419</sup> and where different political choices in risk management at EU and national level have been made. Indeed, consumer organisations have flagged how crucial is for consumers to better understand the political choices and possible risk trade-offs.<sup>420</sup> A more **global risk communication** conducted at **the different steps of the risk analysis process involving risk assessors and risk managers both at EU/MS level** combined **with open dialogue** may be more effective in addressing such criticisms on politically sensitive issues and bolster consumer trust. In addition, there is also potential for an intensified cooperation between Commission, EFSA and the MS to promote the consistency of the global risk analysis process. Similarly, the effectiveness of **communication** in the context of **crisis** should also be enhanced (see Section 4.2.10).

**Lengthy authorisation procedures** in some sectors (*e.g.* feed additives, plant protection products, food improvement agents, novel foods, health claims), with delays in the risk assessment and the risk management phases **can slow down the market access process affective the innovation potential**.

As analysed in Section 4.2.2.4, the length of the authorisation procedures, especially with respect to innovative products, has a direct impact on the expected return on investment; the lengthier the authorisation process, the lower the internal rate of return is. This in turn affects the competitiveness of the EU food and drink industry and its capacity to also address future challenges through innovative products, such as the sustainability of food (for the latter challenge, see earlier Section 5.1.1). In any event, this shortcoming relates to the **modalities** of the authorisation procedures laid down in other EU secondary food legislation, rather than to the **risk analysis principle *per se***, as set out in the GFL Regulation. The overall implementation of the risk analysis principle as well as the authorisation procedures will be further analysed in the context of the ongoing REFIT Evaluation of the EU legislation on plant protection products and pesticides and the future evaluations of Regulation (EC) No 1831/2003 on additives for use in animal nutrition and Food Irradiation. The overall implementation of the risk analysis principle in the area of food claims (including authorisations) will be scrutinised in a future evaluation report, required by Article 27 of the Nutrition and Health Claims Regulation, following the completion of the pending REFIT evaluation of the latter Regulation focusing on the lack of complete implementation with respect to nutrient profiles and the health claims on botanicals.

Finally, as analysed in Sections 4.2.2.1.1 and 4.2.2.4, a number of negative signals have been identified on the capacity of EFSA to maintain a high level of scientific expertise:

- Recent calls on the membership of panels have shown the difficulties encountered to attract new members due to a number of disincentives: insufficient recognition for the scientists' career, modest financial compensation for the experts and their employers considering the amount of time required for their EFSA's contribution, strict rules on independence which do not take into account the increasing trend of public-private partnership in scientific research (see also Section 4.2.2.1.1).
- The distribution of experts per MS in Scientific Committee/Panels show that more than two thirds of the experts (69%) originate from 6 MS, while 86% originate only from 10 MS.
- The current trend of diminishing public administration budget might also have a negative impact on the capacity of national bodies to send experts to EFSA or to contribute to its work.
- As stated in Section 4.2.2.1.1, the finances dedicated to the outsourcing of EFSA's tasks to national risk assessors are considered by the MS as relatively low (€10 million per year, 13% of EFSA's total budget).

These negative signals show the limitations of the current system to ensure in the long-term sufficient expertise and to fully engage all MS in scientific cooperation.

### **5.2.3 Beyond these objectives, has the legislative framework introduced by the GFL Regulation led to any other significant changes both positive and negative?**

Beyond the core objectives, the legislative framework introduced by the GFL Regulation has led to the following positive significant changes, based on the analysis set out in Sections 4.1, 4.2.2.4 and 4.2.8:

The GFL Regulation has contributed to **the development of a global governance** in food and feed:

- The GFL Regulation has been instrumental in a vital cross-fertilisation of EU food law and international standards: Not only has the EU made considerable efforts to ensure alignment of

EU food law (including its definitions) with international standards (and related definitions), especially those adopted at the level of Codex Alimentarius, but it has also contributed to the development of such international standards on the basis of EU standards, which have been underpinned by EFSA's scientific opinions.<sup>421</sup>

- The development of the RASFF Window, an IT tool for countries other than the RASFF members (currently amounting to 107) to access RASFF notifications that relate to their country, as well as the information flow between RASFF and INFOSAN in respect of large international food safety incidents have also contributed to developing a more coordinated response in the prevention and management of food incidents in the international sphere.<sup>422</sup>

The GFL Regulation also had a **positive impact on the competitiveness of EU food and feed industry on the world market**. Indeed, a number of FBOs have considered that the overall food safety requirements, set out in the GFL Regulation, have provided a comparative advantage to EU industry.<sup>423</sup> For example, the stricter requirements for the marketing of feed and food by means of authorisation procedures provide a higher marketing value and strengthen the **comparative advantage of the EU manufacturers**.<sup>424</sup> As concluded in the recent Competitiveness study, for the EU to maintain its competitive advantage, the attention to food safety within the current legislative framework should at least be maintained.<sup>425</sup>

**Traceability and RASFF** are two of the tools used in the prevention and management of food crises, especially as regards food safety. Their combined use, however, has resulted in benefits in addressing **recent non-safety food crises**, such as the 2013 horsemeat scandal, which related to mislabelled meat. The later crisis was effectively managed through the EU-wide traceability given the complicated food chain events linked to the product at hand and the use of RASFF, in the absence at that time of a more effective administrative assistance platform (see also Section 4.2.7.1).

The legislative framework introduced by the GFL Regulation, however, **has posed certain constraints** with respect to the issue of **food waste**, which has recently emerged and is included as part of the priorities of the current Commission (*i.e.* circular economy), as detailed in Sections 5.1.1 and 5.2.2. For example, differences in the implementation of the food safety requirements may result in unnecessary food waste in the case of disproportional withdrawals especially of food 'unfit for human consumption', when action may be taken to render part of the batches concerned 'fit for human consumption'. Similarly, withdrawals of food ordered by MS CAS for not complying with food information requirements may also result in unnecessary food waste where action could be taken to address these non-compliances. The application of the general requirements to food donors and food redistribution centres can also make more difficult the redistribution of food. As already indicated in Section 5.1.1, the Commission has recently adopted EU guidelines on food donation to clarify the relevant provisions of EU food legislation and assist in lifting barriers to food redistribution.

### 5.3 Efficiency

#### 5.3.1 What are the costs and benefits (monetary and non-monetary) associated with the application of the legislative framework introduced by the GFL Regulation in the Member States and in the Union?

The overall benefits from the application of the legislative framework introduced by the GFL Regulation have already been analysed in the previous sections under Chapter 5 (*e.g.* increased

protection of public health especially in terms of food safety and consumers' interests, effective functioning of the internal market while minimising disruptions to trade, increased competitiveness of the EU food and drink industry both within the EU and in the international arena). These benefits accrue to the entire society: MS, FBOs, consumer groups and NGOs.

While, the structure of GFL as a framework and its implementation through other EU secondary food legislation and by the MS **makes it difficult to quantify both costs and benefits** of the relevant GFL provisions, in the overall area of food and feed, considerable efforts have been made to identify at least the categories of costs or benefits involved and their relative importance.

As stated in Section 2.2, the direct general requirements imposed on FBOs are few and goal oriented: primary responsibility, feed and food safety requirements, 'one step back – one step forward' traceability for food safety purposes, withdrawals of unsafe products, imported products compliant with all requirements of EU food law and exported EU products compliant with EU food law or food law requirements of the importing country. Some of these few general requirements form part of what a legitimate FBO is expected to comply with so as to remain on the market, even if the GFL Regulation was not in place: for example, for a FBO to be commercially viable in the food and drink sector, it must ensure the safety of its products and that it complies with the food law requirements applicable in the relevant markets. Other requirements were the codification of pre-existing practices of FBOs – albeit not in a systematic manner – prior to the GFL (*e.g.* traceability).

The evidence available indicates that many FBOs **often go beyond** the main regulatory requirements set out in the GFL Regulation through private standards and/or contractual relationships. These private standards and contractual obligations **build upon the GFL** core requirements.

Given the above-mentioned considerations, **it is difficult to identify the part of the compliance costs that is directly linked with the implementation of the GFL general requirements** imposed on the FBOs. This difficulty is further illustrated with respect to the primary responsibility principle.

As analysed in Section 4.2.3, FBOs were not in a position to quantify the costs for complying with the primary responsibility requirement, which consists of ensuring compliance with food law in general and carry out own controls to verify such compliance. Compliance costs linked to verification are specific to each operator given the profile, needs and position of each operator in the food chain. In addition, the level of these costs is also influenced by a combination and range of factors: business type or size, extent of cross-border trading, sector, product, supplier or customer range *etc.*<sup>426</sup>

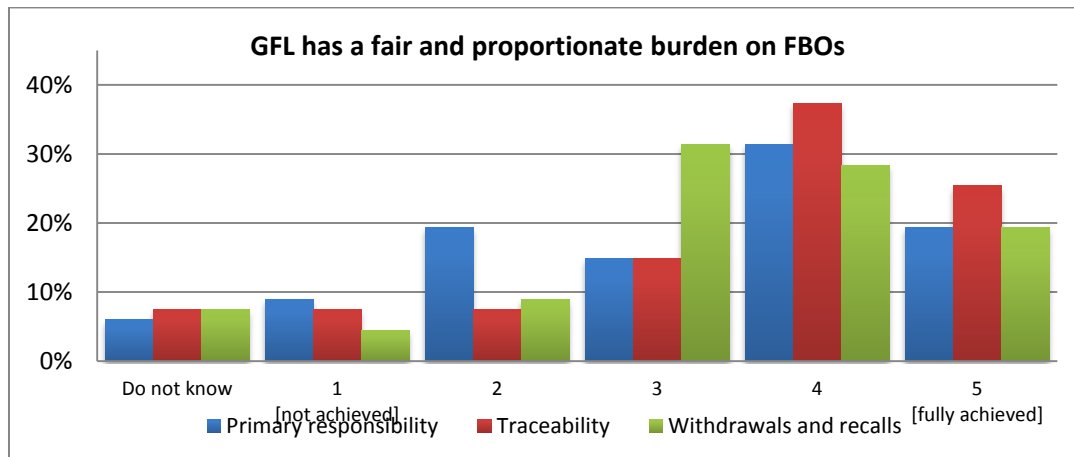
Despite these limitations and according to the available evidence presented below, overall, the framework structure and the goal-oriented provisions of GFL indicate that **the benefits outweigh the costs and their combined effect** has resulted in **efficiency gains** as regards the implementation of the general requirements by the FBOs and the MS CAs along the food chain. By way of example, the design of 'fit for purpose' compliance and traceability systems at FBOs' level has freed up resources in some cases at the level of MS CAs to focus on enforcement.

### **Fair and proportionate burden**

In the context of the General GFL study, survey results indicated that the GFL Regulation has largely entailed a fair and proportionate burden on FBOs, (see Figure 7). A majority of stakeholders had a positive view on the proportionality of GFL. This can be seen in the consistently favourable responses for i) primary responsibility, ii) 'one step back – one step forward' traceability, and iii) withdrawals and recalls. Negative responses (score 1 or 2) regarding withdrawals and recalls were mainly

attributed to the variable level of implementation of withdrawals of unsafe food (see also Section 5.2.2).

**Figure 7:** Stakeholder responses, including NGOs and consumer organisations, as to whether the GFL Regulation has achieved a fair and proportionate burden on FBOs, with respect to primary responsibility, traceability, and withdrawals, General GFL study



### Regulatory benefits and costs

As described in detail in Sections 4.2.3.1 and 4.2.3.3, regulatory costs linked to the GFL Regulation (verification of compliance with food law requirements) are **often integrated either in contractual obligations or in private standards**. Although **private standards mitigate the costs of regulation** by integrating regulatory requirements, they also add additional requirements for the FBOs, as they often go beyond what the GFL Regulation requires.

On one hand, to abolish the existing GFL core requirements on the basis that FBOs often go beyond these through contractual obligations or private standards would jeopardise the application of certain minimum requirements across the food chain as well as the attainment of the two main objectives of the GFL Regulation: the high level of protection of public health and consumers' interests and the effective functioning of the food chain. Although the adherence to private standards and the existence of contractual obligations is considered a common practice, they do not guarantee, as the GFL legislative framework does, that all FBOs throughout the food chain, including importers, comply with these main requirements. This is an essential contribution of the GFL Regulation as the food chain is as strong as its weakest link. Moreover, the non-adherence to private standards cannot be enforced, which may lead to an uneven playing field in terms of food safety.

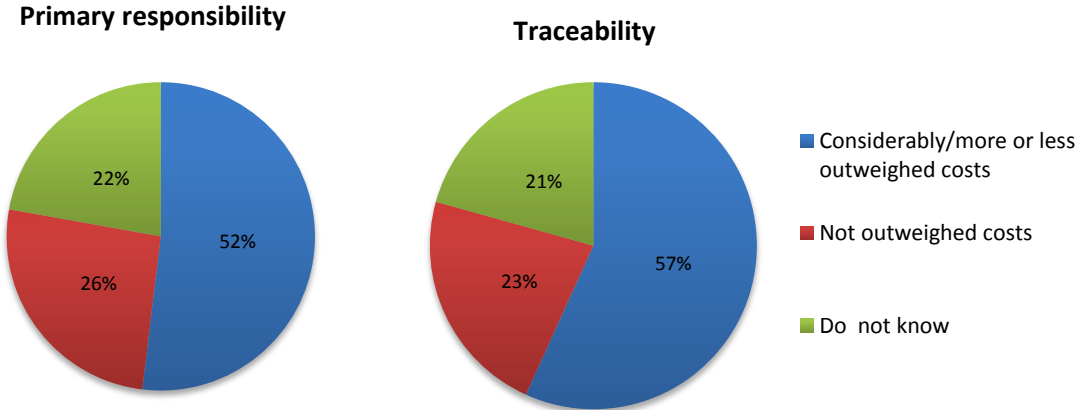
On the other hand, to align the GFL core requirements to the higher standard(s) fixed in contractual obligations or in private standards would add regulatory burden across the board and throughout the food supply chain, regardless of the specificities of each FBO. Given the diversity of the sectors involved, the different levels of production, processing and distribution of food and feed and the variety of the businesses involved, this would result in the generation of unfair and disproportionate burden for the FBOs. Moreover, it would reverse the current system of goal-oriented core obligations set out in the GFL Regulation which provide for the necessary flexibility to design optimal, 'fit for purpose' mechanisms to ensure compliance and which has attracted the overall praise of the industry (see Sections 4.2.3.1 and 4.2.3.3).



It is therefore more appropriate at this stage to address the issue of the additional administrative burden stemming from private standards and contractual relationships through the ongoing initiative of the Commission on Unfair Commercial Practices with respect to agricultural products. As stated in Section 4.2.3.3, the Commission is currently looking into whether EU-level action is needed to address anti-competitive practices caused by the weaker position of farmers and SMEs in the food supply chain with respect to foods of agricultural origin *vis-à-vis* other levels of the chain.<sup>427</sup>

According to the General GFL study, the overall benefits resulting from the implementation of the primary responsibility and traceability have outweighed the relevant costs (*e.g.* costs of own controls and traceability costs respectively) for a majority of the FBOs consulted (see Figure 8 and also Sections 4.2.3.3 and 4.2.4.2). A fifth of the respondents indicated that they were not in a position to know. Benefits were mostly felt by those FBOs trading within the internal market as they can benefit from harmonisation. Nonetheless, a quarter of the consulted stakeholders, which tended to be smaller and craft enterprises that supply their national market and do not rely on imports of raw materials, indicated that benefits have not for the most part outweighed costs.<sup>428</sup> However, given the diversity of the sector, it cannot be concluded that harmonisation benefits larger enterprises more than smaller ones, as in practice a large range of operational contexts can prevail.

**Figure 8:** FBO responses as to whether the benefits resulting from the GFL Regulation with respect to primary responsibility and traceability have outweighed the relevant costs, General GFL study



**Costs of traceability**

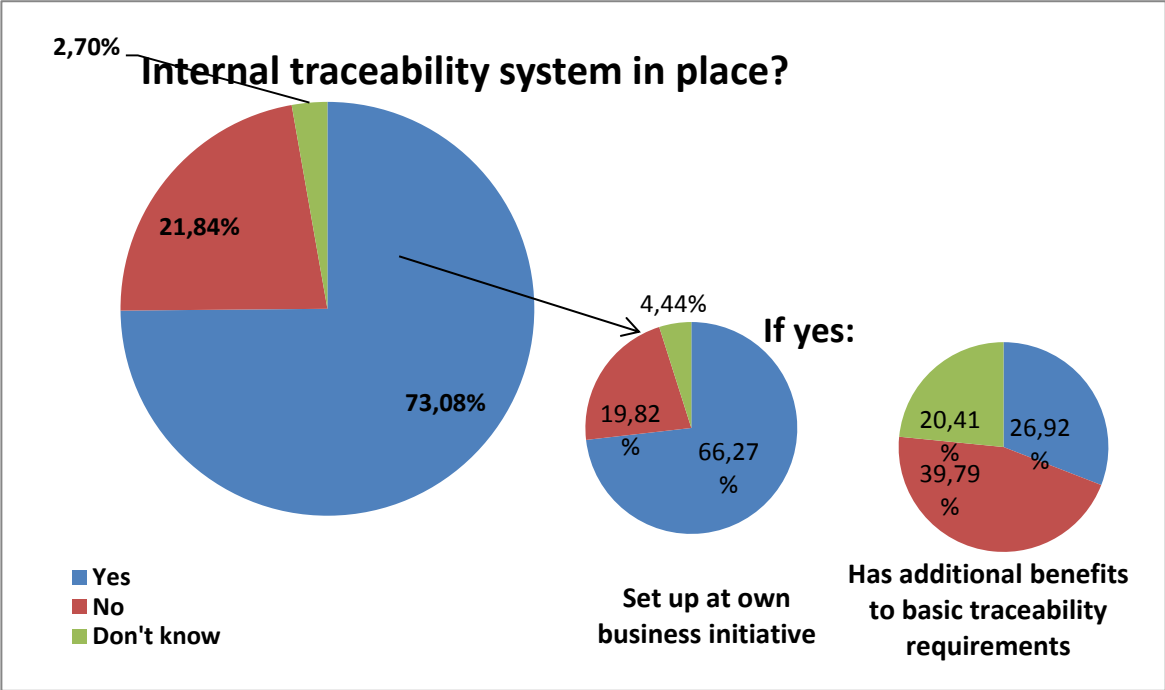
In the absence of EU cost-benefit studies on traceability, it is interesting to note an in-depth review of the costs associated with traceability in the food industry carried out by the Institute of Food Technologists ('IFGT'), commissioned by the U.S. Food and Drug Administration ('FDA'). Amongst the two case studies examined was the 2006 *E.coli* O157:H7 outbreak in spinach in the U.S. The latter study confirms the above-mentioned finding that the overall benefits of traceability outweigh the relevant costs.

More specifically, according to the latter study, the losses to the industry and the public in terms of health were significant. Up to US\$ 129 million in losses were attributed to the contamination of spinach with *E.coli* O157:H7. Costs to the industry of implementing traceability were estimated to be between US\$3.3 and US\$109 million depending on the technologies adopted. Furthermore, significant benefits through reduced illnesses are achieved with more rapid product tracing, which could occur with electronic access to records (US\$10 to US\$94 million). In addition to these direct

benefits, benefits related to more rapidly restoring consumer trust, reduced market disruption and spillover to other fresh produce industries are foreseen. Although there is some uncertainty that accompanies such estimates, the order of magnitude suggests that the benefits of improved product traceability outweigh the costs to industry and society in implementing a product tracing system. However, given that companies incur traceability costs every year, while the likelihood of an outbreak per year is fairly low, a specific assessment that addresses the probability of occurrence of a triggering event vs. the costs and potential benefits per industry sector needs to be done.<sup>429</sup>

To further assess the impact of the traceability requirement on SMEs, an SME survey was carried out. In the context of the SME survey, traceability was considered as one of the most costly EU food law requirements. For nearly half of the respondents, traceability went beyond a normal book-keeping exercise, which can satisfy the requirement of the GFL Regulation. This was further confirmed by the fact that 75% of the respondents had an internal traceability system that went beyond the GFL Regulation requirement, whereas nearly two thirds of these internal traceability systems were set up at businesses' own initiative.

**Figure 9:** SME responses as to whether they have internal traceability in place, General GFL study

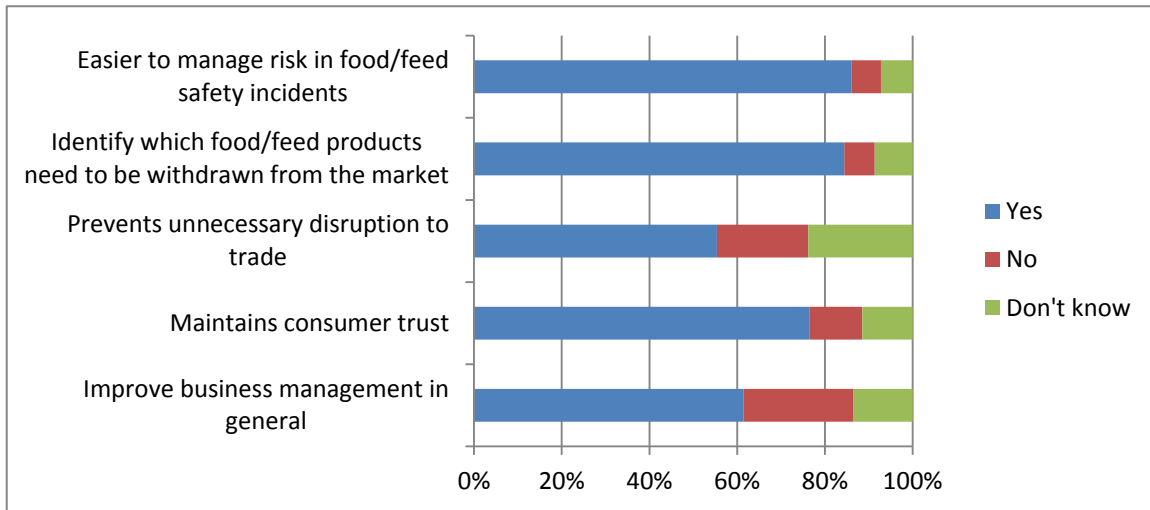


A qualitative analysis and triangulation of this evidence, therefore, demonstrates that the costs incurred by the SMEs in relation to traceability are not, in most cases, attributable to the GFL Regulation. SMEs have in place more sophisticated systems than required by the GFL Regulation framework, which adds to their administrative burden. The motivation to do so seems to be driven by the benefits of a sophisticated traceability system outweighing the costs.

Indeed, a vast majority of the SME respondents indicated the following benefits of the traceability system, as depicted in Figure 10: it makes it easier to manage risk in food/feed safety incidents (85% of respondents); helps identify which products need to be withdrawn from the market (83%); and, 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

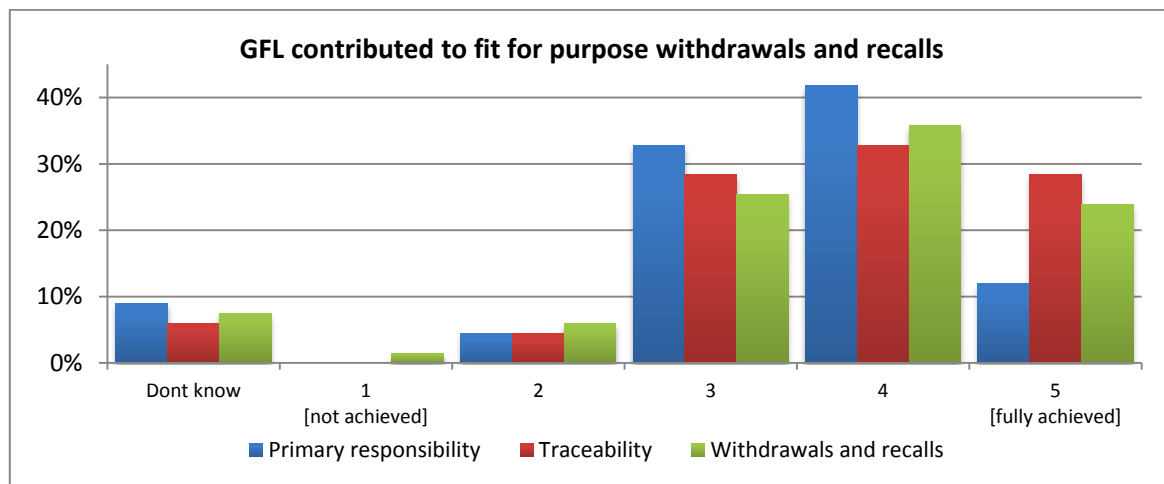
disruption to trade (54%) and improves business management (60%), although a relatively important share of respondents do not know whether the traceability system has these particular benefits (23% and 13% respectively).

**Figure 10:** SME responses with respect to the benefits of traceability, General GFL study



Any negative responses on the costs of traceability should also be balanced with the following survey results indicating that an overwhelming majority of stakeholders find the GFL Regulation to be fit for purpose regarding withdrawals and recalls (Figure 11).

**Figure 11:** Stakeholder responses if the GFL Regulation has contributed to fit for purpose withdrawals and recalls with regards to primary responsibility, traceability, and withdrawals, General GFL study

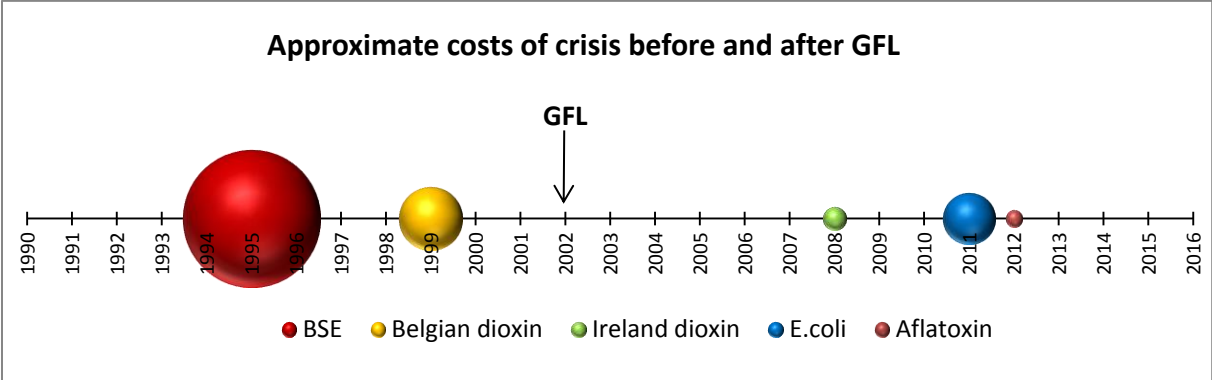


### Costs of 'crisis'

In terms of the effects, the costs and burden imposed on FBOs to comply with the few general requirements of the GFL Regulation are considered justified in view of the achieved outcomes vis-à-vis the prevention and management of food crises. For example, although the costs of withdrawals are not comparable before and after the GFL Regulation or between different incidents, the cost of the dioxin crisis back in the late 1990s was estimated at nearly €1.5-2.0 billion, while the cost of the dioxin contamination in Ireland in 2008 was estimated at €200 million and of the aflatoxin crisis in 2012 at €100 million.<sup>430</sup> Figure 12 shows the proportion of costs before and after the entry into force

of the GFL Regulation. Although it is not possible to know how the crises after 2002 would have unfolded in the absence of the GFL Regulation, the total costs could give an indication that the GFL Regulation has significantly contributed to reducing the financial impact of a major food crisis in the EU. Also the cost of other risk management tools, such as RASFF, is not comparable before and after 2002.<sup>431</sup> Moreover, the introduction of the GFL Regulation has also contributed to limiting the time span of a crisis, allowing the prompt restoration of consumers' trust. While the BSE crisis lasted approximately 10 years, the *E.coli* in sprouts outbreak in mid-2011 was limited in time. As stated in Section 4.2.10.3, once the source of the outbreak was correctly confirmed (sprouts), consumption of the wrongly implicated products (cucumbers) recovered relatively quickly in the weeks following this outbreak, with consumption reaching a higher level than in 2010 by end of 2011.

**Figure 12:** The approximate proportion of costs of crisis', before and after the entry into force of GFL



The same goes for other risk management tools, such as RASFF.<sup>432</sup> Considering the financial resources that are involved in running the system from a Member State perspective, the costs appear to be reasonable in view of the outcomes achieved, such as the speed of information and communication exchange, the management of food safety incidents and the resulting protection of public health. The combined effect of the core obligations set out in the GFL Regulation and the risk management tools (notifications through RASFF, emergency measures, crisis management) aims at containing crises. The ultimate goal is to preserve consumer trust and minimise the impact on the internal market and international trade, while limiting to the extent possible, the economic impact in terms of costs of withdrawals of unsafe products. For example, in the case of the 2008 dioxin crisis in Ireland as regards pork meat, the synergies of EU tools and requirements, such as RASFF, EFSA's involvement, the application of the EU-wide traceability requirement and risk management decisions led to an effective management of the crisis. Consumer trust in the Irish meat sector was preserved avoiding a spill-over effect to the beef sector and limiting the long-term impact on trade of pork products. In the latter case, however, targeted withdrawals were not possible given the limitations of the GFL Regulation traceability requirement (see Section 4.2.4.2).

**Reduction of administrative burden**

Survey results in the General GFL study have also indicated that, by and large, there is limited potential for legislative and non-legislative simplification and reduction of administrative burden in relation to the general requirements. In particular, some potential was noted by stakeholders in the areas of own controls<sup>433</sup> and withdrawals.<sup>434</sup> Consulted stakeholders saw less potential for simplification and reduction of administrative burden in relation to the food and feed safety requirements (less than a third) and to traceability (less than a quarter). About a third of

stakeholders replied 'don't know' to this question. Based on comments received and interviews during the consultation phase in the context of the General GFL study, these findings were read as an indication that there was little concern amongst stakeholders on simplification and reduction of administrative costs for the GFL Regulation as such.

### **Analysis of costs and burden**

In light of the above, there is a clear indication that the **general requirements** applied to FBOs **have overall entailed a fair and proportionate burden**. This has been further supported by the recent Competitiveness study, pursuant to which "*[c]urrent levels of regulatory requirements are considered quite manageable in the light of many companies currently already exceeding the minimum thresholds set in regulations. It is also unlikely that stricter and more comprehensive requirements themselves will harm competitiveness, especially since many manufacturers, including SMEs, already comply with higher requirements than the obligatory requirements set in EU regulation.*"<sup>435</sup>

The centralised approach to risk analysis **has also increased efficiency** in terms of.<sup>436</sup>

- a) **Cost savings:**<sup>437</sup> The application of risk analysis in harmonised areas at EU level has reduced the need for national risk assessments. This had a greater positive impact in terms of cost savings in smaller MS that cannot afford to invest in the required scientific capacity. As stated in Section 4.2.2.1.2, the costs of national risk assessments can be very high, given also the data collection needs underpinning such assessments. For businesses, an EU harmonised system in the area of authorisations – with all its inherent difficulties – is better than having multiple national authorisation systems, considering the higher costs for the businesses as regards the preparation and submission of applications as well as the risk for potentially conflicting outcomes and resulting barriers to the intra Union-trade.
- b) **The benefits of pooling the scientific resources involved in EU and national assessment bodies:** Where national risk assessment bodies were established in parallel to EFSA, this has also generated efficiency gains from access to a larger, complementary pool of EU and national scientific expertise. EFSA was conceived as part of a network with national bodies and it would not be able to deliver the required expertise without this network. The creation of these national structures strengthened the scientific dialogue between EFSA and MS and amongst MS. The operational structure of EFSA including its Advisory Forum with the participation of national assessors has contributed to the convergence of scientific views across the EU, as evidenced by the very small number of scientific divergences between EFSA and national risk assessors: as stated in Section 4.2.2.1.1, out of 3,500 scientific opinions of EFSA, there were only four cases where divergences between EFSA and national assessment bodies persisted, two of which concerned the same substance (Bisphenol A). 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. These have negatively affected national resources and their ability to contribute to EFSA work.

Certain **negative impacts on innovation and trade and the resulting costs** have also been raised by FBOs as regards **authorisation procedures** in relation to the implementation of the risk analysis principle. Elements that slow down the innovation process and increase the latter costs include the cost of complying with data requirements for the submission of an authorisation dossier,<sup>438</sup> the length and uncertainty of authorisation procedures as well as the more stringent requirements applicable to feed additives as opposed to feed materials. These negative impacts are not directly

attributed to the risk analysis principle set out in the GFL Regulation, as they derive from the specific design of the authorisation procedures in other EU secondary food legislation. Despite these negative impacts, the existing system, including in terms of efficiency, is still preferable to having multiple national authorisation systems for the placing on the market of the same feed or food.

Despite the generally positive assessment of the above GFL provisions, in terms of efficiency, certain shortcomings have been identified in some areas which stem from: a) differences in implementation and enforcement between MS; and b) specific provisions in other EU secondary food legislation. A further investigation of those identified shortcomings, however, **has not revealed any link to systemic gaps or failures in the GFL Regulation principles and general requirements per se.**

The most burdensome **Information Obligations**<sup>439</sup> stemming from EU food law in general are those associated with: certification of products or processes (not linked to the GFL Regulation)<sup>440</sup>; cooperation with audits and inspections (including on withdrawals); information labelling for third parties; and, application for individual authorisation or exemption.

According to the SME survey, the share of **administrative costs** stemming from **EU food law in general varies considerably amongst businesses, from 0-5%** (for over a quarter of respondents) **to over 20%** (also for over a quarter of respondents) of total administrative costs. This variation is not necessarily related to business size although it **generally tends to decline as the business size increases** in terms of total operational costs and staff numbers. According to the General GFL study, annual administrative costs of EU food law (*i.e.* GFL and other secondary food legislation) including training<sup>441</sup> represent on average 8.5% for micro-enterprises, 7.8% for small enterprises, 6.7% for medium enterprises and 5.1% for large enterprises, as a share of total operational costs. Similarly, the total number of full time employees ('FTEs') involved represent on average 7.4 % for micro-enterprises, 6.9% for small-enterprises, while declining to 6.1% for medium and large-enterprises, as a share of total staff numbers.<sup>442</sup>

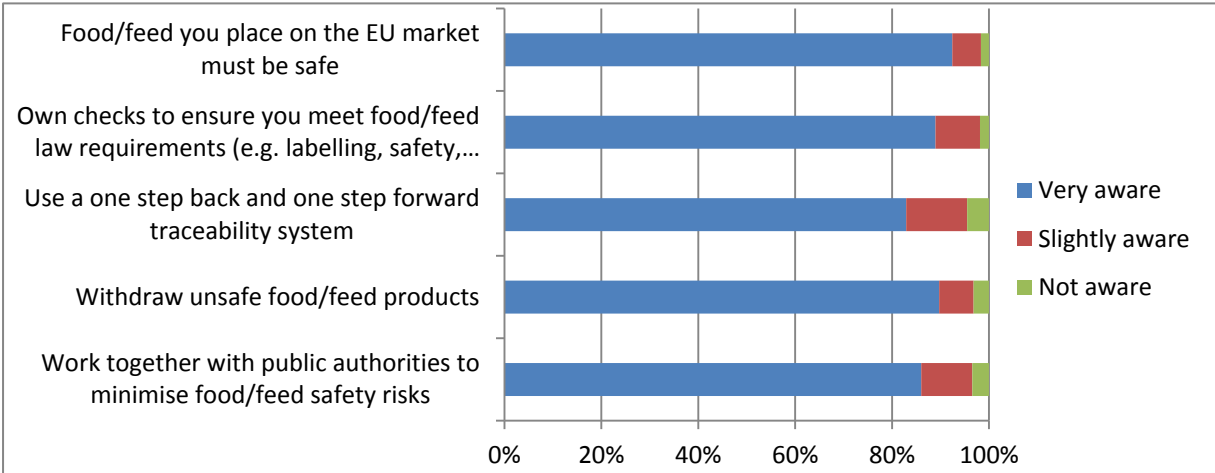
**Business size is not the only factor** that determines the relative impact of administrative burden on overall production costs and competitiveness. Other factors include, amongst others, the range of products, the product sectors and markets in which a business operates, the processes involved, the type of risk, the number of suppliers and the level of standardisation. All other factors being equal, however, the current regulatory environment creates, in general terms, a relative cost advantage for larger-scale FBOs, compared to smaller-scale FBOs to compete. This is especially because the former are more inclined to be active in cross-border trade reaping the benefits of the internal market.<sup>443</sup>

### 5.3.2 What are the specific challenges to SMEs with respect to the implementation of the legislative framework introduced by the GFL Regulation?

Overall, the SME panel and the consultation with SME representatives confirmed the General GFL findings of the stakeholders' survey and provided further insights into the challenges faced by SMEs, relating to costs and burden for SMEs, particularly for small and micro-enterprises.

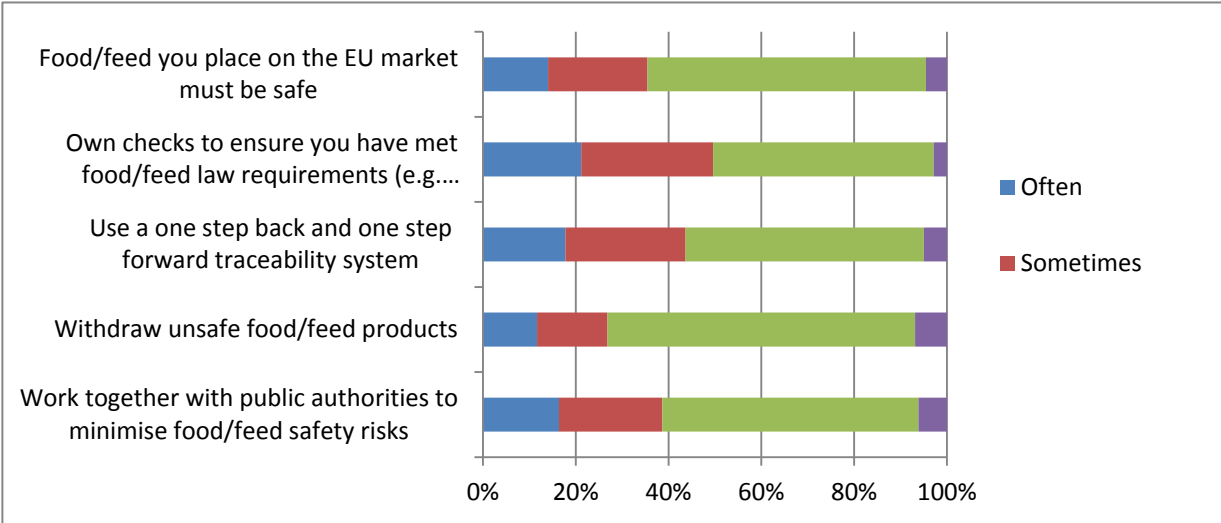
The vast majority of SME respondents to the SME Panel<sup>444</sup> are **well aware of the general requirements** that FBOs active in the food chain must meet (Figure 13).<sup>445</sup> The awareness of small and micro enterprises is nevertheless lower (10% less than the full sample of SMEs).

**Figure 13:** Awareness of SME respondents of the GFL Regulation, General GFL study



The majority of the SME respondents do not find it hard to meet most of the general requirements of the GFL Regulation, particularly the requirement to withdraw unsafe food and feed from the market. Nonetheless, a quarter to a third of respondents finds it difficult. Carrying out their own checks to ensure compliance with food law requirements relating, amongst others to, safety, product specifications and labelling is one requirement that SME respondents find most difficult to meet, as indicated by nearly half of the respondents (Figure 14).

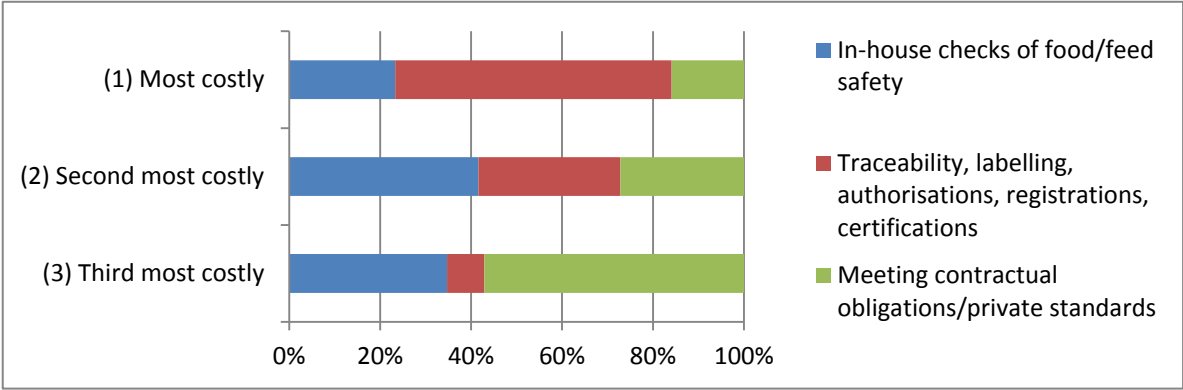
**Figure 14:** SME responses as to whether they ever find it hard to meet the following legal requirements, General GFL study



When comparing the costs and benefits of EU food law in general, **42% of the SME respondents** consider that **benefits outweigh or break even with costs**, while for 32% of respondents benefits do not outweigh costs.<sup>446</sup> This is also consistent with the overall findings mentioned in the previous section. Generally, according to SME sector representatives, **it is not the GFL Regulation requirements as such**, but rather detailed requirements in other EU secondary food legislation that contribute to the costs and burden for SMEs. For them, it is the **cumulative regulatory burden for SMEs of all EU legislation** that needs to be considered, as it has considerably increased over time, and not just the burden relating to EU food law.<sup>447</sup>

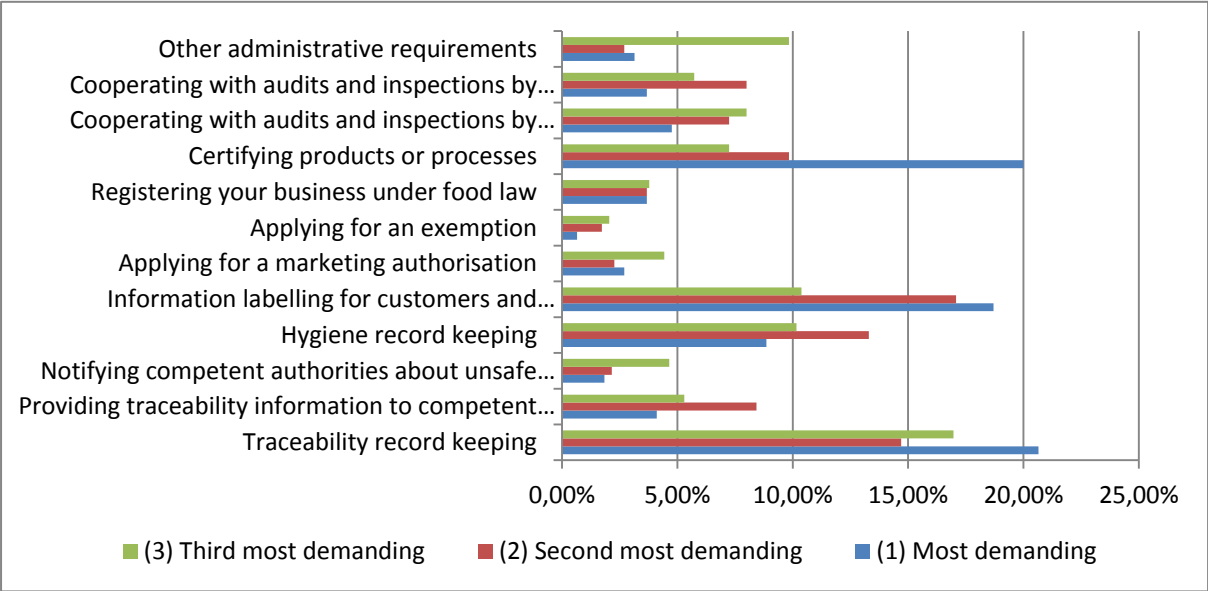
SME respondents to the SME Panel ranked the costs of complying with traceability, labelling, authorisation, registration and certification as the most costly of all food-related requirements, based on total costs in the period 2012-2014. This is followed by the costs of meeting the requirement for in-house checks of food/feed safety, with the costs of meeting contractual obligations and private standards coming in third place (Figure 15).

**Figure 15:** SME respondents' ranking, in order of size, the following costs of complying with food-related requirements based on total costs in the period 2012-2014, General GFL study



Consistent with the general findings mentioned under the previous Section, the **three most demanding administrative tasks** carried out under EU food law obligations for SMEs are: (1) traceability record keeping, (2) certifying products or processes, and (3) food information requirements (Figure 16).

**Figure 16:** SME respondents' ranking of the top 3 most demanding administrative tasks under EU food law, General GFL study



Not all these costs, however, can be attributed to the GFL Regulation as such. As stated in Section 4.2.4.1, prior to the GFL Regulation, operators were already applying 'one step back – one step forward' traceability for the most part on a voluntary basis; however, its application across the food supply chain tended to be fragmented. The GFL Regulation generalised the application of traceability to cover the entire food chain. Currently, traceability systems in place by FBOs may extend beyond the general traceability requirement for food safety purposes set out in the GFL Regulation, to



respond to additional requirements posed by other EU secondary food legislation (e.g. for origin purposes in the case of meat products) or to meet customers' private standards and relevant contractual obligations, or because of businesses own decisions to establish internal traceability). Nonetheless, SME respondents have 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. Certifying products or processes as well as food information requirements stem from other EU secondary food legislation.

With respect to food information requirements, micro and small-enterprises have noted the following: many respondents find it hard to obtain the required information from their suppliers with respect to mandatory origin labelling rules; respondents consider that the procedures relating to the surveillance of allergens entering the food production process are burdensome; bakeries and other artisanal producers often change ingredients which means that the labelling of their products has to be adapted, which they find it burdensome; complying with labelling requirements increases the cost of a product.

Two thirds of the SME respondents have never hired an **external consultant** to help them comply with EU food law; however, several micro and small FBOs reported that they have hired an external consultant for purposes relating to traceability, HACCP systems and labelling.

Other challenges faced by a large number of SME respondents, particularly micro- and small-enterprises, include the following:

- They find it hard to understand and interpret requirements set by EU food law (the GFL Regulation and other EU secondary food legislation);
- It is not clear which authorities they should approach in order to obtain information;
- Local or national authorities are often unwilling to cooperate with FBOs.<sup>448</sup>
- Interpretations of legal requirements in the MS are found to differ, creating additional costs and uncertainty for FBOs and a non-level playing field across the EU.
- In line with the overall findings of the Fitness Check, SME respondents have indicated that many customers require the adoption of additional food quality and safety standards that are not obligatory under EU law;<sup>449</sup> the proliferation of such private standards increases the production costs. They have also reported that customers also ask for certificates and additional proof that standards are implemented by the enterprise.<sup>450</sup> In many cases, customers at least demand to participate in regular audits or require the conduct of external audits.

In the area of EU food law in general (GFL and other EU secondary food legislation), there are **very limited exceptions or simplified rules** for micro-enterprises. Such exceptions **cannot easily be granted**, as there is a risk of jeopardising the core objective of high level of protection of human health and consumers' interests, especially with respect to food safety.<sup>451</sup> Indeed, the food chain is as strong as its weakest link. Nevertheless, an example of such exceptions or simplified rules is to be found in the area of food and feed hygiene. As analysed in Sections 4.2.3.1 and 4.2.3.3, the Food Hygiene Regulations provide certain **flexibility** by allowing for the application of good manufacturing practices rather than fully-fledged HACCP systems. This is **particularly for the benefit of micro- and small-enterprises**; however, this flexibility is not always relied upon by small FBOs, resulting, amongst others, in unnecessary documentation and therefore increased administrative burden. MS CAs face a similar challenge on how to best encourage the application of flexibility provisions to reduce burden on SMEs, while still ensuring that food safety is ensured. The underuse of flexibility in

the area of food hygiene is mainly due to a lack of understanding of the former concept by the FBOs and to inconsistencies in its implementation by MS. To address this shortcoming, the Commission has recently published a notice on the implementation of food safety management systems covering prerequisite programs and procedures based on the HACCP principles.<sup>452</sup>

### 5.3.3 What good practices in terms of cost-effective implementation of the legislative framework introduced by the GFL Regulation can be identified?

According to the available evidence, the following have further contributed to the cost-effective implementation of the GFL Regulation legislative framework:

- **EU guidelines** have been developed in close cooperation with MS CAs to facilitate a cost-effective implementation of the GFL Regulation<sup>453</sup> and other relevant EU secondary food legislation (such as the HACCP systems<sup>454</sup>). Almost half of the consulted stakeholders (49%) considered that EU guidelines have helped them to save money and work more efficiently in meeting their obligations under the GFL Regulation and other EU secondary food legislation, after private codes of good practice (53%), national guidelines (52%) and private guidelines (51%) as well as private standards (49%). FBOs have considered the EU guidelines on GFL to be the most helpful to improve effectiveness of the GFL Regulation framework, followed by national guidelines, private codes of good practice, private guidelines and private standards.<sup>455</sup>
- The **BTSF programme** has been acknowledged by MS CAs as greatly contributing to the understanding and enforcement of EU food law, ensuring a more coherent implementation of the GFL Regulation framework across the Union.
- The **fact-finding missions to MS** carried out by the Commission to identify, amongst others, areas of good practices have also strengthened enforcement of EU food law.
- *Ex post* evaluations by the Commission of food crises, such as the lessons learnt from the 2011 *E.coli* outbreak in Germany, can also facilitate a more cost-effective implementation of the GFL Regulation framework by identifying areas of improvement, *e.g.* in terms of crisis preparedness.
- To increase the **transparency** of the implementation of the risk analysis principle as well as strengthen **risk communication and the acceptability of the risk management decisions**, industry stakeholders have called for **clearer mandates** from the EU risk managers to EFSA. To this end, EFSA and the Commission have recently agreed to generalise across all sectors **an early dialogue** amongst them (risk assessor – risk manager), before the formal submission of mandates to the former. This early dialogue aims at clarifying the different aspects of the mandate for a risk assessment. As stated in Section 2.2, the three components of the risk analysis, *i.e.* risk assessment, risk management and risk communication, are separate but also interrelated. Therefore, it does not interfere with the risk assessment process as such.
- To address the costs for FBOs, and in particular SMEs, with respect to the identification and familiarisation with horizontal and vertical food labelling rules at both EU and national level, the Commission is currently setting up a **Food Labelling Information system**, as announced in the Commission Communication on 'Better Regulation for Better Results – An EU Agenda'.<sup>456</sup> The objective of this system is to provide a user friendly IT solution which will help the users to identify the food they wish as well as the MS in which they want to market that food and automatically retrieve all relevant mandatory EU and national labelling indications.
- Although not directly related to the implementation of the risk analysis principle *per se*, the Commission and EFSA are currently setting up electronic systems to manage the authorisation

process in the area of regulated products (e.g. food improvement agents and novel foods) to support innovation for FBOs and in particular SMEs during the authorisation process. The objective is to simplify the process and alleviate burdens for the applicants, but also to ensure a more efficient use of the Commission and MS resources, while enhancing the transparency of the authorisation procedures.

- EU-wide data collection work and analysis is increasingly undertaken by EFSA given its permanent expert structure that can support such an activity. Indeed, EFSA's data collection work has increased from the monitoring of zoonoses, TSEs and pesticide residues to the presence of contaminants and veterinary drug residues in food. The harmonised EU-wide data collection activity allow comparisons to be made over years or between food categories easier so that EFSA can more accurately calculate human exposure and better estimate the risk they present to human health.

#### 5.3.4 What, if any, specific provisions in the legislative framework introduced by Regulation (EC) No 178/2002 can be identified that make a cost-effective implementation more difficult and hamper the maximisation of the benefits?

Any potential for the reduction of the regulatory burden must be measured against the wider core objective of the GFL Regulation to ensure a high level of protection of human health and consumers' interests; therefore, the focus of this section is to unearth specific GFL provisions for which there is potential for reduction of regulatory burden without undermining the latter objective.

Through this prism and given the framework structure and the **goal-oriented** character of the GFL Regulation, the available evidence has not identified any such specific provisions, which would require legislative amendments to the GFL. More specifically, while there is consensus amongst all consulted parties that the GFL Regulation encourages proportionality in administrative burden, some FBOs have noted some potential for simplification and reduction of administrative costs and burden - mainly through soft interventions - in relation to the following:

- The obligation of verification of compliance with food law requirements in the context of the primary responsibility requirement: This includes notably the possibility 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. This is already the case as laid down in the Official Controls Regulation.<sup>457</sup> The Commission checks on a systematic basis the proper implementation of, amongst others, the Official Controls Regulation in the MS through the work of the audit and inspection service of DG SANTE. Where inconsistencies are found following inspections visits, the audit and inspection service of DG SANTE makes appropriate recommendations to the MS.
- The **2011 E.coli in sprouts outbreak** in Germany has high-lightened **the need to continuously re-evaluate** the management of food crises at EU and national level.
- Withdrawals of unsafe food and feed: As elaborated in Section 5.2.2, the variable level of implementation of withdrawals of unsafe food and feed may result to disproportionate quantities of food products being removed from the market, even in cases where internal traceability may be in place, increasing the costs and administrative burden for FBOs but also contributing to food waste. Although this differential implementation is not systematic but rather on a case-by-case basis, it demonstrates the need for updating the existing EU guidelines on the GFL Regulation,<sup>458</sup> so as to provide further and more detailed guidance to limit disproportionate withdrawals.

More potential – although limited – has been identified in relation to other sectorial EU food legislation, as follows.<sup>459</sup>

- Work towards further harmonisation process in the very few remaining partially harmonised areas of food law/completion of full implementation at EU level of limited sectorial EU food legislation (see also Section 5.2.2): This potential needs to be further explored in the ongoing and planned sectorial evaluations (third phase of the "cascade" approach to evaluate the overall body of EU food legislation), such as the evaluation on the food contact materials legislation (partially harmonised area) and the REFIT evaluation of Regulation (EC) No 1924/2006 with respect to the health claims made on botanicals, the implementation of which is not complete at EU level.
- Revisiting the modalities of the authorisation procedures with a view to improve their coherence and efficiency across EU sectorial food legislation while accelerating the market access process: The feasibility of such exercise would also to be further addressed and analysed in the ongoing and planned sectorial evaluations, such as the evaluation of the EU legislation on plant protection products and pesticide residues and the evaluation of the EU legislation on feed additives. It is noted that these two areas of food law are characterised by lengthy authorisation procedures.
- Consideration of exemptions/simplified rules for micro-enterprises in other EU secondary food legislation: Although such exceptions/simplified rules **cannot easily be granted** given the inherent risk of jeopardising the core objective of high level of protection of human health especially with respect to food safety – and consumers' interests, that underpins EU food law in general (see Section 5.3.2), every sectorial evaluation/revision of existing sectorial legislation or new sectorial legislation has and must always assess the potential for lighter regulation for SMEs.<sup>460</sup>
- Reviews of existing authorisations and impact on workload of EFSA: Even if not directly linked to the GFL Regulation, the peaks of applications for EFSA assessment stemming from reviews of existing authorisations have challenged EFSA's capacity, although there was a spreading over the years of the assessments to be delivered. It may therefore be appropriate that any future review programme takes into account the impact on EFSA and is accompanied by measures alleviating this impact.

## 5.4 Coherence

### 5.4.1 To what extent have the general principles and requirements set out in the GFL Regulation contributed to the coherence of food law?

On the basis of the evidence set out in Section 4, the GFL Regulation has ensured the coherence of food law through an overarching approach across the entire food chain, from 'farm to fork' both at EU and national level.<sup>461</sup>

The structure of GFL as a **common framework** for the development of EU and national food law and its systematic implementation has ensured the **intended integrated approach to food law and a greater harmonisation across the EU compared to the baseline**. This is confirmed by all consulted parties.<sup>462</sup> It is in stark contrast with the baseline, which was marked by complexity, duplication, overlaps and inconsistent approaches to feed and food, given the independent and fragmented development of individual pieces of EU secondary food legislation prior to 2002. In the past,

addressing problems in individual legislation had led to either repetition of the approaches used already in similar cases or to the application of different solutions to similar needs or to a multitude of instruments. This could be dependent on the type of food (food of animal origin v. food of plant origin) or whether it was food or feed.

By being the basis upon which all other EU secondary food legislation and national law concerning food and feed is systematically built upon, the GFL Regulation has reduced complexity, eliminated the risk of inconsistencies and reduced the possibility of duplication and overlaps. For example, the EU wide traceability has submitted to the same requirements both food and feed business operators for all products placed on the EU market, including imports. In the context of crisis management, the possibility of adopting one single set of emergency measures under the GFL Regulation in conjunction, where applicable, with other EU secondary food legislation has contributed to the internal coherence of EU food law. The adoption of a single procedure for the adoption of emergency measures for all types of food and feed, whatever their geographical origin has filled a major gap in addressing food crises compared to the baseline. Indeed, prior to the GFL Regulation, the Commission did not have a legal instrument for emergency measures on its own initiative either for feed or for a processed food of non-animal origin from one of the MS.<sup>463</sup>

The coherence of food law is particularly demonstrated by the systematic application of the risk analysis principle in all EU food secondary food legislation (and not limited to food safety), where relevant, including the EU level risk assessments provided by EFSA. The previously identified inconsistencies in the risk management of food of animal origin and of plant origin are eliminated. Moreover, EFSA's input is not only required for legislation governing feed and food *per se*, but a more holistic approach has been put in place covering all scientific issues pertinent for the food chain, such as plant protection products, food contact materials, animal by-products *etc.* EFSA's tasks also extend to cover human nutrition, animal health and welfare and plant health, even when not related to food safety, as well as products other than food and feed, promoting coherence of food law in general.

At the same time, as analysed in Sections 4.2.2.1.2 and 4.2.2.4, the GFL Regulation ensured a **convergence of the national scientific bodies responsible for risk assessment** at national level contributing to the coherence of the GFL Regulation objectives pursued at national level. The latter have largely worked in synergy and have been in some instances complementary to the work of EFSA. This has been evidenced by the very limited cases of scientific divergences, most of which have been addressed through the Advisory Forum of EFSA. In addition, the participation of national experts in EFSA's work ensures a cross-fertilisation and coherence of the EU and national risk assessors.

At the same time, because the GFL Regulation framework is also applicable for the development of **national laws**, where national competence persists, it has also ensured the alignment of national laws (and their development) under the umbrella of the GFL Regulation. The GFL Regulation common framework has simplified and streamlined the various concepts, provisions and procedures that existed in individual MS or in individual sectors of EU food law and ensured convergence.

The coherence of food law has also been ensured by the streamlining of comitology procedures through the replacement of all previous standing committees by a single Standing Committee on the Food Chain and Animal Health ('PAFF' Committee). The Committee is responsible for all matters pertaining to the food chain, and it is not limited to issues regulating feed and food *per se*. The use of a single committee across the food chain has been considered to have contributed to improving the

link between the objectives, issues and principles transcending policy implementation on food and feed safety, animal health and welfare and plant health measures, thereby also improving coherence between the various relevant policy areas.<sup>464</sup> Again this is in stark contrast with the baseline, where one of the problems identified was that multiple committees were dealing with sectorial issues without ensuring the passing of relevant information from one committee to the other. Similarly, the regular consultation of the Advisory Group on the food chain and animal and plant health since 2004, consisting of stakeholders in the area of food and feed, on all issues of food legislation has been beneficial in understanding the position of the different operators in the food chain in a more global context.

#### **5.4.2 To what extent has the legislative framework introduced by the GFL Regulation proved complementary to other Union interventions in the field of food policy?**

Food policy is closely connected with public health policies, especially in the area of food-borne diseases. In that respect and in terms of emergency preparedness, closer links are increasingly established between the GFL legislative framework and legislative initiatives taken in the area of public health. Directive 2003/99/EC establishes a EU system for the monitoring and collection of information of zoonoses.<sup>465</sup> MS are obliged to collect relevant and, where applicable, comparable data on zoonoses, zoonotic agents, antimicrobial resistance and food-borne outbreaks and to assess trends and sources of these agents, as well as outbreaks in their territory. While EFSA is assigned the tasks of examining these data and publishing the EU annual Summary Reports, the data collection on human diseases from the MS is conducted in accordance with Decision No 1082/2013/EU on serious cross-border threats to health.<sup>466</sup> The latter Decision provides the framework to improve preparedness and coordinate response to health emergencies across the EU caused by biological, chemical, environmental agents and threats of unknown origin. Building upon existing systems and structures, it lays down rules on epidemiological surveillance, monitoring, early warning of, and combating serious cross-border threats to health, including preparedness and response planning to coordinate and complement national policies, and establishes strategic networks and mechanisms. These include the Health Security Committee (HSC) for information exchange, consultation and coordination; the Network for epidemiological surveillance of communicable diseases; and the Early Warning and Response System (EWRS). The HSC coordinates national responses to serious cross-border health threats and risk and crisis communication aimed at providing consistent and coordinated information to the public and to health professionals. Through the EWRS, the Commission and the competent public health authorities in Member States (EU and European Economic Area) are in permanent communication for the purposes of alerting, assessing public health risks and determining the measures that may be required to protect public health. According to the Decision No 1082/2013/EU, risk assessments of the potential severity of the threat to public health, including possible public health measures, are carried out by the ECDC and/or EFSA and/or other EU agencies. While the impact of the latter Decision in relation to the GFL legislative framework in areas of common interest was not evaluated in the context of this exercise given that it only entered into application in 2013, it is expected to ensure greater coherence in terms of crisis preparedness.

Furthermore, EFSA and ECDC, with due regard to their respective mandates as set out in the GFL Regulation and Regulation (EC) No 851/2004<sup>467</sup> respectively, have enhanced over time their cooperation to ensure a high level of protection of public health in areas of common interest, *e.g.* in the area of food safety, control of communicable diseases, infectious diseases prevention and

emergency response. The two agencies have joined forces on issues, such as zoonoses, antimicrobial resistance, food-borne outbreaks, microbial risk assessment, surveillance/monitoring, epidemiological investigation, rapid alert, early warning, identification of emerging risks, emergency response and risk communication.<sup>468</sup> Their cooperation has been proven particularly instrumental in managing the *E.coli* in sprouts crisis in 2011.

The linkages between RASFF and EWRS as regards early warning have also been acknowledged. As stated in Section 4.2.9.1, the RASFF has been found to perform well together with EWRS. While the RASFF is generally not considered to duplicate EWRS, some potential duplication has been noted. This is partly unavoidable and may be necessary when a product concerns two or more networks covering distinct scopes. For instance, alerts on serious cross-border human health threats deriving from both food and feed must be posted on both RASFF and EWRS.<sup>469</sup> As the EWRS system is currently being updated, there is an ongoing reflection on how to improve the coordination of the two systems to avoid such duplications.

Another major Union intervention that has had an impact in the field of food policy is the establishment and development of the Common Agricultural Policy ('CAP') in the founding Treaties of the EU.<sup>470</sup> According to the General GFL study, the pursuit of a high level of protection of human health, including food safety, is fully complementary to the CAP objective of supporting agricultural production. Because of the high level of safety ensured by the legislative framework of GFL (as further developed by other EU secondary food legislation and national legislation in the area of food and feed), it ensures a safe and therefore viable supply of raw materials and food products of plant and animal origin. The GFL Regulation tools available to prevent and to manage food crises as well as to maintain consumer trust and trust in international trading partners<sup>471</sup> contribute to the stabilisation of markets, as pursued by CAP. The shift in the instruments of the CAP from support to production to direct support on condition of compliance with EU rules protecting food and feed safety, the environment and animal health and welfare (cross-compliance) has further strengthened the link and complementarity between CAP and GFL.<sup>472</sup> This is also recognised by the inclusion of food safety in the Commission Communication on "The CAP towards 2020".<sup>473</sup>

An example of synergies between the pursuit of high level of protection of health in nutrition terms pursued by the GFL Regulation and the implementation of CAP is the introduction of the School Fruit, Vegetables and Milk Scheme in the context of the Common Market Organisation of CAP, which aims to promote consumption of healthy agricultural products in specific sensitive environments such as schools. This scheme aims at making the healthy option available through the creation of a joint legal and financial framework for the distribution of fresh fruit, vegetables and milk, educational measures to improve awareness of farming while promoting healthy eating habits. Another example of synergies is the strengthening of the EU rules to tackle fraudulent practices: as analysed in Section 4.2.7.3, the new Regulation on Official Controls and other Official Activities will also apply to checks carried out according to rules governing checks on marketing standards of agricultural products, to identify possible fraudulent or deceptive practices.<sup>474</sup>

The complementarity of the GFL Regulation legislative framework with other Union interventions is also evidenced by interventions that followed its introduction. Most recently, the adoption of the Animal Health Law Regulation<sup>475</sup> has implicitly acknowledged the contribution of the GFL Regulation structure to addressing similar drivers in the food chain to those identified in the area of animal health.<sup>476</sup> Accordingly, a similar structure to that of the GFL Regulation is also followed under the

Animal Health Law, namely a 'general framework law" merging animal health, animal welfare and food safety into a single framework and setting out general principles similar to those set out in the GFL Regulation. At the same time, it addresses the coherence between animal and public health legislation with respect to primary production needs (coherence of animal health certification and provision of food chain information) and establishes a relation between animal health law and food safety.<sup>477</sup> An indicative example is the incorporation of the science-based principle as laid down in the GFL Regulation.<sup>478</sup> Similarly, the PAFF committee will also be addressing all issues covered by the Animal Health Law and other EU legislation that will be adopted on the basis of the latter. This is expected to bolster the coherence of all EU legislation adopted in the context of the GFL Regulation framework and the Animal Health Law.

#### **5.4.3 What, if any, specific inconsistencies and unjustified overlaps, obsolete provisions and/or gaps can be identified with other pieces of Union legislation? How do they affect the application/performance of the GFL Regulation?**

The General GFL study has not identified any systematic inconsistencies, although divergences as regards the implementation of certain GFL provisions have been remarked. This aspect has already been discussed under Section 6.2.2.

#### **5.5 What has been the EU added value of the legislative framework introduced by the GFL Regulation and what would be the likely situation, in case of not having in place such a legislative framework at Union level?**

The EU added value is examined with respect to the establishment of the GFL Regulation at EU level compared to what could be achieved in the absence of a common framework by MS at national level and/or regional levels or at international level (*e.g.* Codex Alimentarius and OIE).

The objective of a high level of protection of public health and consumers' interests across the EU can be better achieved through EU action.<sup>479</sup> In particular:

Food safety is a dynamic process with many and diverse players intervening in the food chain, which is becoming increasingly longer. While no system can guarantee that all food is always safe everywhere in the EU, a harmonised EU framework covering the entire food chain, as set out in the GFL Regulation, can provide more guarantees to that effect. For example, by addressing feed at EU level in the context of the food chain strengthens food safety at an early stage and averts food crises like the ones that the EU experienced prior to the GFL Regulation. This is because feed crises, when food-producing animals are involved, have the potential to affect negatively the entire food chain. Moreover, the integrated approach of the GFL Regulation can ensure that food safety is considered at all stages of production, processing and distribution of food across the EU, while this cannot be achieved as effectively by national measures alone.

As analysed in further detail under Section 5.2.1, the current situation in terms of food safety is also more favourable than before the adoption of the GFL Regulation. This is evidenced for example by the eradication of the classical BSE, the extraordinary decrease in the number of BSE cases in cattle and the decreasing trend in cases of human salmonellosis.

Risks to human health stemming from food and feed are the same across the EU. The systematic implementation of the risk analysis at EU level has the effect that EU measures are not aligned to the lowest national standard, but rather the contrary. An achievement of this approach is the removal of



many active substances in plant protection products from the EU market. National measures, on the other hand, can provide an incentive for businesses to divert their activity in MS with the lowest level of protection of public health. In addition, setting an acceptable level of risk at EU level through a centralised science-based approach (EFSA) results in a higher level of scientific expertise, while preventing the duplication of efforts in MS in terms of risk assessments and risk management decisions. As already indicated in Sections 4.2.2.4, 5.2.1 and 5.3.1, the centralised science-based approach has overall improved the scientific basis of measures taken in the area of food law. Moreover, it has resulted in cost savings for MS, especially for the smaller MS that cannot afford to invest in the required scientific capacity. Therefore, **food and feed safety measures have the greatest effect when taken at EU level.**

Similarly, there is also EU added value arising from the GFL Regulation framework vis-à-vis the protection of consumers' interests. The GFL Regulation recognises the right of consumers not to be misled and to have access to accurate information. This is a general principle to underpin any future EU food law. As such, action at EU level in the context of the GFL Regulation framework does not seek to align to the lowest national denominator, but rather to achieve a high and more uniform level of consumer protection across all EU MS. A positive example of this approach is the Food Information to Consumers Regulation. National measures cannot have the same effect. This is demonstrated by the variation in the imposition of penalties and other measures for violations of food law, a matter of national competence that leads to different levels of consumer protection *e.g.* as regards fraudulent practices.

The GFL Regulation by providing a single, uniform framework with common definitions and general principles underpinning both EU and national food law has also improved both the internal coherence (development of other EU legislation) and external coherence (development of national laws) in the entire food chain, *i.e.* from 'farm' to 'fork'. It therefore created a common culture for action in the food chain area. From the perspective of MS CAs, the GFL Regulation 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 administrative and control bodies covering food safety issues in most MS. A harmonised approach at EU level has therefore facilitated enforcement of food law.

The GFL Regulation framework has been proven necessary to achieve the objective of the effective functioning of the internal market. This broad harmonisation across the food chain has enhanced EU internal trade in the food and drink sector (72% increase over the past decade). This is to be contrasted with national measures in the area of food and feed. Even if similar in concept and principle, they are still likely to have differences in approach and level of detail. These differences can cause disruptions to the internal market and create an uneven playing field for businesses. Those differences could also have an impact on the overall competitiveness of the food and drink sector, as they would imply different compliance costs on FBOs depending on the national measures in place. By means of an example, for FBOs, an EU harmonised system in the area of authorisations – with all its inherent difficulties – is better than having multiple national authorisation systems, considering the higher costs for the businesses as regards the preparation and submission of applications as well as the risk for potentially conflicting outcomes and resulting barriers to intra Union-trade. This effect is still visible in partially harmonised areas of other EU secondary food legislation where risk assessments and risk management decisions vary amongst MS (see also Section 5.2.2).

The EU added value of a high level of protection of public health and consumers' interests, which is achieved through the GFL Regulation, also has a direct positive impact on securing the trust of EU consumers and of trading partners in the EU food supply. As analysed in Sections 4.1 and 4.2.8, the GFL Regulation has contributed to the increased competitiveness of the EU food and drink sector both within the EU and in the international context. It has brought important advantages in terms of international trade, in that it allowed both EU and non EU food 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 non EU country markets, supporting the EU competitiveness and contributing to a global governance.

**Food crises are also better prevented and managed when harmonised requirements and tools** are in place across the EU; food crises have 'no frontiers', as experience demonstrated in the late 1990s have demonstrated. Given the increasing complexity and length of the food chain and the increasingly globalised context in which it operates, the prevention and management of crises presupposes EU-wide action. In that respect, the EU-wide primary responsibility of FBOs and EU-wide traceability of feed and food set out in the GFL Regulation, combined with the EU-wide operation of RASFF, the coordination through RASFF and PAFF Committee of emerging crises, the adoption of emergency measures at the appropriate level when necessary, and the possibility to enact a crisis management plan at EU level have played a key role in preventing and managing food crises. These impacts are both quantitative and qualitative. The added value of the synergies of these EU requirements and tools as opposed to what could be achieved at national level are even more apparent when considering the extent of the cross-border trade in the internal market. For example, in the absence of EU-wide traceability, it would have been more difficult to identify the source of a given crisis as well as the products at risk so as to take appropriate action.

Finally, given the advanced stage of integration of the food chain across the EU, it is difficult to make assumptions about a situation where the GFL Regulation would no longer be in place, be it as a consequence of deregulation or of re-nationalisation of food and feed safety rules. Deregulation could potentially leave it to the economic sectors concerned to agree on standards with an equivalent effect; it is uncertain how the perspective of consumers would be reflected in such standards and whether voluntary action by the sectors concerned could replace public action in all cases, especially when it comes to the handling of risks and of emergencies. Re-nationalisation would likely undermine the existing level playing field as a basis for the single market, as different national measures would no longer be based on common definitions, general principles and requirements, giving rise to new obstacles to the free movement of goods.

## 6 Conclusions

The Fitness Check on the GFL Regulation constitutes the second phase of EU food chain law evaluations. The evidence that has been gathered suggests that the regulatory framework set up by the GFL Regulation is **broadly fit for purpose** and has made a positive contribution to the EU legislative *acquis* in the area of food law. Given the baseline situation at the time of the introduction of the GFL Regulation in the food crises in late 1990s, which had shaken consumer trust in the EU food chain, there is **consensus that, as a framework, the GFL Regulation has established a new era in EU food law design and implementation**. Overall, the GFL Regulation is widely acknowledged by all consulted parties to be still relevant, effective, efficient, coherent and with EU added value.

In overall terms, the evaluation indicates that the GFL legislative framework **remains relevant** given that its original core objectives, *i.e.* a high level of protection of human health and consumers' interests in relation to food and the effective functioning of the internal market are still relevant today. The GFL framework has also been found adequate to address most of the current trends: growth and competitiveness and increased globalisation. In addition, the issue of 'dual quality' of foodstuffs, *i.e.* foods marketed in different EU MS under the same brand and packaging, but with differences in composition, has recently spurred interventions by a few MS and by some Members of the European Parliament. Some MS have conducted studies and laboratory testing on the issue, comparing the composition of a limited number of branded products on different EU markets. Although there is agreement that this issue does not relate to food safety and that the GFL Regulation is currently adequate in terms of food safety requirements, the issue still remains that consumers' perceptions in certain MS are that they are being treated unfairly and do not receive the same quality of food from certain brands. The GFL legislative framework is, however, less adequate to address food sustainability in general and food waste in particular. To clarify the relevance of the GFL Regulation in the context of food sustainability and to assist in lifting barriers to food redistribution, the Commission has recently adopted EU guidelines on food donation, in close cooperation with the EU Platform on Food Losses and Food Waste.

The synergies between the GFL Regulation tools and procedures and the implementation of the GFL Regulation principles in other EU secondary food legislation have ensured a high level of protection of human health in terms of food safety in the Union. The current situation in terms of food safety is also more favourable than before the adoption of the GFL Regulation, as evidenced for example by the eradication of the classical BSE, the extraordinary decrease in the number of BSE cases in cattle and the decreasing trend in cases of human salmonellosis. The creation of EFSA and its increased scientific capacity has also improved the scientific basis and transparency of EU measures. It has also filled in two main gaps of the EU food safety system prior to the GFL: the absence of a data collection system at EU level linked to food safety in order to support a high quality risk assessment and the lack of tools for the identification of emerging risks.

Nevertheless, human nutrition related issues have not achieved the same level of implementation as food safety with respect to other EU secondary food legislation, although improvements have been made, compared with the situation prior to the GFL Regulation. The GFL Regulation as well as other EU secondary food legislation have contributed to an increased level of protection of consumers' interests compared to the situation prior to the GFL Regulation, although to a lesser degree than food safety.

The GFL Regulation as a framework legislation providing one common and consistent basis both at EU and national level for the entire food chain combined with a great degree of harmonisation in other EU secondary food legislation has contributed to the effective functioning of the internal market by creating a level playing field for all feed and food business operators ('FBOs') in the EU market while reducing disruptions of trade where problems have occurred.

The GFL Regulation's commitment to international standards and the rigorous application of the risk analysis principle have resulted in a vital cross-fertilisation between the development of EU food law and international standards. The GFL Regulation has also served in some cases as a source of inspiration for non-EU countries developing their national legislation. The GFL Regulation requirements including the science-based approach to food legislation, underpinned by the

establishment and operation of EFSA, have contributed to the EU product safety recognition worldwide and to an improved quality perception for EU products in non-EU markets. This allowed the EU to achieve a more globally competitive position since 2003 vis-à-vis its main trading partners.

EFSA is found to be generally independent and to have one of the most advanced and robust systems in place for ensuring its independence from political influences. In contrast with other EU agencies (*e.g.* EMA, ECHA), MS do not appoint members of its Scientific Panels. The **separation** of the risk assessment and risk management at EU level, set out in the GFL Regulation, has been improved over time. The governance and structure of EFSA as laid down in the GFL guarantees a clear separation between EFSA's scientific work and political management. Nevertheless, it is not in line with the Common Approach endorsed by the European Parliament, the Council and the European Commission on decentralised agencies in 2012. The Common Position foresees that all MS are represented in the Management Board of decentralised agencies amongst others, in order to improve the performance of agencies' boards and reinforce their capacity to supervise the administrative, operational and budgetary management of those agencies, while guaranteeing full participation of the MS.

Nevertheless, certain shortcomings have been identified:

- National differences in the implementation of the GFL Regulation at MS level have been observed creating in some instances uneven playing field of businesses confronted with similar situations in the following contexts:
  - variable level of implementation of withdrawals amongst the MS with respect to the determination of a food or feed as safe;
  - in the few partly harmonised areas of food law, *e.g.* with respect to food contact materials other than plastics and the setting of maximum levels of substances in food supplements and in foods with added vitamins and minerals;
  - occasional differential interpretation of the common definitions set out in the GFL by MS CAs;
  - national differences in relation to information to the public on food safety incidents;
  - variable **national approaches** to the implementation of **official controls** by MS CAs, which, however, also depend also on differences in the **reliability of FBO's own controls**; and,
  - variable measures and penalties currently in place to address violations of food law in terms of form, specificity and severity, a matter mostly regulated at national level.

Although these national differences are not systematic but rather on a case-by-case basis, the Commission endeavours to alleviate these national differences through discussions within the Working Groups composed of MS' representatives, through the work of the audit and inspection service of DG SANTE and last but not least, through the issuing/updating of general guidelines.

- Although **transparency of the risk analysis process** has been improved compared to the baseline, it remains a sensitive issue in terms of perception. In that respect, certain concerns still remain with respect to risk assessment and risk communication.
  - As regards risk assessment in the context of authorisation dossiers, EFSA is bound by **strict confidentiality rules** that are laid down in the GFL Regulation and in the multiple authorisation procedures in EU secondary food legislation. This **creates a perception of a**

**certain lack of transparency**, which is further reinforced by the civil society's concerns over EFSA's independence from industrial interests, as EFSA bases its risk assessment on studies conducted by the industry. These criticisms **can have a negative impact on the acceptability of EFSA's scientific work by the general public**. There is therefore a need to address perceived issues with respect to the transparency as well as the quality and independence of studies underpinning EFSA's assessments, while protecting legitimate confidential business information, in order to safeguard the reputation of EFSA's work. This can be achieved, for example, through measures to increase transparency of the supporting studies, an involvement of public authorities in the process of deciding which studies need to be conducted for an application dossier, enhanced auditing of studies conducted in accordance with the principles of GLP, and the possibility to exceptionally commission ad-hoc studies in case of serious doubts or conflicting results, for example, in case of widely used substances.

- Furthermore, **risk communication** is, overall, considered **not to be effective enough**, especially given the growing challenges that it has to face in current times, such as the increasing complexity of scientific findings, including the time it can take to reach conclusions, and the difficulty to translate in simple words, the perception of risk often being emotional, cultural and disconnected from rational thinking, as well as the pluralism of news sources in combination with the increasing use of social media and the social amplification of risk. This has a negative impact on **consumer trust and on the acceptability of risk management decisions**.
- A number of negative signals have been identified on the capacity of EFSA to maintain a high level of scientific expertise, as follows:
  - Recent calls on the membership of some panels have shown the difficulties encountered to attract new members due to a number of disincentives: insufficient recognition for the scientists' career, modest financial compensation for the experts and their employers considering the amount of time required for their EFSA's contribution, strict rules on independence which do not take into account the increasing trend of public-private partnership in scientific research.
  - The distribution of experts per MS in Scientific Committee/Panels show that more than two thirds of the experts (69%) originate from 6 MS, while 86% originate only from 10 MS.
  - The current trend of diminishing public administration budget might also have a negative impact on the capacity of national bodies to send experts to EFSA or to contribute to its work.
  - The finances dedicated to the outsourcing of EFSA's tasks to national risk assessors are considered by the MS as relatively low (€10 million per year, 13% of EFSA's total budget).These negative signals show the limitations of the current system to ensure in the long-term sufficient expertise and to fully engage all MS in scientific cooperation.
- Lengthy authorisation procedures in some sectors (*e.g.* feed additives, plant protection products, food improvement agents, novel foods, health claims), including long 'stop-the-clock' procedures during the risk assessment phase and long deliberations before the Standing Committee on Plants, Animals, Food and Feed ('PAFF') slow down the market access process. This affects the innovation potential and the competitiveness of the EU food and drink industry as well as its capacity to also address future challenges, such as the sustainability of food. To remedy delays in

the risk assessment phase, EFSA has initiated since 2012 a series of actions, *e.g.* introduction of a single entry point for applicants (application desk unit), dialogue with industry in particular through info sessions and work shop helping applicants for the submission of their dossiers and better involvement of stakeholders in the guidance on authorisations. In addition, a new Regulation on novel foods with simplified centralised authorisation procedure at EU level has also been recently adopted, which sets out specific deadlines for risk assessment and for the Commission to propose a draft risk management measure to the PAFF committee. Furthermore, the Commission and EFSA are currently setting up electronic systems to manage the authorisation process in the area of regulated products (*e.g.* food improvement agents and novel foods) to support innovation by FBOs, and in particular SMEs.

In addition, in the light of the experience gained over the years and especially in the aftermath of the *E.coli* in sprouts crisis in 2011, there is a need to continuously re-evaluate the management of food crises at EU and national level. To this end, the Commission intends to revisit the 2004 general plan on crisis management to ensure a stronger focus on prevention and preparedness.

The present Fitness Check faced certain limitations in terms of implementation and enforcement data at MS level. Given the structure of the GFL Regulation as a framework legislation with general objectives, the absence in its original design – as in many other EU secondary food legislation – of appropriate monitoring arrangements, and thus the limited availability of centrally compiled data on the general implementation and enforcement at EU level or at MS level, it has proven difficult to identify quantitative indicators to measure the overall impacts (costs and benefits) of the general principles and requirements laid down in the GFL Regulation. Although MSs transmit data on the implementation of official controls on an annual basis to the Commission under the existing Official Controls Regulation, such data are not currently comparable and cannot be relied upon for drawing conclusions on the implementation and enforcement of EU food law. As stated in Section 4.2.3.2, the recently adopted Regulation (EU) 2017/625 on Official Controls and other Official Activities<sup>480</sup> is expected to facilitate the collection and transmission of comparable data, its subsequent compilation into EU-wide statistics and the preparation of reports by the Commission on the operation of official controls across the EU; such reports can provide in the future considerable evidence for undertaking in-depth evaluations of EU secondary food legislation.

The present Fitness Check has not identified any specific margin for simplification and burden reduction with respect to the general framework established by the GFL Regulation itself, as far as legislative action is concerned. Indeed, in terms of administrative burden, the evaluation has assessed the core obligations imposed on FBOs. Overall, the GFL Regulation regulatory requirements are considered manageable and many FBOs, including SMEs, go beyond the minimum thresholds of the GFL Regulation due to contractual obligations and adherence to private standards, which have gained importance during the last decade. Private standards, in particular, serve as the basis for integrating regulatory requirements. But at the same time, they add to the burden of FBOs, as they often lay down additional non-regulatory requirements. For example, large retailers, cautious to avoid any potential risks and driven to accommodate what consumers are interested in, often require from their suppliers voluntary 'marketing' requirements (*e.g.* origin indications), which also need to be part of the verification systems in place. Smaller FBOs, which tend to be mostly in direct and long-standing contracts with retailers, may therefore commit to non-regulatory requirements to ensure customer loyalty through contractual obligations or adherence to private standards. The Commission is currently considering whether EU-level action is needed to address anti-competitive

practices with respect to foods of agricultural origin, caused by the weaker position of farmers and SMEs in the food supply chain vis-à-vis other levels of the chain.<sup>481</sup> Some limited potential for simplification and reduction of administrative burden in relation to the GFL Regulation – mainly by updating the existing EU guidelines on the GFL Regulation – has been identified with respect to the implementation of the food and feed safety criteria, so as to limit disproportionate withdrawals of unsafe food and feed.

Any administrative burden identified in this Fitness Check is rather linked to other EU secondary food legislation (*e.g.* certification of products or processes and food information requirements). As regards the latter, to alleviate the burden on FBOs (and in particular SMEs) relating to the identification and familiarisation of food labelling requirements, the Commission is currently setting up a Food Labelling Information system, which will provide a comprehensive and reliable overview of all applicable EU and MS requirements for food labelling per food product.

The Fitness Check has also further identified some potential for simplification and burden reduction in sectorial EU food legislation: work towards further harmonisation process in the very few remaining partially harmonised areas, revisiting the modalities of the authorisation procedures to improve coherence and efficiency while accelerating the market access process, consideration of exemptions/simplified rules for micro-enterprises where these do not jeopardise the high level of protection of public health, especially with respect to food safety and the impact of reviews of existing authorisations on the workload of EFSA.

The above-mentioned potential for simplification and burden reduction existing at sectorial level will be further explored in detail during the third phase of EU food chain law evaluations, which has already been launched. This third phase consists of more sectorial evaluations in this area currently being carried out or planned in the near future, which will take into account the findings of this Fitness Check and are as follows:

- a) Regulation (EC) No 1924/2006 on nutrition and health claims made on food with regard to nutrient profiles and health claims made on plants and their preparations and the general regulatory framework for their use in foods;
- b) EU legislation on plant protection products and pesticide residues;
- c) Food contact materials legislation;
- d) EU legislation on food irradiation; and,
- e) Regulation (EC) No 1831/2003 on additives for use in animal nutrition.

These sectorial evaluations will also permit a more in-depth assessment of the way the principles and requirements of the GFL Regulation are translated into sectorial rules (*e.g.* modalities of the authorisation procedures implementing the risk analysis principle). More specifically, the ongoing evaluation on food contact materials will address, amongst others, the lack of full harmonisation in this area and the impact on public health and consumers' interests. Similarly, the ongoing REFIT evaluation of Regulation (EC) No 1924/2006 will address the lack of complete implementation as far as the establishment of nutrient profiles and the health claims on botanicals are concerned. The findings of this evaluation will feed into an overall future evaluation report, as required by Article 27 of the same Regulation, which will also scrutinise the implementation of the risk analysis principle including the overall authorisation process in this area. The implementation of the risk analysis principle, including the risk communication aspect, as well as the modalities of the authorisation

procedures, where relevant, will also be analysed in the context of the ongoing REFIT Evaluation of the EU legislation on plant protection products and pesticides and the future evaluations of Regulation (EC) No 1831/2003 on additives for use in animal nutrition and Food Irradiation.

In parallel, a more detailed analysis of EFSA's operation and governance structure will be undertaken in the context of the mandatory external evaluation launched in 2017. This evaluation will address, amongst others, the trends for the future of EFSA in particular the reduced attractiveness of EFSA for national experts, the relevance of the EFSA governance model, EFSA's effectiveness and efficiency in particular for the delivery of scientific opinions as well as its capacity to minimise administrative burdens, the cooperation with MS and the link between citizens' trust and the scientific excellence, independence and transparency of EFSA.

Finally, this Fitness Check has also highlighted the need to establish a more comprehensive monitoring system of the implementation of EU food law, so as to provide policy makers and the public with more solid data and evidence base to regularly assess the relevant impacts. The GFL Regulation, and most of other EU secondary food legislation, were adopted at a time when *ex ante* impact assessment was not required. No baseline or impact indicators exist, despite the fact that several data sets are made available through specific reporting and monitoring requirements laid down in some sectorial frameworks (*e.g.* pesticides, zoonoses, import checks, *etc.*). This lack should be addressed in future policy development, for instance by making better coordinated use of existing reporting requirements. Evaluations of related secondary legislation will also pay more attention to the revision of existing monitoring arrangements and possible improvements in order to establish a more systematic way to collect data and use it for future evaluations – with special attention to quantifications of costs and benefits. Future EU food policy initiatives and evaluations are also likely to benefit from the future implementation of the recently adopted Regulation on Official Controls, which is expected to facilitate the collection and transmission of comparable data, its subsequent compilation into EU-wide statistics and the preparation of reports by the Commission on the operation of official controls across the EU.

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<sup>1</sup> Commission Staff Working Document, 'A fitness check of the Food Chain – State of play and next steps', SWD(2013)516, dated 5.12.2013.

<sup>2</sup> Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (General Food Law), (OJ L 31, 1.2.2002, p. 1).

<sup>3</sup> Annex to Commission Communication 'Regulatory Fitness and Performance (REFIT): Results and next steps' COM(2013)685.

<sup>4</sup> *I.e.* REFIT Evaluation of (a) Regulation (EC) No 1924/2006 on nutrition and health claims made on food with regard to nutrient profiles and health claims made on plants and their preparations and of (b) the general regulatory framework for their use in foods; REFIT Evaluation of the EU legislation on plant protection products and pesticide residues (Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005); Evaluation of the food contact materials legislation (Regulation 1935/2004); Evaluation of the legislation on Food Irradiation; and, Evaluation of Regulation (EC) No 1831/2003 on additives for use in animal nutrition.

<sup>5</sup> For the purpose of this document, the definition of 'food law' comprises all laws, regulations and administrative provisions governing food in general, and food safety in particular, whether at Union or national level; it covers any stage of production, processing and distribution of food, and also of feed produced for, or fed to food-producing animals.



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<sup>6</sup> According to the GFL Regulation, pre-existing food law principles and procedures both at Union and national level were required to be adapted to the general principles of the GFL Regulation.

<sup>7</sup> Article 62 of the GFL Regulation.

<sup>8</sup> For example, Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs (OJ L 109, 6.5.2000, p. 29), which predated the GFL Regulation, was revised by means of Directive 2003/89/EC (OJ L 308, 25.11.2003, p. 15) to incorporate the risk analysis principle in establishing a list of food ingredients causing allergies.

<sup>9</sup> White Paper on Food Safety, COM(99)719, dated 12.01.2000, at p. 6.

<sup>10</sup> The Codex Alimentarius of the Food and Agriculture Organisation (FAO) of the United Nations (UN), established in 1963, is a set of guidelines, codes of practice, voluntary reference standards and advisory documents that are aimed at protecting the health of the consumers and ensuring fair practices in the food trade. Currently the Codex Alimentarius Commission has 186 nation-members (including the EU as a member organisation) which cover 99% of the world's population, as well as 224 observers (intergovernmental organisations-IGOs, NGOs and UN organisations). See Mylona K., Livanou A., Maragkoudakis P., Bock A.-K., Wollgast J., Caldeira S. and Ulberth F.; Overview of the food chain system and the European regulatory framework in the fields of food safety and nutrition, JRC Technical Reports, EUR 28033 EN. Publications Office of the European Union, Luxembourg, 2016, ISBN 978-92-79-60536-9, doi:10.2787/410688, at p. 114.

<sup>11</sup> The World Organisation for Animal Health (OIE), created in 1924, is an intergovernmental organisation aiming to improve animal health and welfare. It numbers 180 members and it develops normative documents relating to diseases and pathogens. *Id.*

<sup>12</sup> Alberto Alemanno, "Trade in Food – Regulatory and Judicial Approaches in the EC and the WTO", 2007, at pp. 73-76.

<sup>13</sup> Green Paper on the General Principles of Food Law in the European Union, COM(97)176 final, at p. 40; White Paper on Food Safety, at p. 27.

<sup>14</sup> For example, it was not clear whether the Commission was competent to act with respect to composite products (food of both animal and non-animal origin).

<sup>15</sup> *I.e.* the Standing Committee on Foodstuffs, the Standing Committee for Feedingstuffs, the Standing Veterinary Committee and the Standing Committee on Plant Health were all involved in matters relating to plant protection products and the setting of maximum residue levels.

<sup>16</sup> White Paper on Food Safety, at p. 28.

<sup>17</sup> This Committee was established by Commission Decision 80/1073/EEC (OJ L 318, 26.11.1980, p. 28).

<sup>18</sup> This Committee was established by Commission Decision 98/235/EEC (OJ L 88, 24.3.1998, p. 59).

<sup>19</sup> General GFL study, at p. 117.

<sup>20</sup> *Id.*, at p. 120.

<sup>21</sup> In 1996, the UK government announced that, according to new scientific evidence, BSE was not only an animal disease but it could also be transmitted to humans.

<sup>22</sup> Court of Auditors, Special Report No 14/2001, Follow-up to Special Report No 19/98 on BSE, together with the Commission's replies, OJ C 324, 20.11.2001, at p. 1 (paragraphs 1, 14 and 15).

<sup>23</sup> Study commissioned from DTZ/PIEDA consultants by the UK Agriculture Department and Treasury, titled "Economic impact of BSE on the UK economy", 1998.

<sup>24</sup> The net job losses in the UK as a result of BSE crisis in the first 12 months were estimated to 1,000. Study commissioned from DTZ/PIEDA consultants by the UK Agriculture Department and Treasury, titled "Economic impact of BSE on the UK economy", 1998.

<sup>25</sup> Report of the Temporary Committee of Enquiry of the European Parliament on alleged contravention or maladministration in the implementation of Community law in relation to BSE, without prejudice to the jurisdiction of the Community and national courts, Rapporteur Mr. Manuel Medina Ortega, European Parliament, 7 February 1997, A4-0020/97/Part A ('Medina report).

<sup>26</sup> *Id.* See also D. Chalmers, "'Food for thought': Reconciling European risks and traditional ways of life", 66 *The Modern Law Review* (2003), at p. 534.

<sup>27</sup> See ft. 11.

<sup>28</sup> COM(97)183 final, dated 30.04.1997.

<sup>29</sup> The five scientific committees that were covering the agri-food area were the following: Food, Animal nutrition, Veterinary-Public Health, Plants and Animal Health and Animal Welfare. The remaining non-food

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related scientific committees concerned Cosmetic products & non-food products, Medicinal products and medical devices, Toxicity, Eco-toxicity and Environment.

<sup>30</sup> The experts were selected on the basis of open calls on the basis of excellence and independence. A declaration of interests was mandatory on an annual basis.

<sup>31</sup> Many of those opinions, including but not limited to food and feed areas, concerned evaluations of a large number of individual substances. White Paper on Food Safety, at p. 12.

<sup>32</sup> *Id.*, at pp. 12-13.

<sup>33</sup> Dioxin was introduced into the Belgian food supply, including exports, through contaminated fat used in animal feed supplied to Belgian, French and Dutch farms; meat products from poultry, pigs and cattle as well as eggs were detected with high levels of dioxin. The uncertainty about the real extent of the contamination resulted in an embargo on all Belgian food products of animal origin. The absence of traceability led to huge withdrawals from the market. Slaughter and transport of poultry, pigs and cattle were prohibited and many (EU and non-EU) countries temporarily banned imports from Belgium. For a short period, USA also banned all European poultry and pork imports from the EU. This had a considerable negative impact on the Belgian meat industry, which exported at the time half of its products: several food producing companies went bankrupt, farmers were demanding compensation from the government, thousands of employees lost their jobs and farmers were having problems selling their products. "The Belgian PCB/dioxin crisis – 8 years later: An overview" by Andrian Covaci, Stefan Voorspoels, Paul Schepens, Philippe Jorens, Ronny Blust, Hugo Neels, *Environmental Toxicology and Pharmacology* 25 (2008), pp. 164-170.

<sup>34</sup> Commission Regulation (EC) No 1825/2000 of 25 August 2000 laying down detailed rules for the application of Regulation (EC) No 1760/2000 of the European Parliament and of the Council as regards the labelling of beef and beef products (OJ L 216, 26.8.2000, p. 9).

<sup>35</sup> The processed aquaculture products industry estimated the rate of application of traceability in their sector prior to 2002 at 80-90%. The traceability systems in place tended to be company specific, less formalised and driven by business needs and customer requirements. Study on the evaluation of Regulation (EC) No 178/2002 ("the General Food Law Regulation"), Food Chain Evaluation Consortium, [2015] ('General GFL study'), at p. 38.

<sup>36</sup> As a result, the scope of the problem was not fully understood until the crisis had spread and some 6 million chickens were culled as a result. See "The Rapid Alert System for Food and Feed of the European Union – 30 years of keeping consumers safe", DG Health and Consumers, European Commission, [2009], at pp. 23 and 26.

<sup>37</sup> See fn. 7.

<sup>38</sup> Prior to the GFL, the only explicit reference to the precautionary principle at EU level was to be found in Article 174 EC Treaty in relation to environment. The precautionary principle in the GFL provision must be applied in light of the Commission's Communication on the precautionary principle adopted in 2000 (COM(2000)1 final, dated 2.2.2000).

<sup>39</sup> Originally named as Standing Committee on the Food Chain and Animal Health, it is currently named as Standing Committee on Plants, Animals, Food and Feed, following a recent amendment of the GFL Regulation by Regulation (EU) No 652/2014 of the European Parliament and of the Council of 15 May 2014 laying down provisions for the management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material (OJ L 189, 27.6.2014, p. 1).

<sup>40</sup> It is a Committee in the meaning of Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers – 'Comitology Regulation' – (OJ L 55, 28.2.2011, p. 13). Comitology refers to a set of procedures through which EU MS control how the Commission implements EU law.

<sup>41</sup> To determine the safety level of a feed and food, the GFL Regulation sets out a set of criteria. In addition, it provides a legal presumption of compliance: a feed or food is deemed safe, when it complies with specific EU provisions governing food safety, or in their absence, with the applicable safety national provisions. As such, products that do not comply with specific safety EU (or in their absence, national) provisions are deemed to be unsafe, unless a risk assessment proves otherwise. Similarly, even if a product complies with specific EU or national food law, national CAs may nevertheless restrict its placing on the market or require its withdrawal where there are reasons to consider it unsafe.

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<sup>42</sup> Withdrawal is not defined in the GFL Regulation, but it is commonly understood to be the process by which a product is removed from the supply chain, with the exception of a product that is in the possession of consumers. A recall means asking consumers to take the product back to the place of purchase or to destroy it.

<sup>43</sup> For the purposes of this fitness check, the term 'withdrawals' also covers 'recalls'.

<sup>44</sup> *E.g.* Commission Implementing Regulation (EU) No 1337/2013 of 13 December 2013 laying down rules for the application of Regulation (EU) No 1169/2011 of the European Parliament and of the Council as regards the indication of the country of origin or place of provenance for fresh, chilled and frozen meat of swine, sheep, goats and poultry (OJ L 335, 14.12.2013, p. 19) for food information purposes as regards the origin of unprocessed meat of poultry, swine, pig and goat.

<sup>45</sup> Where the product originates in the EU and if the risk cannot be contained satisfactorily by measures taken by the MS concerned, the Commission may suspend the placing on the market of the product in question, lay down special conditions for its placing on the market, or apply any other appropriate interim measure. For products imported into the EU, the Commission may suspend the imports, lay down special conditions for the product in question, or adopt any other appropriate interim measure (Article 53 of the GFL).

<sup>46</sup> The Commission must, however, review the emergency measure put in place by the Member State within 10 working days in order to extend, amend or abrogate the given national measures (Article 54 of the GFL).

<sup>47</sup> Article 62 of the GFL Regulation.

<sup>48</sup> For example, Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs (OJ L 109, 6.5.2000, p. 29), which predated the GFL Regulation, was revised by means of Directive 2003/89/EC (OJ L 308, 25.11.2003, p. 15) to incorporate the risk analysis principle in establishing a list of food ingredients causing allergies.

<sup>49</sup> Mylona K., Maragkoudakis P., Bock A.-K., Wollgast J., Caldeira S. and Ulberth F.; Delivering on EU Food Safety and Nutrition in 2050 – Future challenges and policy preparedness, JRC Science for Policy Report, EUR 27957 EN. Publications Office of the European Union, Luxembourg, 2016, ISBN 978-92-79-58916-4, doi:10.2787/625130, at p. 18.

<sup>50</sup> *Id.*, at p. 20.

<sup>51</sup> To be found at: [https://ec.europa.eu/food/safety/general\\_food\\_law/fitness\\_check\\_en](https://ec.europa.eu/food/safety/general_food_law/fitness_check_en).

<sup>52</sup> Evaluation of the Rapid Alert System for Food and Feed and of crisis management procedures, Food Chain Evaluation Consortium, [2015] ('RASFF study'). To be found at: [https://ec.europa.eu/food/safety/general\\_food\\_law/fitness\\_check\\_en](https://ec.europa.eu/food/safety/general_food_law/fitness_check_en).

<sup>53</sup> European Food Safety Authority, External Evaluation of EFSA – Final report, [2012], Ernst & Young ('EFSA 2012 external evaluation'), to be found at <http://www.efsa.europa.eu/en/keydocs/docs/efsafinalreport.pdf>.

<sup>54</sup> Commission Staff Working Document, 'Impact Assessment on the Revision of Regulation 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 on the establishment of fees for EFSA', SWD(2013) 45 final, dated 11.2.2013.

<sup>55</sup> See Appendix 7.

<sup>56</sup> The Working Group on REFIT Fitness Check of Regulation (EC) No 178/2002 has held four meetings during 2014-2015. The meetings were held on 4 March 2014, 19 December 2014, 6 May 2015 and 21-22 September 2015. The first meeting was dedicated to the preparation of the Terms of Reference for the External study on the general part of the GFL Regulation. All relevant documentation about these meetings (*e.g.* agenda, and summary reports) are to be found at [http://ec.europa.eu/dgs/health\\_food-safety/dgs\\_consultations/advisory\\_group\\_en.htm](http://ec.europa.eu/dgs/health_food-safety/dgs_consultations/advisory_group_en.htm).

<sup>57</sup> See Annex 2b to the General GFL study and Annex 12 to the RASFF study.

<sup>58</sup> Further details on the work of the inter-service steering group are to be found in Appendix 2.

<sup>59</sup> The consolidated results of the targeted surveys are presented in Annex 3 to the General GFL study (To be found at: [https://ec.europa.eu/food/safety/general\\_food\\_law/fitness\\_check\\_en](https://ec.europa.eu/food/safety/general_food_law/fitness_check_en)).

<sup>60</sup> A full list of the stakeholders targeted by this survey is presented in Annex 7 to the General GFL study (To be found at: [https://ec.europa.eu/food/safety/general\\_food\\_law/fitness\\_check\\_en](https://ec.europa.eu/food/safety/general_food_law/fitness_check_en)).

<sup>61</sup> The consolidated results of the survey are presented in Annex 3 to the General GFL study.

<sup>62</sup> *I.e.* enterprises up to 250 employees.

<sup>63</sup> The results and the questionnaire of the SME survey are presented in Annexes 4 and 5 to the General GFL study (To be found at: [https://ec.europa.eu/food/safety/general\\_food\\_law/fitness\\_check\\_en](https://ec.europa.eu/food/safety/general_food_law/fitness_check_en)).

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<sup>64</sup> *i.e.* enterprises covering from self-employed up to enterprises with 250 employees.

<sup>65</sup> *i.e.* from self-employed up to enterprises with 9 employees.

<sup>66</sup> *i.e.* enterprises with 10 and up to 49 employees.

<sup>67</sup> *i.e.* enterprises with 50 and up to 250 employees.

<sup>68</sup> *i.e.* Austria, Estonia, Finland, France, Germany, Hungary, Italy, the Netherlands, Slovakia and the UK. For more details on the topics of the thematic case studies and the selection criteria for the choice of the Member States involved, *see* Appendix 3. *See also* General GFL study, at pp. 15-17 (To be found at: [https://ec.europa.eu/food/safety/general\\_food\\_law/fitness\\_check\\_en.](https://ec.europa.eu/food/safety/general_food_law/fitness_check_en.)).

<sup>69</sup> The focus of the two workshops with the stakeholders, which were carried out on 19 December 2014 and on 6 May 2015, were detailed aspects of the thematic case studies on traceability and on the allocation of responsibilities under the GFL Regulation.

<sup>70</sup> The focus of the two workshops with the MS CAs, which were carried out on 16 January 2015 and on 27 April 2015, were detailed aspects of the thematic case studies on risk analysis and transparency provisions under the GFL Regulation.

<sup>71</sup> Sixteen MS CAs provided further written feedback on the case studies of risk analysis and transparency provisions, including nine of the ten case study MS. One MS CA has also provided some feedback to the case studies on traceability and allocation of responsibilities. A relatively limited number of stakeholders have provided written feedback to the detailed Working Documents.

<sup>72</sup> In 2008, melamine was fraudulently added to milk and milk products produced in China to give the appearance of increased protein levels. The high level of melamine in infant milk resulted in very severe health effects in infants and young children in China. In EU, the substance was detected in composite products containing milk and soya ingredients, and in sodium bicarbonate.

<sup>73</sup> The incident involved a large producer who issued a voluntary recall of three types of glass-packaged instant coffee following the company's own checks. The checks revealed a risk of the presence of small pieces of glass in the instant coffee resulting from damaged jars, probably incurred during transport. These pieces of glass were not visible to consumers prior to consumption due to an opaque film label covering the entire surface of the jar.

<sup>74</sup> The *E.coli* outbreak in Germany in 2011 was characterised by a high incidence of infections with a novel strain of *E.coli* bacteria, *i.e.* Shiga toxin-producing *Escherichia coli* (STEC) of serotype O104:H4, caused by the consumption of fenugreek sprouted seeds. It is the largest known STEC-associated outbreak worldwide, with roughly 900 cases of the life-threatening post-diarrhoeal sequel of haemolytic uremic syndrome (HUS) and 55 deaths.

<sup>75</sup> The competitive position of the European food and drink industry, ECSIP consortium, Rotterdam, February 2016, published at [http://ec.europa.eu/growth/sectors/food/competitiveness/studies/index\\_en.htm](http://ec.europa.eu/growth/sectors/food/competitiveness/studies/index_en.htm) ('Competitiveness study').

<sup>76</sup> The Better Regulation Package, introducing the requirement of public consultations in all evaluation was introduced in May 2015.

<sup>77</sup> Out of these sixteen submissions, 9 were the MS selected for the case-studies while 7 originated from additional MS outside the context of the case-studies. One MS provided additional input on the other two case-studies as well, which were mainly addressed to stakeholders: traceability and allocation of responsibilities.

<sup>78</sup> A very limited impact assessment accompanied the proposal for the GFL Regulation (COM/2000/0716 final, COD 2000/0286), which does not meet the current applicable standard for impact assessments.

<sup>79</sup> Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents (OJ L 325, 12.12.2003, p. 31) establishes a EU system for the monitoring and collection of information of zoonoses. According to the latter, MS are obliged to collect relevant and, where applicable, comparable data on zoonoses, zoonotic agents, antimicrobial resistance and food-borne outbreaks. In addition, the MS are required to assess trends and sources of these agents, as well as outbreaks in their territory. While EFSA is assigned the tasks of examining these data and publishing the EU annual Summary Reports, the data collection on human diseases from the MS is conducted in accordance with Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2012 on serious cross-border threats to health (OJ L 293, 5.11.2013, p. 1), which provides the framework to improve preparedness and coordinate response to health emergencies across the EU caused by biological, chemical, environmental agents and threats of unknown origin.

<sup>80</sup> To be found at: [https://ec.europa.eu/food/safety/general\\_food\\_law/fitness\\_check\\_en.](https://ec.europa.eu/food/safety/general_food_law/fitness_check_en.)

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<sup>81</sup> To be found at: [http://ec.europa.eu/smart-regulation/impact/consultation\\_2014/contributions/index\\_en.htm](http://ec.europa.eu/smart-regulation/impact/consultation_2014/contributions/index_en.htm).

<sup>82</sup> Indicatively, a 2014 overview report of the audit and inspection service of DG SANTE (former FVO) on the effectiveness and efficiency of official controls under Regulation 882/2004 acknowledges “*the lack of a prescribed or generally accepted standard or performance indicators for measuring effectiveness of official controls*”. Overview report of a series of FVO fact-finding missions and audits carried out in 2012 and 2013 in order to evaluate the systems put in place to give effect to Article 8(3) of Regulation (EC) No 882/2004, DG(SANCO) 2014-7263.

<sup>83</sup> The term ‘food supply chain’ describes a wide concept comprising all actors and activities from primary production (agriculture and inputs including feed), 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 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.

<sup>84</sup> “Data and trends of the EU Food and Drink Industry”, FoodDrinkEurope, 2016, to be found at: [http://www.fooddrinkeurope.eu/uploads/static\\_pages\\_documents/FDE\\_Data\\_and\\_Trends\\_FINAL\\_3011\\_PRIN\\_T.pdf](http://www.fooddrinkeurope.eu/uploads/static_pages_documents/FDE_Data_and_Trends_FINAL_3011_PRIN_T.pdf), at p. 11.

<sup>85</sup> *Id.*, at p. 2.

<sup>86</sup> *Id.*, at p. 4.

<sup>87</sup> *Id.*, at p. 10.

<sup>88</sup> *Id.*, at p. 12.

<sup>89</sup> Competitiveness study, at p. 31.

<sup>90</sup> *Id.*, at p. 58.

<sup>91</sup> Data and trends of the EU Food and Drink Industry”, FoodDrinkEurope, 2016, at p. 7.

<sup>92</sup> General GFL study, at p. 10.

<sup>93</sup> Data and trends of the EU Food and Drink Industry”, FoodDrinkEurope, 2016, at pp. 2-3.

<sup>94</sup> *Id.* at p. 12.

<sup>95</sup> Competitiveness study, at pp. 58-59.

<sup>96</sup> Data and trends of the EU Food and Drink Industry”, FoodDrinkEurope, 2016, at p. 16.

<sup>97</sup> The word ‘implementation’ throughout the present fitness check is used in the broader sense covering all acts and actions required to apply the legislation concerned, unless otherwise indicated.

<sup>98</sup> Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed (OJ L 140, 30.5.2002, p. 10); Regulation (EC) No 2160/2003 of the European Parliament and of the Council of 17 November 2003 on the control of salmonella and other specified food-borne zoonotic agents (OJ L 325, 12.12.2003, p. 1); Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ L 268, 18.10.2003, p. 1); Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (OJ L 268, 18.10.2003, p. 24) – the latter Regulation, however, does not follow the definition of ‘placing on the market’ as defined in the GFL Regulation; Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268, 18.10.2003, p. 29); Regulation (EC) No 2065/2003 of the European Parliament and of the Council of 10 November 2003 on smoke flavourings used or intended for use in or on foods (OJ L 309, 26.11.2003, p. 1); Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1); Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55. Corrected version in OJ L 226, 25.6.2004, p. 22); Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption (OJ L 139, 30.4.2004, p. 206); Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (OJ L 165, 30.4.2004, p. 1); Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with

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food (OJ L 338, 13.11.2004, p. 4); Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene (OJ L 35, 8.2.2005, p. 1); Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin (OJ L 70, 16.3.2005, p. 1); Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods (OJ L 404, 30.12.2006, p. 9. Corrected version in OJ L 12, 18.1.2007, p. 3); Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes (OJ L 354, 31.12.2008, p. 7); Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16); Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods (OJ L 354, 31.12.2008, p. 34); Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin (OJ L 152, 16.6.2009, p. 11); Regulation (EC) No 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed (OJ L 229, 1.9.2009, p. 1); Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption (Animal by-products Regulation), (OJ L 300, 14.11.2009, p. 1); Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market (OJ L 309, 24.11.2009, p. 1); Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers (OJ L 304, 22.11.2011, p. 18); Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes and total diet replacement for weight control (OJ L 181, 29.6.2013, p. 35); Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods (OJ L 327, 11.12.2015, p. 1); Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 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 and plant protection products (OJ L 95, 7.4.2017, p. 1). See also Appendix 1.

<sup>99</sup> For example, Regulation (EC) No 1935/2004 regulating the placing on the market of food contact materials does not share the same scope of the GFL Regulation (which regulates feed and food *per se*) although it is closely linked thereto. To this end, the definitions of 'placing on the market' and 'traceability' were adapted for the purposes of Regulation (EC) No 1935/2004. Similarly, Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market.

<sup>100</sup> Stakeholders have cited the following examples: application of the definition of 'food' and its distinction from medicinal products or medical devices; application of the definition of 'retail' especially in the context of other EU secondary food legislation, such as the food hygiene rules and the rules governing food information to consumers. General GFL study, at p. 34.

<sup>101</sup> For a more complete account of the establishment and operation of EFSA, see Appendix 7.

<sup>102</sup> Commission Regulation (EC) No 1304/2003 of 11 July 2003 on the procedure applied by the European Food Safety Authority to requests for scientific opinions referred to it (OJ L 185, 24.7.2003, p. 6); Commission Regulation (EC) No 2230/2004 of 23 December 2004 laying down detailed rules for the implementation of European Parliament and Council Regulation (EC) No 178/2002 with regard to the network of organisations operating in the fields within the European Food Safety Authority's mission (OJ L 379, 24.12.2004, p. 64).

<sup>103</sup> Court of Auditors, Report on the annual accounts of the European Food Safety Authority for the 2003 financial year together with the Authority's replies (OJ C 324, 30.12.2004, p. 39).

<sup>104</sup> Court of Auditors, Report on the annual accounts of the European Food Safety Authority for the financial year 2015, together with the Authority's reply (OJ C 449, 1.12.2016, p. 97).

<sup>105</sup> EFSA 2012 external evaluation, at p. 178.

<sup>106</sup> The GFL Regulation does not specify the exact time limit within which EFSA is obliged to deliver its scientific opinions: this is laid down either in the specific EU secondary food legislation in the context of which an opinion is requested or in the request itself.

<sup>107</sup> A procedure by which the deadline for the adoption of the scientific output is suspended due to the request for additional information sent to the applicant/requestor in order to better understand the Term of Reference. The clock starts running again when the requested information is provided, according to

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the relevant sectorial law. This mechanism, designed mainly for applications with legal deadlines where renegotiations are not usually possible. 'Stop the clock' procedures constitute a *de facto* extension of the deadline for the completion of the risk assessment, with repercussions on the possibility of fast market access.

<sup>108</sup> It should be mentioned that the estimated backlog does not take into account additional 1548 requests which concerned health claims on botanicals and which were put on hold by EFSA following a request from the Commission. EFSA 2012 external evaluation, at pp. 165-166.

<sup>109</sup> Indicatively, EFSA's risk assessment process in 2012 was based on 39 different workflows, whereas in other regulated areas of product safety (e.g. medicines, chemicals) risk assessment processes by European agencies are based on one or two workflows, applicable across the board. *Id.*, at pp. 104-105.

<sup>110</sup> EFSA Science Strategy 2012-2016, at p. 11, to be found at

[https://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/sciencestrategy12.pdf](https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/sciencestrategy12.pdf).

<sup>111</sup> See Appendix 7.

<sup>112</sup> General GFL study, Box 4, at p. 107.

<sup>113</sup> In 2013-2014, EFSA conducted a survey on stakeholders' needs regarding the application process, which was published. In general, stakeholders found the application process very complex due to the variety of workflows for each vertical scientific area, the lack of information on the status of the applications, the lack of communication with EFSA staff involved, the lack of predictability of workflows and timeline, the lack of clarity regarding the questions raised during the risk assessment and the conclusions reached in the final scientific output. Applicants would like to have the possibility to attend a pre-submission meeting with EFSA. See also Appendix 7.

<sup>114</sup> *I.e.* Panel on Plant Health and the splitting of Panel on food additives, flavourings, processing aids and food contact materials in two new ones.

<sup>115</sup> These data are accessible to risk assessors and managers, researchers and the general public at different level of granularity.

<sup>116</sup> Established in 2005 by means of Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004 (OJ L 142, 30.4.2004, p. 1), the ECDC aims at strengthening EU's defences against infectious diseases. Its mission is to identify, assess and communicate current and emerging threats to human health posed by infectious diseases. In order to achieve this goal, the ECDC works in partnership with national public health bodies across EU to strengthen and develop the EU-wide disease surveillance and early warning systems. By working with experts throughout EU, the ECDC pools Europe's knowledge in health to develop authoritative scientific opinions about the risks posed by current and emerging infectious diseases.

<sup>117</sup> Other new initiatives in the area of data collection include data on pests and diseases of apple fruit present in the EU to support plant risk assessments, food additive usage and occurrence to support the review of old food additives and TSE data base.

<sup>118</sup> European Food Safety Authority – Quality Management, "Annual Quality Manager's report 2014" to be found at: [http://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/qmr14.pdf](http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/qmr14.pdf).

<sup>119</sup> For more information, see at:

[https://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/qmr15.pdf](https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/qmr15.pdf).

<sup>120</sup> For more information, see at:

[https://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/qmr16.pdf](https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/qmr16.pdf).

<sup>121</sup> The seven cases which were solved at the level of the Advisory Forum concerned the following: QRA tallow, MON 810, TTC, sweeteners, coumarin, caffeine, perchlorate. The remaining four for which the scientific divergence was confirmed were: lycopene, bisphenol A/FIP, bisphenol A/CEF, mycotoxins T2/HT2.

<sup>122</sup> Meeting of Working Group on General Food Law, focusing on EFSA, 29 June 2015.

<sup>123</sup> See Joint Statement of the European parliament, the Council of the EU and the European Commission on decentralised agencies and accompanying annex, endorsed on 19 July 2012 and to be found at:

[https://europa.eu/european-union/sites/europaeu/files/docs/body/joint\\_statement\\_and\\_common\\_approach\\_2012\\_en.pdf](https://europa.eu/european-union/sites/europaeu/files/docs/body/joint_statement_and_common_approach_2012_en.pdf).

<sup>124</sup> European Court of Auditors, Management of conflict of interest in selected EU Agencies, Special report No 15 [2012]; all recommendations are now implemented by EFSA.

<sup>125</sup> In the period 2012-2013, NGOs brought three complaints against EFSA before the European Ombudsman (Case 0622/2012/ NGO v EFSA ; Case 2522/2011/ NGO v EFSA ; and, Case 346/2013/SID, NGO v EFSA), which led to a recommendation towards EFSA in 2015 as regards the presumption of independence of universities, to be found at: <http://www.ombudsman.europa.eu/en/cases/decision.faces/en/58868/html.bookmark>.

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<sup>126</sup> The application of the independence rules of EFSA and of other EU agencies is scrutinised on a yearly basis by the European Parliament in the framework of the granting of the discharge.

<sup>127</sup> For more information, see at:

[http://www.eca.europa.eu/Lists/ECADocuments/SR12\\_15/SR12\\_15\\_EN.PDF](http://www.eca.europa.eu/Lists/ECADocuments/SR12_15/SR12_15_EN.PDF).

<sup>128</sup> EFSA's policy on independence, adopted by EFSA's Management Board on 21 June 2017, to be found at: [https://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/policy\\_independence.pdf](https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf).

<sup>129</sup> *Id.*

<sup>130</sup> *E.g.* Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (OJ L 43, 14.2.1997, p. 1), to be soon replaced by Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods; Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed; Regulation (EC) No 1831/2003 on additives for use in animal nutrition; Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food; Regulation (EC) No 1924/2006 of the European Parliament and of the Council on nutrition and health claims made on foods; Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 354, 31.12.2008, p. 1); Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market.

<sup>131</sup> Indeed, in the chemicals sector, Regulation (EC) No 1907/2006 has reversed the responsibility to assess the risks and hazards of substances from national regulators to the business operators. See Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency (OJ L 396, 30.12.2006, p. 1).

<sup>132</sup> Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, (OJ L 136, 30.4.2004, p. 1).

<sup>133</sup> The GLP principles promote the quality and validity of data generated in the testing of chemicals and prevent fraudulent practices. The principles have been developed in accordance with the Organisation for Economic Cooperation and Development ('OECD') and the EU has adopted these principles as annexes to its two GLP Directives: Directive 2004/9/EC of the European Parliament and of the Council of 11 February 2004 on the inspection and verification of good laboratory practice (OJ L 50, 20.2.2004, p. 28) and Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances (OJ L 50, 20.2.2004, p. 44). Compliance of holders of GLP certificates with the applicable principles is subject to monitoring.

<sup>134</sup> *I.e.* EMA, ECHA and ECDC.

<sup>135</sup> Some MS have centralised risk assessment body, while other have several scientific organisations covering the different fields and which are coordinated in different ways. General GFL study, at p. 97.

<sup>136</sup> 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) 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 (*e.g.* food supplements, enriched foods, flavourings, additives). As an illustration, the German Federal Institution for Risk Assessment had a budget of nearly €68 million in 2013 for its statutory tasks, while the French Agency for Food, Environmental and Occupational Health and Safety, since its establishment in 2010 had a budget of about €130 million; even in smaller MS, such as Belgium and Finland, budgets of national risk assessment bodies have been very considerable. *Id.* at p. 88.

<sup>137</sup> *Id.*, at p. 103;

<sup>138</sup> *Id.*, at pp. 90-91.

<sup>139</sup> Where necessary, EFSA asks additional scientific information and data 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. *Id.*, at p. 90.



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<sup>140</sup> According to the GFL Regulation, where feed or food products do not comply with EU provisions, or in their absence with specific national provision), they are deemed unsafe unless a risk assessment proves otherwise. This legal presumption builds into the fact that EU provisions are considered to set a very high safety standard. There is, however, EU secondary food legislation that it is not only premised on safety grounds. For example, maximum residue levels for pesticides set in EU legislation take account of good agricultural practices. As such, food that is in breach of the latter legal limits is not automatically considered to be unsafe, to trigger withdrawals pursuant to GFL (although such food would still be in breach of the relevant legislation on pesticide residues and should not be placed on the market). Where food is found not to comply with EU secondary food legislation and is also subsequently assessed to be in breach of the food safety requirements, the requirements relating to withdrawals would be applicable. Therefore, there is a need to assess each incident on a case-by-case basis for the purposes of applying the GFL requirements.

<sup>141</sup> General GFL study, at p. 94.

<sup>142</sup> Certain other EU secondary food legislation incorporating the risk analysis principle (especially when authorisations are concerned), make explicit reference that risk managers must also consider other legitimate factors, without providing an exhaustive list. Indicatively, see Regulation (EC) No 1831/2003 on additives for use in animal nutrition, at recital (17) which refers to legitimate factors including societal, economic or environmental factors, feasibility of controls and the benefit for the animal or for the consumer of animal products; Regulation (EC) No 2065/2003 on smoke flavourings used or intended for use in or on foods, at Article 9(1) stating that Community authorisation must also take into account other legitimate factors relevant to the matter under consideration; Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food, at Article 11(2), stating that Community authorisation must also take into account other legitimate factors relevant to the matter under consideration; Regulation (EC) No 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin at Article 14(2)(f) which states that a risk management decision must take into account other legitimate factors relevant to the matter under consideration, without specifying them; Regulation (EC) No 1924/2006 on nutrition and health claims made on foods, at recital ( 29 ), which states in abstract that in addition to risk assessment, other legitimate factors relevant to the matter under consideration be taken into account; Regulation (EC) No 1331/2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings at recital (14), which repeats the wording of the GFL Regulation as regards legitimate factors; and, Regulation (EC) No 470/2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, at recital (17) stating that other legitimate factors, including the technological aspects of food production and the feasibility of controls, should be taken into account in risk management decisions. Even if other EU secondary food legislation does not explicitly provide for legitimate factors, those can be relied upon on the basis of the GFL in risk management decisions.

<sup>143</sup> Commission Regulation (EU) No 432/2012 of 16 May 2012 establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health (OJ L 136, 25.5.2012, p. 1).

<sup>144</sup> Commission Regulation (EU) 2015/8 of 6 January 2015 refusing to authorise certain health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health (OJ L 3, 7.1.2015, p. 6).

<sup>145</sup> See also Commission Implementing Regulation (EU) 2016/862 of 31 May 2016 refusing to authorise a health claim made on foods, other than those referring to the reduction of disease risk and to children's development and health (OJ L 144, 1.6.2016, p. 24).

<sup>146</sup> Judgment of 16 March 2016 in *Dextro Energy GmbH & Co. KG v European Commission*, T-100/15, EU:T:2016:150, at paragraph 30 and the case-law cited.

<sup>147</sup> Judgment of 5 May 1998 in *United Kingdom of Great Britain and Northern Ireland v Commission of the European Communities*, C-180/96, ECLI:EU:C:1998:192, at paras. 99-100; Judgment of the Court of First Instance of 16 July 1998, *Laboratoires pharmaceutiques Bergaderm SA and Jean-Jacques Goupil v Commission of the European Communities*, Case T-199/96, ECLI:EU:T:1998:176, at paras. 66-67.

<sup>148</sup> Communication from the Commission on the precautionary principle, COM(2000)1 final, dated 2.2.2000.

<sup>149</sup> Judgment of the General Court of 9 September 2011 in *France v. Commission*, T-257/07, EU:T:2011:444 (at paras. 79-80); Confirmed in appeal by judgement of the Court of Justice of 11 July 2013, in *France v Commission*, C-601/11 P, EU:C:2013:465; See also Judgment of the Court of First Instance of 11 September

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2002 in *Pfizer Animal Health SA v Council of the European Union*, T-13/99, ECLI:EU:T:2002:209 (at paras. 152-153).

<sup>150</sup> Commission Regulation (EC) No 746/2008 of 17 June 2008 amending Annex VII to Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (OJ 2008 L 202, p. 11)

<sup>151</sup> Judgment of the General Court of 9 September 2011 in *France v. Commission*, T-257/07, EU:T:2011:444; Confirmed in appeal by judgement of 11 July 2013, in *France v Commission*, C-601/11 P, EU:C:2013:465.

<sup>152</sup> Food contact materials legislation does not regulate food *per se* and as such, it does not share exactly the same scope as the GFL Regulation. However, since its subject matter is so closely linked to/affects food, the general principles of the GFL Regulation apply (including the precautionary principle).

<sup>153</sup> The use of azodicarbonamide as blowing agent in plastic materials and articles was provisionally suspended in 2004 by Commission Directive 2004/1/EC of 6 January 2004 amending Directive 2002/72/EC (OJ L 7, 13.1.2004, p. 45) on the basis of the precautionary principle (recital (7)). Following conclusive scientific evidence, this ban was confirmed three years later in 2007, by means of Commission Directive 2007/19/EC of 30 March 2007 amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with food and Council Directive 85/572/EEC laying down the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs (OJ L 91, 31.3.2007, p. 17) at recital (9).

<sup>154</sup> By means of Commission Directive 2011/8/EU of 28 January 2011 amending Directive 2002/72/EC, the use of Bisphenol A in plastic infant feeding bottles (OJ L 26, 29.1.2011, p. 11) is temporary banned, until further scientific data are available to clarify the toxicological relevance of some observed effects of BPA, in particular as regards biochemical changes in brain, immune-modulatory effects and enhanced susceptibility to breast tumours (recitals 17-20). See also Commission Implementing Regulation (EU) No 321/2011 of 1 April 2011 amending Regulation (EU) No 10/2011 as regards the restriction of use of Bisphenol A in plastic infant feeding bottles Text (OJ L 87, 2.4.2011, p. 1). This provisional ban is still applicable.

<sup>155</sup> See recital (7) of Commission Decision 2005/317/EC of 18 April 2005 on emergency measures regarding the non-authorized genetically modified organism Bt10 in maize products (OJ L 101, 21.4.2005, p. 14). Those emergency measures were reviewed twice in October 2005 and March 2006 and they were eventually repealed by Commission Decision 2007/157/EC of 7 March 2007 repealing Decision 2005/317/EC on emergency measures regarding the non-authorized genetically modified organism Bt10 in maize products (OJ L 68, 8.3.2007, p. 8). Similarly, see recital (5) of Commission Decision 2006/601/EC of 5 September 2006 on emergency measures regarding the non-authorized genetically modified organism LL RICE 601 in rice products (OJ L 244, 7.9.2006, p. 27). The latter measures were repealed by Commission Decision 2010/315 of 8 June 2010 repealing Decision 2006/601/EC on emergency measures regarding the non-authorized genetically modified organism 'LL RICE 601' in rice products, and providing for random testing for the absence of that organism in rice products (OJ L 141, 9.6.2010, p. 10). Also see recital (11) of Commission Decision 2008/289 of 3 April 2008 on emergency measures regarding the unauthorised genetically modified organism Bt 63 in rice products (OJ L 96, 9.4.2008, p. 29). Those measures were also repealed by Commission Implementing Decision 2011/884/EU of 22 December 2011 on emergency measures regarding unauthorised genetically modified rice in rice products originating from China and repealing Decision 2008/289/EC, (OJ L 343, 23.12.2011, p. 140).

<sup>156</sup> Commission Implementing Decision 2011/402/EU on emergency measures applicable to fenugreek seeds and certain seeds and beans imported from Egypt, (OJ L 179, 7.7.2011, p. 10).

<sup>157</sup> Commission Implementing Decision 2011/718/EU of 28 October 2011 amending Implementing Decision 2011/402/EU on emergency measures applicable to fenugreek seeds and certain seeds and beans imported from Egypt (OJ L 285, 1.11.2011, p. 53).

<sup>158</sup> Commission Directive 1999/50/EC of 25 May 1999 amending Directive 91/321/EEC on infant formulae and follow-on formulae (OJ L 139, 2.6.1999, p. 29).

<sup>159</sup> Commission Directive 1999/39/EC of 6 May 1999 amending Directive 96/5/EC on processed cereal-based foods and baby foods for infants and young children (OJ L 124, 18.5.1999, p. 8).

<sup>160</sup> See in particular Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC, (OJ L 401, 30.12.2006, p. 1) at recitals 15-16 and Commission Directive 2006/125/EC of 5 December 2006 on processed cereal-based foods and baby foods for infants and young children (Codified version) (OJ L 339, 6.12.2006, p. 16) at recitals 10-11.

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<sup>161</sup> See Commission Delegated Regulation (EU) 2016/127 of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding (OJ L 25, 2.2.2016, p. 1) at recitals 7-10 and the request for Scientific Advice to EFSA (Ref. Ares(2015)4978278 - 10/11/2015), to be found at: <http://registerofquestions.efsa.europa.eu/roqFrontend/wicket/page?4-1.lLinkListener-mandateForm-documents-1-fileNameLnk>.

<sup>162</sup> Directive 2003/74/EC of the European Parliament and of the Council of 22 September 2003 amending Council Directive 96/22/EC concerning the prohibition on the use in stock-farming of certain substances having a hormonal or thyrostatic action and of beta-agonists (OJ L 262, 14.10.2003, p. 17).

<sup>163</sup> General GFL study, at p. 113.

<sup>164</sup> Impact Assessment for a Regulation replacing Regulation (EC) No 258/97 on novel foods and novel food ingredients, SEC(2008)12, Graphic 1, at p. 10, to be found at: [https://ec.europa.eu/food/sites/food/files/safety/docs/novel-food\\_impact-assessment\\_en.pdf](https://ec.europa.eu/food/sites/food/files/safety/docs/novel-food_impact-assessment_en.pdf).

<sup>165</sup> Nonetheless, while for MS CAs this has occurred always/in most cases (14 out of 25 MS CAs), the majority of stakeholders (57%) have indicated that this had not occurred systematically. General GFL study, at p. 90.

<sup>166</sup> *E.g.* in judgment of 28 January 2010 in *European Commission v. French Republic*, C-333/08, EU:C:2010:44, at paragraph 29, the Court found amongst others that a Member State cannot justify a systematic and untargeted prior authorisation scheme such as that laid down France in relation to food processing aids, by pleading the impossibility of carrying out more exhaustive prior examinations by reason of the considerable quantity of processing aids which may be used or by reason of the fact that manufacturing processes are constantly changing. Such an approach was found not to correspond to the risk analysis principle of the GFL Regulation. Similarly, see *Queisser Pharma GmbH & Co. KG v Bundesrepublik Deutschland*, C-282/15, EU:C:2017:26, pursuant to which the application of the risk analysis principle laid down in the GFL Regulation precludes national legislation which prohibits the manufacture, processing or marketing of any food supplement containing amino acids, unless a derogation has been issued by a national authority with discretion in that respect, where that legislation is based on a risk analysis which concerns only certain amino acids, which it is for the referring court to verify.

<sup>167</sup> Annex 3 to the General GFL study, at p. 92.

<sup>168</sup> General GFL study, at pp. 110-111.

<sup>169</sup> Consolidated Annual Activity Report 2015, EFSA, adopted on 16 March 2016, at p. 25, to be found at: [https://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/ar2015.pdf](https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/ar2015.pdf).

<sup>170</sup> This Working Group brings together EFSA and the communications departments of the National Food Safety Agencies to build a more collaborative and informed approach to communicate risk in the food chain and to promote coherence of messages across the Union. It holds regular meetings and produce specific guidelines to increase the use of best practice and share knowledge and expertise. See EFSA 2012 external evaluation, at p. 81.

<sup>171</sup> This Group aims at supporting the Executive Director in the development of appropriate risk communication strategies in the identification of appropriate channels and in the evaluation of the impact of risk communication on public perception.

<sup>172</sup> EFSA 2012 external evaluation, at pp. 84-85.

<sup>173</sup> Indicatively, EFSA has registered 12,000 followers on EFSA Twitter feed in mid-2015, which is high among the EU agencies using Twitter.

<sup>174</sup> For example, the 'Understanding Science' series contains short videos about EFSA's scientific work explained in simple terms and has proved very popular with over 100,000 views for all videos (to be found at: <http://www.efsa.europa.eu/en/topics/videos>). In 2013, EFSA also introduced its 'Lay Summary' series to explain scientific outputs on issues of high public interest (*e.g.* aspartame and Bisphenol A).

<sup>175</sup> General GFL study, at pp. 94-95.

<sup>176</sup> *Id.*

<sup>177</sup> *Id.*, at p. 102.

<sup>178</sup> In the later context, industry stakeholders had put forward certain cases of EU measures, which were alleged not to have been adopted on the basis of the risk analysis principle. A closer examination of those cases, indicated, however, that the risk analysis process had been applied. *Id.*, at p. 82.

<sup>179</sup> EFSA 2012 external evaluation, at pp 179-180.

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<sup>180</sup> Commission Staff Working Document, 'Impact Assessment on the Revision of Regulation 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 on the establishment of fees for EFSA', SWD(2013) 45 final, dated 11.2.2013.

<sup>181</sup> *Id.*, at p. 202.

<sup>182</sup> See Joint Statement of the European parliament, the Council of the EU and the European Commission on decentralised agencies and accompanying annex, endorsed on 19 July 2012 and to be found at:

[https://europa.eu/european-union/sites/europaeu/files/docs/body/joint\\_statement\\_and\\_common\\_approach\\_2012\\_en.pdf](https://europa.eu/european-union/sites/europaeu/files/docs/body/joint_statement_and_common_approach_2012_en.pdf).

<sup>183</sup> *Id.*, at p. 221.

<sup>184</sup> General GFL study, at p. 100.

<sup>185</sup> Some consulted parties have nevertheless commented that EFSA's scientific opinions sometimes extend beyond risk assessment into risk management. EFSA has clarified that it 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. *Id.*, at p. 93.

<sup>186</sup> *Id.*, at pp. 102 and 107.

<sup>187</sup> Competitiveness study, at p. 124.

<sup>188</sup> *Id.* at p. 128.

<sup>189</sup> Graham Brookes, "Economic impact assessment of EU food related regulations on research, innovation and competitiveness in the specialty food ingredients sector", commissioned by the Federation of European Specialty Food Ingredients industries (ELC), January 2016, at pp. 24 and 30. To be found at:

[https://www.specialtyfoodingredients.eu/uploads/news\\_documents/Brookes\\_innovation\\_report\\_June\\_2016.pdf](https://www.specialtyfoodingredients.eu/uploads/news_documents/Brookes_innovation_report_June_2016.pdf).

<sup>190</sup> *Id.*, at p. 5. See also Competitiveness study at pp. 127-128.

<sup>191</sup> Graham Brookes, "Economic impact assessment of EU food related regulations on research, innovation and competitiveness in the specialty food ingredients sector", at p. 28.

<sup>192</sup> Regulation (EU) 2015/2283 on novel foods.

<sup>193</sup> General GFL study, at p. 95.

<sup>194</sup> Heads of national Food Agencies Working group on transparent use of risk assessment in decision making Reports, April 2012 to be found at:

<https://www.food.gov.uk/sites/default/files/multimedia/pdfs/decision-making-docs.pdf>; See also Second report dated September 2014, to be found at <https://www.food.gov.uk/sites/default/files/head-of-agencies-2nd-report.pdf>.

<sup>195</sup> Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EU) No 182/2011 laying down the rules and general principles concerning mechanism for control by Member States of the Commission's exercise of implementing powers, COM/2017/085 final, dated 14.2.2017.

<sup>196</sup> Regulation (EU) No 182/2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers, at recital 13.

<sup>197</sup> This may be particularly the case for SMEs that do not have the capacity or the resources to invest in preparing complex authorisation dossiers. General GFL study at p. 102.

<sup>198</sup> *Id.*, at pp. 102-107;

<sup>199</sup> Source: Annex II – Processed data from associations' consultation – questionnaire, Commission Staff Working Document – Impact assessment on the revision of Regulation 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 on the establishment of fees for EFSA, SWD(2013)45, dated 11.2.2013, at pp. 50-51.

<sup>200</sup> *Id.*, at p. 107.

<sup>201</sup> Regulation (EC) No 852/2004 on the hygiene of foodstuffs; Regulation (EC) No 853/2004 on the hygiene of food of animal origin; Regulation (EC) No 1831/2003 laying down requirements for feed hygiene.

<sup>202</sup> Article 5(2)(i) of Regulation (EC) No 852/2004 on the hygiene of foodstuffs.

<sup>203</sup> Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers.

<sup>204</sup> Guidance on the implementation of Articles 11, 12, 14, 17, 18, 19 and 20 of Regulation (EC) No 178/2002 on General Food Law – Conclusions of the Standing Committee on the Food Chain and Animal Health, dated 26

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January 2010, to be found at:

[https://ec.europa.eu/food/sites/food/files/safety/docs/gfl\\_req\\_guidance\\_rev\\_8\\_en.pdf](https://ec.europa.eu/food/sites/food/files/safety/docs/gfl_req_guidance_rev_8_en.pdf).

<sup>205</sup> General GFL study, at pp. 51-52.

<sup>206</sup> 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 similar responses. *Id.*

<sup>207</sup> *Id.* at p. 63.

<sup>208</sup> *Id.* at p. 62.

<sup>209</sup> 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). More recently introduced, the GSSI reproduces for seafood the same concept as the GFSI for food. *Id.*, at p. 53.

<sup>210</sup> *Id.*, at p. 60.

<sup>211</sup> See Annex 4 of the General GFL study on the summary findings of the SME survey.

<sup>212</sup> General GFL study, at pp. 68-75.

<sup>213</sup> Annex 4 to the General GFL study.

<sup>214</sup> Regulation (EC) No 882/2004 of the European Parliament and of the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules. Currently, the latter regulation is the most harmonised legal instrument at EU level as regards the official control system in MS.

<sup>215</sup> The definition of risk in this context is wider than that of GFL as it includes the actual characteristics of each business, including compliance records, having in place reliable systems of own controls *etc.* The intention therefore is for controls to be tailored to the specific risk profile of each type of business/business sector.

<sup>216</sup> For example, the frequency and depth of controls varies between MS, while 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 the premises. General GFL study at p. 61.

<sup>217</sup> *Id.*, at p. 60.

<sup>218</sup> Overview report of the audit and inspection service of DG SANTE (former 'FVO') on a series of fact finding missions carried out in five Member States in 2013 and 2014 in order to gather information regarding the controls on food supplements, DG(SANTE) 2015-7186 - MR, European Commission, to be found at: [http://ec.europa.eu/food/audits-analysis/overview\\_reports/details.cfm?rep\\_id=80](http://ec.europa.eu/food/audits-analysis/overview_reports/details.cfm?rep_id=80).

<sup>219</sup> Regulation (EU) 2017/625 on official controls and other official activities.

<sup>220</sup> See also Section 4.2.7.3 as regards the improvements expected to be brought about by this new Regulation in tackling food fraud, once it enters into application.

<sup>221</sup> Commission Communication on "Better Training for Safer Food", COM(2006) 51, dated 20.9.2006; Commission Staff Working Document on challenges and strategies for the Better Training for Safer Food programme", SEC(2019) 1394, dated 11.11.2010.

<sup>222</sup> General GFL study, at pp. 64-66.

<sup>223</sup> *Id.*, at p. 52.

<sup>224</sup> More information can be found at: [http://ec.europa.eu/food/audits\\_analysis\\_en](http://ec.europa.eu/food/audits_analysis_en).

<sup>225</sup> The rating average was above 4, on a scale from 1 to 5. Consumers shared the same opinion about the combined effect of the primary responsibility principle with other core GFL requirements such as responsibility to place only safe products on the market, traceability and the application of withdrawals when required. General GFL study, at p. 55.

<sup>226</sup> 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 primary responsibility to the achievement of these outcomes, only few stakeholders (4-7, out of 67 responses) considered that the primary responsibility has not been positive or effective in terms of achieving the above outcomes. *Id.*, at p. 55.

<sup>227</sup> 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 those outcomes. However, stakeholders scored lower than MS CAs the contribution of Article 17 to the achievement of these outcomes,

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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. *Id.*, at p. 59.

<sup>228</sup> It should be noted that the producer's liability for defective food and feed products is set out in Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products (OJ L 210, 7.8.1985, p. 29). According to the latter Directive, in case of damage caused by the defect of (any) product (except primary agricultural products), the producer shall be liable.

<sup>229</sup> However, there is a link with primary responsibility: where a product is found failing food law requirements, the liability of each link in the food chain must be reviewed according to whether or not it has properly fulfilled its primary responsibility (*i.e.* compliance with food law requirements within the context of its own specific activities/activities within its control).

<sup>230</sup> Final Overview report of the audit and inspection service of DG SANTE (former 'FVO') on the state of implementation of HACCP in the EU and areas for improvement, DG(SANTE) 2015-7752, European Commission, to be found at:

[http://ec.europa.eu/food/audits-analysis/overview\\_reports/details.cfm?rep\\_id=78](http://ec.europa.eu/food/audits-analysis/overview_reports/details.cfm?rep_id=78).

<sup>231</sup> OJ C 278, 30.7.2016, p.1.

<sup>232</sup> Hazard analysis approaches for certain small retail establishments in view of the application of their food safety management systems, EFSA Journal 2017;15(3):4697.

<sup>233</sup> A quarter of stakeholders were not able to respond to this question. General GFL study, at p. 64.

<sup>234</sup> *Id.*, at p. 63.

<sup>235</sup> Initiative to Improve the Food Supply Chain – Consultation Strategy, July 2017, European Commission, to be found at: [https://ec.europa.eu/info/sites/info/files/2017\\_07\\_31\\_consultation\\_strategy\\_en.pdf](https://ec.europa.eu/info/sites/info/files/2017_07_31_consultation_strategy_en.pdf); Inception Impact Assessment (IIA) on an initiative to "Improve the Functioning of the Food Supply Chain", European Commission, published on 26 July 2017, to be found at: [https://ec.europa.eu/info/news/inception-impact-assessment-food-supply-chain-published\\_en](https://ec.europa.eu/info/news/inception-impact-assessment-food-supply-chain-published_en). See also Commission Work Programme 2017, Delivering a Europe that protects, empowers and defends, COM(2016) 710 final, dated 24.10.2016, to be found at: [https://ec.europa.eu/info/sites/info/files/cwp\\_2017\\_en.pdf](https://ec.europa.eu/info/sites/info/files/cwp_2017_en.pdf).

<sup>236</sup> *Id.*, at p. 61.

<sup>237</sup> *Id.*, at pp. 68-75.

<sup>238</sup> While the former action is covered by the GFL Regulation, the latter falls within the scope of the Official Controls Regulation, which provides that in cases where non-compliance is identified, MS CAs must ensure that the business operator remedies the situation and that includes, amongst others, ordering the withdrawal of non-compliant products.

<sup>239</sup> Commission Implementing Regulation (EU) No 931/2011 of 19 September 2011 on the traceability requirements set by Regulation (EC) No 178/2002 of the European Parliament and of the Council for food of animal origin (OJ L 242, 20.9.2011, p. 2). As indicated in recital (4) of the latter Regulation, past food crises in the area of foods of animal origin had revealed that documentary records were not always sufficient to allow full traceability of suspect goods. During the combined implementation of the GFL Regulation with the EU food hygiene Regulations, experience had shown that FBOs did not generally possess the information needed to ensure that their systems identifying the handling or storage of foods was adequate, in particular in the sector of food of animal origin. This had resulted in that sector to unnecessarily high economic losses due to the lack of quick and full traceability of the food.

<sup>240</sup> Commission Implementing Regulation (EU) No 208/2013 of 11 March 2013 on traceability requirements for sprouts and seeds intended for the production of sprouts (OJ L 68, 12.3.2013, p. 16). This Regulation was adopted in the aftermath of the *E.coli* outbreak in May 2011 in the Union, where the consumption of sprouts was identified as the most likely origin thereof. Following an EFSA opinion, it was considered that the conditions for the production of sprouts may pose a potentially high public health risk which would require specific rules for the traceability of sprouts and of seeds intended for the production of sprouts.

<sup>241</sup> General GFL study, at pp. 38-43.

<sup>242</sup> According to the MS CAs, full traceability has been achieved always/in most cases (13 out of 25 MSCAs) or has been achieved but not systematically (11 of 25 MS CAs). *Id.*

<sup>243</sup> 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, *e.g.* private standards, codes of practices,

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contractual obligations) requirements, including the traceability provision set out in the GFL Regulation. FBOs may 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. For example, in the retail and distribution sectors, some companies have integrated the traceability requirements of the GFL Regulation in their stock keeping programs while others link it to track-and-trace operations for e-commerce, which is a growing trend. *Id.*

<sup>244</sup> *Id.*, at p. 40.

<sup>245</sup> However, over a quarter of respondents do not know whether traceability goes beyond a normal book-keeping exercise. *Id.*

<sup>246</sup> *E.g.* for origin purposes with respect to food information requirements on unprocessed meat from swine, poultry, sheep and goat. See Regulation (EU) No 1169/2011 on food information to consumers read in conjunction with Commission Regulation (EU) No 1337/2013 of 13 December 2013 laying down rules for the application of Regulation (EU) No 1169/2011 of the European Parliament and of the Council as regards the indication of the country of origin or place of provenance for fresh, chilled and frozen meat of swine, sheep, goats and poultry (OJ L 335, 14.12.2013, p. 19).

<sup>247</sup> This variation could range from providing a recommendation to FBOs and assessing the situation on a case-by-case basis in the event of withdrawals, to stricter application. General GFL study, at pp. 41-42.

<sup>248</sup> *E.g.* regarding what type of information to be kept, time for keeping records.

<sup>249</sup> 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. General GFL study, at pp. 44-50.

<sup>250</sup> While food business operators were already applying some sort of traceability prior to the GFL, this was not the case for feed business operators. This had resulted in the major 1999 Belgian dioxin crisis, as stated in Section 2.1.

<sup>251</sup> Annex 3 to the General GFL study.

<sup>252</sup> RASFF Annual Report 2008, at pp. 21-23.

<sup>253</sup> At around 10% less than the full sample of SMEs.

<sup>254</sup> General GFL study, at p. 45.

<sup>255</sup> Commission Decision (2004/613/EC) of 6 August 2004 concerning the creation of an advisory group on the food chain and animal and plant health (OJ L 275, 25.8.2004, p.17). The Advisory Group regrouped and replaced the Advisory Committee on Foodstuffs and the Advisory Committee on Agricultural Product Health and Safety, as well as certain standing groups attached to it (veterinary matters, plant health, animal welfare, feedingstuffs). This action was already announced in the Commission's White Paper on Food Safety.

<sup>256</sup> Including aspects relating to the labelling and presentation of food and feed, safety of food and feed, human nutrition in relation to food legislation, animal health, including measures relating to animal welfare, and the various aspects of plant health, such as plant protection, plant protection products and their residues, and conditions for the marketing of seed and propagation material, including biodiversity, and including matters pertaining to industrial property.

<sup>257</sup> 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 food law, during the three phases of its development (preparation, evaluation and revision). General GFL study, at p. 118.

<sup>258</sup> See also at [https://ec.europa.eu/commission/priorities/democratic-change/better-regulation\\_en](https://ec.europa.eu/commission/priorities/democratic-change/better-regulation_en).

<sup>259</sup> General GFL study, at pp. 117-120.

<sup>260</sup> 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. *Id.*, at p. 117.

<sup>261</sup> Contrary to the carrying out of public consultations for the development of EU food law, stakeholders had mixed views on whether there has been an open and transparent public consultation for national food law, 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

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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 food law. *Id.*, at p. 118.

<sup>262</sup> *Id.*, at pp. 117-124.

<sup>263</sup> In that respect, MS have indicated that they tend to inform the public in high profile cases even when these are of low food safety risk a such (*e.g.* in the case of the 2013 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 German *E.coli* in sprouts outbreak, other non-affected MS provided information to the general public). *Id.*, at p. 123.

<sup>264</sup> 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). *Id.*, at p. 121.

<sup>265</sup> *Id.*, at p. 119.

<sup>266</sup> *Id.*

<sup>267</sup> *Id.* at pp. 119-121.

<sup>268</sup> 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. *Id.*

<sup>269</sup> Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers.

<sup>270</sup> Report from the Commission to the European Parliament and the Council regarding trans fats in foods and in the overall diet of the Union population, COM(2015)619 final, dated 3.12.2015. In line with Better Regulation principles, the Commission is currently conducting a complementary analysis by means of an impact assessment. Further information can be found in the Inception Impact Assessment (first step in the Impact Assessment process) prepared by the Commission services and published on 11 October 2016 [http://ec.europa.eu/smart-regulation/roadmaps/docs/2016\\_sante\\_143\\_trans\\_fats\\_en.pdf](http://ec.europa.eu/smart-regulation/roadmaps/docs/2016_sante_143_trans_fats_en.pdf).

<sup>271</sup> Regulation (EC) No 1924/2006 of the European Parliament and of the Council on nutrition and health claims made on foods. The objective of these rules is to enable consumers to make healthier choices. Any nutrition or health claim in relation to a food must be clear, accurate and based on scientific evidence. Claims on foods which have not been authorised at EU level are prohibited.

<sup>272</sup> Directive 2002/46/EC of the European Parliament and of the Council on the approximation of the laws of the Member States relating to food supplements.

<sup>273</sup> Regulation (EC) No 1925/2006 of the European Parliament and of the Council on the addition of vitamins and minerals and of certain other substances to foods.

<sup>274</sup> White Paper on a Strategy for Europe on Nutrition, Overweight and Obesity related health issues, COM(2007) 279, dated 30.5.2007.

<sup>275</sup> The High Level Group on nutrition and physical activity is a group of government representatives from all 28 EU MS and the 2 EFTA countries Norway and Switzerland, dealing with this issue, led by the Commission. It seeks European solutions by offering an overview of all government policies on nutrition and physical activity, by helping governments share policy ideas and practice and by improving liaison between governments and the EU platform for diet, physical activity and health. It focuses actively on tackling childhood obesity, but it also supports the reformulation of foods to improve products by reducing levels of nutrients of public health concern (*e.g.* salt, saturated fat) and to bring intakes closer to recommended levels. *See also* at [http://ec.europa.eu/health/nutrition\\_physical\\_activity/high\\_level\\_group\\_en](http://ec.europa.eu/health/nutrition_physical_activity/high_level_group_en).

<sup>276</sup> Established in 2005 and under the auspices of the Commission, the EU platform for action on diet, physical activity and health is a forum for EU level organisations, ranging from the food industry to consumer protection NGOs, willing to commit to tackling current trends in diet and physical activity. The current platform members have more than 300 commitments in six activity areas such as consumer information, education, marketing and advertising and reformulation where excessive intakes of energy, saturated fat, sugars and salt in the average consumer diets is addressed. *See also* at: [http://ec.europa.eu/health/nutrition\\_physical\\_activity/platform\\_en](http://ec.europa.eu/health/nutrition_physical_activity/platform_en)

<sup>277</sup> *See also* at:

[http://ec.europa.eu/health/sites/health/files/nutrition\\_physical\\_activity/docs/euframework\\_national\\_nutrients\\_en.pdf](http://ec.europa.eu/health/sites/health/files/nutrition_physical_activity/docs/euframework_national_nutrients_en.pdf); [http://ec.europa.eu/health/ph\\_determinants/life\\_style/nutrition/documents/salt\\_initiative.pdf](http://ec.europa.eu/health/ph_determinants/life_style/nutrition/documents/salt_initiative.pdf); [https://ec.europa.eu/health/sites/health/files/nutrition\\_physical\\_activity/docs/saturated\\_fat\\_eufnism\\_en.pdf](https://ec.europa.eu/health/sites/health/files/nutrition_physical_activity/docs/saturated_fat_eufnism_en.pdf); and, [https://ec.europa.eu/health/sites/health/files/nutrition\\_physical\\_activity/docs/added\\_sugars\\_en.pdf](https://ec.europa.eu/health/sites/health/files/nutrition_physical_activity/docs/added_sugars_en.pdf).



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<sup>278</sup> See also at: <https://ec.europa.eu/jrc/sites/jrcsh/files/public-procurement-food-health-technical-report.pdf>.

<sup>279</sup> General GFL study, at pp. 143-144.

<sup>280</sup> The objective of establishing the nutrient profiles in Regulation (EC) No 1924/2006 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. Consumers, however, are not directly exposed to nutrient profiles (*i.e.* not part of the food information to be provided to the consumers) so that are not immediately affected by them.

<sup>281</sup> *Id.*, at p. 150.

<sup>282</sup> Article 8 of the GFL Regulation.

<sup>283</sup> Amongst others, Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers establishes the principle that food information must not be misleading. Specific labelling requirements, also within the context of protecting consumers' interests, are further included in Regulation (EC) No 1333/2008 on food additives; Article 1 of the latter Regulation specifically mentions the protection of consumers' interests as one of the objectives to be pursued.

<sup>284</sup> In order to facilitate, amongst others, consumers' choice and avoid misleading labelling, food supplements must bear adequate and appropriate labelling and at the same time, declared vitamins and minerals on the label of food supplements must be present in the product concerned in a significant amount. See Directive 2002/46/EC of the European Parliament and of the Council on the approximation of the laws of the Member States relating to food supplements.

<sup>285</sup> The objective of these rules is to enable consumers to make healthier choices. Any nutrition or health claim in relation to a food must be clear, accurate and based on scientific evidence. Food bearing claims that could mislead consumers are prohibited on the EU market. See Regulation (EC) No 1924/2006 of the European Parliament and of the Council on nutrition and health claims made on foods.

<sup>286</sup> To ensure that consumers make informed choices, appropriate labelling should accompanied foods to which vitamins, minerals and other substances have added. In addition, declared vitamins and minerals on the label of such foods must be present in a significant amount. See Regulation (EC) No 1925/2006 of the European Parliament and of the Council on the addition of vitamins and minerals and of certain other substances to foods.

<sup>287</sup> RASFF annual report 2015, at p. 26, to be found at:

[https://ec.europa.eu/food/sites/food/files/safety/docs/rasff\\_annual\\_report\\_2015.pdf](https://ec.europa.eu/food/sites/food/files/safety/docs/rasff_annual_report_2015.pdf).

<sup>288</sup> General GFL study, at pp. 140-144.

<sup>289</sup> *Id.*

<sup>290</sup> The other objectives were: protection of public health, free movement of food in the internal market and free movement of feed in the internal market.

<sup>291</sup> OJ L 95, 7.4.2017, p. 1.

<sup>292</sup> Article 9(2) thereof.

<sup>293</sup> Article 9(1)(b) thereof.

<sup>294</sup> Articles 73-91 thereof.

<sup>295</sup> Article 139(2) thereof.

<sup>296</sup> Article 98 thereof.

<sup>297</sup> General GFL study, at pp. 124-132. These findings were also based on in-depth consultation with certain selected 3<sup>rd</sup> parties, including some of the most significant trading partners, based on the value of food trade with the EU: USA, Chile, Brazil, Canada and China. However, complete feedback was only received from three of those (*i.e.* USA, Chile and Canada).

<sup>298</sup> The EU is a member of Codex Alimentarius in addition to MS' individual membership. See Council Decision 2003/822/EC of 17 November 2003 on the accession of the European Community to the Codex Alimentarius Commission, (OJ L 309, 26.11.2003, p. 14).

<sup>299</sup> Indicatively the following other EU secondary food legislation include references to international standards: Regulation (EC) No 1829/2003 on genetically modified food and feed as well as Commission Implementing Regulation (EU) No 503/2013 of 3 April 2013 on applications for authorisation of genetically modified food and feed (OJ L 157, 8.6.2013, p. 1); Regulation (EC) No 1831/2003 on feed hygiene; Regulation (EC) No 396/2005 on maximum levels of pesticides in or on food and feed of plant and animal origin; Regulation (EC) No 853/2004 on the hygiene of foodstuffs; Regulation (EC) No 854/2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption; Regulation (EC) No 882/2004 on official controls; Regulation (EC) No 396/2005 on maximum levels of pesticides in or on food and feed of

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plant and animal origin and subsequent amendments of annexes thereto; Regulation (EC) No 1924/2006 on nutrition and health claims made on foods; Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods; Regulation (EC) No 1333/2008 on food additives and amendments to annexes thereto; Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs (OJ L 364, 20.12.2006, p. 5); Commission Directive 2006/141/EC on infant formulae and follow-on formulae; Commission Regulation (EC) No 41/2009 of 20 January 2009 concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten (OJ L 16, 21.1.2009, p. 3); Regulation (EC) No 470/2009 on the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin; Regulation (EU) 2015/2283 on novel foods; Regulation (EU) 2017/625 on official controls and other official activities.

<sup>300</sup> Indicatively, Regulation (EC) No 1924/2006 on nutrition and health claims made on foods established a list of permitted nutrition claims and their conditions of use on the basis of the similar list of the Codex Guidelines for the Use Nutrition and Health Claims (Guidelines for use of nutrition and health claims, CAC/GL 23-1997). It also introduced new rules for health claims and in particular requirements for their scientific substantiation. This resulted in an updating of the Codex Guidelines with the addition of recommendations on the scientific substantiation of health claims in line with the EU principles.

<sup>301</sup> General GFL study at p. 129.

<sup>302</sup> For example, Regulation (EC) No 1831/2003 on additives for use in animal nutrition subjects imports from non EU countries of additives for use in animal nutrition to requirements equivalent those applying to additives produced in the Community. Provisions concerning imports are also foreseen in Regulation (EC) No 853/2004 laying down rules for food of animal origin and Regulation (EC) No 854/2004 laying down rules for the organisation of official controls on products of animal origin intended for human consumption.

<sup>303</sup> 20 out of the 25 responding MS CAs have indicated that they have always/in most cases implemented restrictions on imports, while 3 MS CAs have done so but not systematically. General GFL study, at pp. 129-130.

<sup>304</sup> 16 of 25 responding MS CAs have indicated that they had always/in most cases taken measures, while a further 2 MS CAs had taken measures but not systematically. *Id.*

<sup>305</sup> *Id.*

<sup>306</sup> As regards imports of food and feed from non-EU countries into the EU, the positive impacts include, amongst others: quality/safety of imports; business trust in imported products; avoiding/limiting the impact of a food crisis in the EU; the acceptance/use of EU standards in international trade; and, consumer trust in imported products. As regards exports of feed and food from the EU to non EU countries, the positive impacts include: business trust in exported products; quality/safety of exports; consumer trust in exported products; quantity of exports; acceptance/use of EU standards in international trade; avoiding/limiting the impact of a food crisis on international trade; and, competitiveness of EU exports in international markets. *Id.*, at p. 126.

<sup>307</sup> Competitiveness study, at pp. 18-20.

<sup>308</sup> General GFL study at pp. 130-131.

<sup>309</sup> Regulation (EC) No 183/2005 of the European Parliament and of the Council laying down requirements for feed hygiene.

<sup>310</sup> RASFF Annual Report, 2015, European Commission, at p. 9, to be found at:

[https://ec.europa.eu/food/sites/food/files/safety/docs/rasff\\_annual\\_report\\_2015.pdf](https://ec.europa.eu/food/sites/food/files/safety/docs/rasff_annual_report_2015.pdf).

<sup>311</sup> Follow-up notifications are notifications that refer to one or more consignments of a food, feed, or food contact material that has been previously notified to RASFF.

<sup>312</sup> Commission Regulation (EU) No 16/2011 of 10 January 2011 laying down implementing measures for the Rapid Alert System for Food and Feed, OJ L 6, 11.1.2011, p. 7.

<sup>313</sup> The RASFF SOPs and WI are to be found at:

[http://ec.europa.eu/food/safety/rasff/implementing\\_regulation\\_guidance\\_en](http://ec.europa.eu/food/safety/rasff/implementing_regulation_guidance_en).

<sup>314</sup> RASFF study, at pp. 74-75.

<sup>315</sup> *Id.*

<sup>316</sup> EFSA's support is not usually needed when RASFF notifications concern standard non-compliance with legal provisions already based on an EFSA risk assessment. There are, however, specific cases where EFSA usefully contributes because specific exposure levels for the product at stake need to be taken into account for the management of the problem.

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<sup>317</sup> In particular, 90 non EU countries have direct access through the IT tool, 4 non EU countries have access to RASFF Window through country desks at the European External Action Service, and 19 other countries receive information from RASFF Window through EU Delegations. RASFF study, at p. 81.

<sup>318</sup> While on average, RASFF NCPs tend to consider that FBOs and other stakeholders are sufficiently informed, other respondents to the survey tend to disagree. Overall, a majority of respondents saw a need for improving the information flow to FBOs and other stakeholders, though National Contact Points (NCPs) saw this need to a lesser degree than other stakeholders. *Id.*, at p. 96.

<sup>319</sup> See Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2012 on serious cross-border threats to health (OJ L 293, 5.11.2013, p. 1).

<sup>320</sup> RASFF study, at pp. 57 and 59.

<sup>321</sup> National authorities of 181 Member States are part of INFOSAN. For more information, see at [http://www.who.int/foodsafety/areas\\_work/infosan/en/](http://www.who.int/foodsafety/areas_work/infosan/en/).

<sup>322</sup> RASFF study, at p. 84.

<sup>323</sup> *Id.*, at pp. 76-80.

<sup>324</sup> *Id.*, at p. 128.

<sup>325</sup> For example, WI 3.2 and 5.1 provide guidance on how to proceed where a notification to INFOSAN and TRACES respectively is required.

<sup>326</sup> RASFF study, at p. 88.

<sup>327</sup> Indicatively, in the reference year 2013 a total of 3,137 original notifications were transmitted (on average more than 8 per day) relating to a wide range of food safety concerns, including residues of veterinary medicinal products, food poisoning, the composition of dietetic foods and food supplements, pesticide residues, unsafe feed, and mycotoxins. These were followed by a total of 5,158 follow-up notifications (on average 14 per day). In the same reference year, information was transmitted to non EU countries in 2,373 instances concerning products originating therefrom or distributed thereto (on average more than 6 times per day).

<sup>328</sup> Data and trends of the EU Food and Drink Industry", FoodDrinkEurope, 2016, at p. 12.

<sup>329</sup> Annex to RASFF study, Table 3, at p. 104.

<sup>330</sup> *Id.*, at p. 107.

<sup>331</sup> Annex to Commission Decision 2004/478/EC of 29 April 2004 concerning the adoption of a general plan for food/feed crisis management, (OJ L 212, 12.6.2004, p. 60).

<sup>332</sup> Regulation (EC) No 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

<sup>333</sup> Overview Report of a series of fact-finding missions carried out in 2013 and 2014 in order to gather information on emergency preparedness arrangements, 2014-7651, DG SANTE, European Commission, to be found at: [http://ec.europa.eu/food/audits-analysis/overview\\_reports/details.cfm?rep\\_id=73](http://ec.europa.eu/food/audits-analysis/overview_reports/details.cfm?rep_id=73).

<sup>334</sup> RASFF study at pp. 106-107.

<sup>335</sup> *Id.*, at p. 103.

<sup>336</sup> Public perceptions of the Dioxin Crisis in Irish Pork, June 2009, UCD Geary Institute, Discussion Paper Series, to be found at: <http://www.ucd.ie/geary/static/publications/workingpapers/gearywp200919.pdf>.

<sup>337</sup> Commission Staff Working Document, Lessons learned from the 2011 outbreak of Shiga toxin-producing *Escherichia coli* (STEC) O104:H4 in sprouted seeds, SANCO/13004/2011, to be found at: [https://ec.europa.eu/food/sites/food/files/safety/docs/biosafety-crisis-cswd\\_lessons\\_learned\\_en.pdf](https://ec.europa.eu/food/sites/food/files/safety/docs/biosafety-crisis-cswd_lessons_learned_en.pdf) at p. 3.

*See also* RASFF study at p. 103.

<sup>338</sup> *Id.*, at p. 100.

<sup>339</sup> EFSA 2012 external evaluation report, at p. 89.

<sup>340</sup> V. Bitsch, N. Koković, M. Rombach, *E.coli* and Fresh Produce: Comparing Media Coverage and Market Effects in the U.S. and in Germany, Paper presented at the 24<sup>th</sup> Annual World Forum and Symposium of the International Food and Agribusiness Management Association in Cape Town, South Africa, June 15-19, 2014, to be found at: <https://www.ifama.org/resources/files/2014-Conference/1022.pdf>.

<sup>341</sup> RASFF study, at p. 106

<sup>342</sup> Commission Staff Working Document, Lessons Learned from the 2011 Outbreak of Shiga Toxin-Producing *Escherichia Coli*, SANCO/13004/2011, to be found at: [https://ec.europa.eu/food/sites/food/files/safety/docs/biosafety-crisis-cswd\\_lessons\\_learned\\_en.pdf](https://ec.europa.eu/food/sites/food/files/safety/docs/biosafety-crisis-cswd_lessons_learned_en.pdf).

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<sup>343</sup> Typing food-borne pathogens ('disease-causing) such as *Salmonella*, *Listeria*, *E.coli* and *Campylobacter* helps identify the specific strains that are responsible for foodborne outbreaks and detect emerging health threats. By establishing a link between specific strains and specific food types, it is possible to estimate the role of different foods in human infections. This is known as "source attribution". For more information, see at <https://www.efsa.europa.eu/en/topics/topic/molecular-typing>.

<sup>344</sup> RASFF study, at p. 100.

<sup>345</sup> Overview Report of a series of fact-finding missions carried out in 2013 and 2014 in order to gather information on emergency preparedness arrangements, 2014-7651, DG SANTE, European Commission, to be found at: [http://ec.europa.eu/food/audits-analysis/overview\\_reports/details.cfm?rep\\_id=73](http://ec.europa.eu/food/audits-analysis/overview_reports/details.cfm?rep_id=73), at pp. 14-16.

<sup>346</sup> General GFL study, at pp. 168-171.

<sup>347</sup> Such as on the methodology applied in the public/consumer options polls/surveys, when measured, as well as on the timing of the surveys (*e.g.* before or after food incidents).

<sup>348</sup> See also B. Ballantine, Improving the quality of risk management in the European Union: Risk communication, European Policy Centre Working Paper, June 2003/WP 05.

<sup>349</sup> General GFL study, at p. 139.

<sup>350</sup> According to the General GFL study, although all general requirements for FBOs have largely ensured consumer trust in feed and food, the feedback received has not scored as high in the consultation (by stakeholders in particular), as the achievement of a high level of protection of consumer health. Indeed, 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 were above or nearly (4) for all requirements, while for stakeholders they were under (4). *Id.*

<sup>351</sup> *Id.*, at p. 150.

<sup>352</sup> *Id.*, at p. 169.

<sup>353</sup> Indicatively, EU initiatives aimed at fostering innovation, include 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). The 'Circular Economy Package' (European Commission, 2014) also aims at stimulating Europe's transition towards a circular economy so as to boost global competitiveness, foster sustainable growth and generate new job, which also addresses the issue of food waste prevention.

<sup>354</sup> General GFL study, at p. 151.

<sup>355</sup> Competitiveness study, at p. 128.

<sup>356</sup> For instance, not only no evidence was provided during the General GFL consultation on adverse impacts on innovation and trade in instances where the precautionary principle is correctly applied, but there is growing evidence that precautionary measures can even encourage innovation, in particular when supported by public consultation, identification of the actual needs of society and smart regulation. General GFL study, at pp. 112-114. See also Section 4.2.2.4.

<sup>357</sup> General GFL study, at p. 10.

<sup>358</sup> Competitiveness study, at pp. 18-19.

<sup>359</sup> Stakeholder Dialogue Group on Food Sustainability. (2014). Actions towards a more sustainable European food chain, to be found at: [http://www.fooddrinkeurope.eu/uploads/press-releases\\_documents/Declaration\\_Sustainability\\_of\\_Food\\_System.pdf](http://www.fooddrinkeurope.eu/uploads/press-releases_documents/Declaration_Sustainability_of_Food_System.pdf).

<sup>360</sup> Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of Regions, [Closing the loop - an EU action plan for the Circular Economy](#), (COM(2015) 614 final), dated 02.12.2015. In addition, the EU and MS are committed to meeting the Sustainable Development Goals [ <https://sustainabledevelopment.un.org/topics>] (SDG), adopted in September 2015, including a target to halve per capita food waste at the retail and consumer level by 2030, and reduce food losses along the food production and supply chains.

<sup>361</sup> 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). General GFL study, at p. 149.

<sup>362</sup> See Comparative study on EU Member States' legislation and practices on food donations (EESC, 2014), to be found at [http://www.eesc.europa.eu/resources/docs/executive-summary\\_comparative-study-on-eu-member-states-legislation-and-practices-on-food-donation.pdf](http://www.eesc.europa.eu/resources/docs/executive-summary_comparative-study-on-eu-member-states-legislation-and-practices-on-food-donation.pdf); Counting the Cost of Food Waste: EU food waste prevention (UK House of Lords, 2013-14), to be found at: <https://www.parliament.uk/documents/lords-committees/eu-sub-com-d/food-waste-prevention/154.pdf>; Review of EU legislation and policies with

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implications on food waste (FUSIONS, 2015; Food redistribution in the Nordic Region (Nordic Council of Ministers, TemaNord 2014-2016), to be found at [http://www.google.be/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0ahUKEWjlqremPofQAhUiisAKHVXeA9cQFggcMAA&url=http%3A%2F%2Fwww.eu-fusions.org%2Findex.php%2Fdownload%3Fdownload%3D161%3Areview-of-eu-legislation-and-policies-with-implications-on-food-waste&usg=AFQjCNGhOMy8WijOjIKD5scfxoi6W\\_yMdQ](http://www.google.be/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0ahUKEWjlqremPofQAhUiisAKHVXeA9cQFggcMAA&url=http%3A%2F%2Fwww.eu-fusions.org%2Findex.php%2Fdownload%3Fdownload%3D161%3Areview-of-eu-legislation-and-policies-with-implications-on-food-waste&usg=AFQjCNGhOMy8WijOjIKD5scfxoi6W_yMdQ); See also Commission meetings with, and individual contributions received from, national competent authorities and stakeholders, to be found at [http://ec.europa.eu/food/safety/food\\_waste/eu\\_actions/index\\_en.htm](http://ec.europa.eu/food/safety/food_waste/eu_actions/index_en.htm)) and General GFL study, at p. 149.

<sup>363</sup> For example, several national food industry associations indicated that the application of the criteria to determine whether a food is 'fit for human consumption' – and therefore safe - differs across the EU and is sometimes used 'excessively'. As such, it often leads to unnecessary cases of food waste. General GFL study, at p. 151.

<sup>364</sup> In Italy, the so-called "Good Samaritan Law" (L.155/2003) exceptionally provides legal protection from possible litigation arising from donated food. While organisations engaging in food redistribution activity are food business operators, this law specifies that, in regard to liability, non-profit organisations carrying out, for charitable purposes, free distribution of food products to those in need (ONLUS), have an equivalent status to that of final consumers. Food donors are thereby only liable towards the recipients of the food (*i.e.* redistribution organisations or charities) which are considered as final consumers and relieved of their liability in regard to the final beneficiaries.

<sup>365</sup> Regulation (EC) No 853/2004 laying down specific hygiene rules for food of animal origin provides for a derogation from this obligation where the supply of food of animal origin is marginal, restricted or local.

<sup>366</sup> Commission Notice, EU Guidelines on food donation (OJ C 361, 25.10.2017, p. 1).

<sup>367</sup> General GFL study, at p. 149.

<sup>368</sup> Article 14 of Regulation (EC) No 1169/2011 on food information to consumers; Article 11(3) of Regulation (EC) No 767/2009 on feed marketing.

<sup>369</sup> 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). General GFL study, at p. 149.

<sup>370</sup> Directive 2005/29/EC of the European Parliament and of the Council of 11 May 2005 concerning unfair business-to-consumer commercial practices in the internal market (OJ L 149, 11.6.2005, p. 22).

<sup>371</sup> Commission Notice of 26.9.2017 on the application of EU food and consumer protection law to issues of Dual quality of products – The specific case of food, C(2017)6532, dated 26.9.2017, to be found at: [http://ec.europa.eu/newsroom/just/item-detail.cfm?item\\_id=604475](http://ec.europa.eu/newsroom/just/item-detail.cfm?item_id=604475).

<sup>372</sup> That was the case for example with respect to Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (OJ L 43, 14.2.1997, p. 1), where the provision of scientific advice by the Scientific Committee for Food was automatically aligned to that of EFSA. See also Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food (OJ L 37, 13.2.1993, p. 1) and Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed (OJ L 140, 30.5.2002, p. 10), which was adopted very soon after the GFL Regulation.

<sup>373</sup> For example, Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs (OJ L 109, 6.5.2000, p. 29), which predated the GFL Regulation, was revised by means of Directive 2003/89/EC (OJ L 308, 25.11.2003, p. 15) to incorporate the risk analysis principle in establishing a list of food ingredients causing allergies.

<sup>374</sup> See Appendix 1, Table B.

<sup>375</sup> FCEC study, at p. 93.

<sup>376</sup> EFSA 2012 external evaluation, at pp. 8-12.

<sup>377</sup> See for example at:

<http://www.fda.gov/food/ingredientspackaginglabeling/gras/noticeinventory/ucm449901.htm>.

<sup>378</sup> EFSA 2012 external evaluation, at p. 40.

<sup>379</sup> See Appendix 7.

<sup>380</sup> The European Union summary report on data of the surveillance of ruminants for the presence of transmissible spongiform encephalopathies (TSEs) in 2015, EFSA Journal 2016; 14(12):4643.

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<sup>381</sup> The European Union summary report on trends and sources of zoonoses, zoonotic agents and food-borne outbreaks in 2015, EFSA Journal 2016;14(12):4634.

<sup>382</sup> *Id.*

<sup>383</sup> The 2015 European Union report on pesticide residues in food, EFSA Journal 2017;15(4):4791.

<sup>384</sup> Report for 2014 on the results from the monitoring of veterinary medicinal product residues and other substances in live animals and animal products, EFSA Supporting Publications, 25 May 2016, DOI 10.2903/sp.efsa.2016.EN-923.

<sup>385</sup> Commission Recommendation 2003/598/EC of 11 August 2003 on the prevention and reduction of patulin contamination in apple juice and apple juice ingredients in other beverages ((OJ L 203, 12.8.2003, p. 34).

<sup>386</sup> Commission Recommendation of 17 August 2006 on the prevention and reduction of Fusarium toxins in cereals and cereal products (OJ L 234, 29.8.2006, p. 35).

<sup>387</sup> General GFL study, at p. 132.

<sup>388</sup> 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, to be found at: <http://tacd.org/wp-content/uploads/2013/09/TACD-FOOD-Resolution-on-the-approach-to-food-and-nutrition-related-issues-in-the-TTIP.pdf>. See also General GFL study, at p. 129.

<sup>389</sup> Charlebois et al, Comparison of Global Food Traceability Regulations and Requirements, in Comprehensive Reviews in Food Science and Food Safety, Vol 13, (2014) at p. 1104.

<sup>390</sup> More specifically: Canada was 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 was also ranked as 'average' because it was 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 was ranked as 'poor' because their specific traceability regulations are either limited or not yet fully implemented.

<sup>391</sup> More recent EU-level data following the *E.coli* outbreak (June 2011) and the horsemeat fraudulent labelling scandal in 2013, were not available during the General GFL study, while available data at MS level did not allow a systematic analysis across the EU. General GFL study, at pp. 139-140.

<sup>392</sup> *Id.*, at p. 137.

<sup>393</sup> RASFF study, at p. 44.

<sup>394</sup> General GFL study, at p. 138.

<sup>395</sup> All consulted parties, including consumer associations and NGOs, considered that the risk analysis principle including the consideration of other legitimate factors than science and the use of precautionary principle has contributed to a high level of protection of consumers' interests in the EU. *Id.*, at p. 99.

<sup>396</sup> REFIT evaluation of (a) Regulation (EC) No 1924/2006 on nutrition and health claims made on food with regard to nutrient profiles and health claims made on plants and their preparations and of (b) the general regulatory framework for their use in foods.

<sup>397</sup> Data and trends of the EU Food and Drink Industry", FoodDrinkEurope, 2016, to be found at: [http://www.fooddrinkurope.eu/uploads/static\\_pages\\_documents/FDE\\_Data\\_and\\_Trends\\_FINAL\\_3011\\_PRIN\\_T.pdf](http://www.fooddrinkurope.eu/uploads/static_pages_documents/FDE_Data_and_Trends_FINAL_3011_PRIN_T.pdf), at pp. 2-4.

<sup>398</sup> White Paper on Food Safety, COM(99)719, dated 12.01.2000, at p. 6.

<sup>399</sup> Data and trends of the EU Food and Drink Industry", FoodDrinkEurope, 2016, to be found at: [http://www.fooddrinkurope.eu/uploads/static\\_pages\\_documents/FDE\\_Data\\_and\\_Trends\\_FINAL\\_3011\\_PRIN\\_T.pdf](http://www.fooddrinkurope.eu/uploads/static_pages_documents/FDE_Data_and_Trends_FINAL_3011_PRIN_T.pdf), at pp. 2-4.

<sup>400</sup> *Id.*, at p. 12.

<sup>401</sup> General GFL study, at p. 10.

<sup>402</sup> Data and trends of the EU Food and Drink Industry", FoodDrinkEurope, 2016, at pp. 2-3.

<sup>403</sup> As stated in Section 4.2.2.4, MS CAs were more positive than stakeholders on the impacts of such measures; 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. General GFL study, at p. 100.

<sup>404</sup> 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

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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. With respect to feed, 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 the 67 responding stakeholders did not provide an assessment on this aspect. *Id.*, at p. 144.

<sup>405</sup> *Id.*

<sup>406</sup> 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). *Id.*

<sup>407</sup> 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). *Id.*

<sup>408</sup> 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). *Id.*

<sup>409</sup> *Id.*, at p. 33.

<sup>410</sup> Annex 3 to the General GFL study.

<sup>411</sup> 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 on the GFL 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 of unsafe food and feed(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). General GFL study, at p. 161.

<sup>412</sup> While the former action is covered by the GFL Regulation, the latter falls within the scope of the Official Controls Regulation, which provides that in cases where non-compliance is identified, MS CAs must ensure that the business operator remedies the situation and that includes, amongst others, ordering the withdrawal of non-compliant products.

<sup>413</sup> The RASFF SOPs and WI are to be found at:

[http://ec.europa.eu/food/safety/rasff/implementing\\_regulation\\_guidance\\_en](http://ec.europa.eu/food/safety/rasff/implementing_regulation_guidance_en).

<sup>414</sup> Fitness Check of the Food Chain, at pp. 24-25; *See also* Non-harmonised food contact materials in the EU: regulatory and market situation (Baseline study – Final report) – C. Simoneau et al, JRC Science for Policy Report, 2016, EUR 28357 EN; doi:10.2788/234276, to be found at:

<https://ec.europa.eu/jrc/en/publication/eur-scientific-and-technical-research-reports/non-harmonised-food-contact-materials-eu-regulatory-and-market-situation-baseline-study>.

<sup>415</sup> General GFL study, at p. 34.

<sup>416</sup> *Id.*, at pp. 121-122.

<sup>417</sup> Competitiveness study, at p. 149.

<sup>418</sup> The same concern has been raised by FBOs alike. Nevertheless, this concern seems to reflect more their different vested interests. While consumer organisations and NGOs on one hand consider that more weight and priority should be given to legitimate factors (and the use of a precautionary approach) over the risk assessment in risk management decisions, FBOs consider the reverse. General GFL study at p. 99.

<sup>419</sup> *E.g.* FR ANSES vs. EFSA opinions on BPA.

<sup>420</sup> As state above, risk trade-offs occur when efforts to combat a 'target risk' unintentionally results in the increase of other 'countervailing risks'.

<sup>421</sup> General GFL study, at p. 132.

<sup>422</sup> RASFF study, at p. 84.

<sup>423</sup> Competitiveness study, at p. 124.

<sup>424</sup> *Id.* at p. 128.

<sup>425</sup> *Id.*, at p. 23.

<sup>426</sup> General GFL study, at p. 63.

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<sup>427</sup> Initiative to Improve the Food Supply Chain – Consultation Strategy, July 2017, European Commission, to be found at: [https://ec.europa.eu/info/sites/info/files/2017\\_07\\_31\\_consultation\\_strategy\\_en.pdf](https://ec.europa.eu/info/sites/info/files/2017_07_31_consultation_strategy_en.pdf); Inception Impact Assessment (IIA) on an initiative to "Improve the Functioning of the Food Supply Chain", European Commission, published on 26 July 2017, to be found at: [https://ec.europa.eu/info/news/inception-impact-assessment-food-supply-chain-published\\_en](https://ec.europa.eu/info/news/inception-impact-assessment-food-supply-chain-published_en). See also Commission Work Programme 2017, Delivering a Europe that protects, empowers and defends, COM(2016) 710 final, dated 24.10.2016, to be found at: [https://ec.europa.eu/info/sites/info/files/cwp\\_2017\\_en.pdf](https://ec.europa.eu/info/sites/info/files/cwp_2017_en.pdf).

<sup>428</sup> Annex 3 to the General GFL study. General GFL study, at pp. 48-49 and 64.

<sup>429</sup> Traceability (Product Tracing) in Food Systems: an IFT report submitted to the FDA, Volume 2: Cost Considerations and Implications), Comprehensive reviews in food science and food safety, Vol. 9, Issue 1, January 2010, at pp. 159-175, to be found at: <http://onlinelibrary.wiley.com/doi/10.1111/j.1541-4337.2009.00098.x/full>.

<sup>430</sup> General GFL study, at p. 180. These figures are not directly comparable. All figures are expressed in nominal terms.

<sup>431</sup> RASFF study, at p. 88.

<sup>432</sup> *Id.*

<sup>433</sup> 51%, of which 'considerable potential' amounted to 17% while potential 'to some extent/in some cases' amounted 34%. See Annex 3 to the General GFL study.

<sup>434</sup> 43%, of which 'considerable potential' amounted to 15% while potential 'to some extent/in some cases' amounted to 28%. *Id.*

<sup>435</sup> Competitiveness study, at p. 148.

<sup>436</sup> General GFL study, at p. 180.

<sup>437</sup> As indicated in the General GFL study, due to lack of data to ensure a 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 are more cost-effective in comparison to multiple – and potentially diverse – national risk assessments. *Id.*, at p. 103;

<sup>438</sup> This may be particularly the case for SMEs that do not have the capacity/resources to invest in preparing complex authorisation dossiers. *Id.*, at p. 102.

<sup>439</sup> Information in the context of the General GFL study must be understood in a broad sense, *i.e.* including labelling, reporting, registration, monitoring and assessment needed to provide information required. In some cases the information has to be transmitted to the public authorities or private parties. In others, it must be available for inspection or be supplied on request. Those costs include recurring administrative costs and, where significant, one-off administrative costs.

<sup>440</sup> Such requirements are generated by other EU secondary food legislation, *e.g.* registration of FBOs in the context of the Food Hygiene Regulations.

<sup>441</sup> These percentages exclude capital investment, 'business-as-usual' costs, and private contractual obligations.

<sup>442</sup> Annex 3 to General GFL study, at p. 119.

<sup>443</sup> General GFL study, at p. 182.

<sup>444</sup> Annex 4 to General GFL study.

<sup>445</sup> SMEs are particularly well aware of the requirement to place safe products on the EU market, to carry out own controls to ensure compliance with food law requirements and to withdraw/recall unsafe products.

<sup>446</sup> General GFL study, at p. 158.

<sup>447</sup> *Id.*, at p. 157.

<sup>448</sup> Over one third of SME respondents indicated that authorities do not help; however, more than half of them indicated the opposite. Annex 4 to General GFL study.

<sup>449</sup> *E.g.* DIN, EN, ISO 9001, IFS, GFSI and HALAL.

<sup>450</sup> *E.g.* eco-food certificate and GMP+B3 (Good Manufacture Practice).

<sup>451</sup> General GFL study, at p. 158.

<sup>452</sup> OJ C 278, 30.7.2016, p.1.

<sup>453</sup> Guidance on the implementation of Articles 11, 12, 14, 17, 18, 19 and 20 of Regulation (EC) No 178/2002 on General Food Law – Conclusions of the Standing Committee on the Food Chain and Animal Health, dated 26



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January 2010, at p. 10, to be found at:

[https://ec.europa.eu/food/sites/food/files/safety/docs/gfl\\_req\\_guidance\\_rev\\_8\\_en.pdf](https://ec.europa.eu/food/sites/food/files/safety/docs/gfl_req_guidance_rev_8_en.pdf).

<sup>454</sup> Commission Notice on the implementation of food safety management systems covering prerequisite programs (PRPs) and procedures based on the HACCP principles (OJ C 278, 30.7.2016, p.1).

<sup>455</sup> Annex 3 to the General GFL study.

<sup>456</sup> Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, 'Better Regulation for Better results – an EU agenda', COM(2015)215, dated 19.5.2015.

<sup>457</sup> Regulation (EC) No 882/2004 of the European Parliament and of the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules. The latter Regulation will be repealed and replaced as of December 2019 by Regulation (EU) 2017/625 on official controls and other official activities.

<sup>458</sup> Guidance on the implementation of Articles 11, 12, 14, 17, 18, 19 and 20 of Regulation (EC) No 178/2002 on General Food Law – Conclusions of the Standing Committee on the Food Chain and Animal Health, dated 26 January 2010, at p. 10, to be found at:

[https://ec.europa.eu/food/sites/food/files/safety/docs/gfl\\_req\\_guidance\\_rev\\_8\\_en.pdf](https://ec.europa.eu/food/sites/food/files/safety/docs/gfl_req_guidance_rev_8_en.pdf).

<sup>459</sup> General GFL study, at pp. 196-197.

<sup>460</sup> In the context of the General GFL study, SMEs have called for some simplification in the area of food information, as they claim that they do not have enough sufficient resources to maintain appropriate procedures for fulfilling their food information obligations, especially as regards surveillance of allergens entering into the food production process. Nevertheless, the Food Information to Consumers Regulation was adopted in 2011 on the basis of an impact assessment which had addressed, amongst others, the impact of this specific surveillance obligation on SMEs and was measured against the overall objective of protection of public health (e.g. presence of allergens in foods) and consumers' interests (see Commission Staff Working Document accompanying the Proposal for a Regulation of the European Parliament and of the Council on the provision of food information to consumers – Impact assessment report on general food labelling issues, SEC(2008)92, dated 30.1.2008, to be found at:

[https://ec.europa.eu/food/sites/food/files/safety/docs/labelling\\_legislation\\_general-food-labelling\\_en.pdf](https://ec.europa.eu/food/sites/food/files/safety/docs/labelling_legislation_general-food-labelling_en.pdf)).

The adopted Regulation imposing that surveillance requirement corresponded to the findings of the latter impact assessment.

<sup>461</sup> General GFL study, at pp. 133 and 184.

<sup>462</sup> Including MS CAs, supply chain stakeholders, consumers, and experts. *Id.*, at pp. 32-33.

<sup>463</sup> White paper on Food Safety, at p. 27.

<sup>464</sup> General GFL study at p. 133.

<sup>465</sup> Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents (OJ L 325, 12.12.2003, p. 31).

<sup>466</sup> Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2012 on serious cross-border threats to health (OJ L 293, 5.11.2013, p. 1).

<sup>467</sup> Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004 (OJ L 142, 30.4.2004, p. 1).

<sup>468</sup> Memorandum of Understanding between the European Food Safety Authority and the European Centre for Disease Prevention and Control, renewed in 2014, to be found at:

[https://www.efsa.europa.eu/sites/default/files/assets/mouecdc\\_renewed.pdf](https://www.efsa.europa.eu/sites/default/files/assets/mouecdc_renewed.pdf).

<sup>469</sup> RASFF study, at pp. 57 and 59.

<sup>470</sup> Article 39 of the TFEU.

<sup>471</sup> Such as primary responsibility (including own controls), safety requirements, traceability, withdrawals, official controls, emergency measures, use of RASFF to ensure a swift exchange of information amongst its members so as to better contain food incidents and its outreach to other non-member countries and international organisations, crisis management plan, and risk communication.

<sup>472</sup> General GFL study, at p. 136.

<sup>473</sup> Communication on "The CAP towards 2020: meeting the food, natural resources and territorial challenges of the future", COM(2010) 672 final, p.2.

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<sup>474</sup> Article 1(4) of Regulation (EU) 2017/625 on official controls and other official activities read in conjunction with Article 89 of Regulation (EU) No 1306/2013 of the European Parliament and of the Council of 17 December 2013 on the financing, management and monitoring of the common agricultural policy (OJ L 347, 20.12.2013, p. 549).

<sup>475</sup> Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law'), (OJ L 84, 31.3.2016, p. 1). Although the Animal Health Law will only enter into application in April 2021, it is still pertinent to assess its complementarity to the GFL Regulation taking into account the accompanied explanatory memorandum and the impact assessment.

<sup>476</sup> According to the Explanatory Memorandum of the Commission proposal for a Regulation of the European Parliament and of the Council on Animal Health (COM(2013)0260 final, dated 6.5.2013), the needs behind the latter initiative were: the high complexity of the pre-existing legislative framework, composed of almost 50 basic directives and regulations and some 400 pieces of secondary food legislation, some of them adopted as early as 1964; the lack of an overall strategy; an insufficient focus on disease prevention, with a particular focus on the need for increased biosecurity; and problems relating to the intra-Union trade in live animals. A comparison of these problems/needs with the problems/needs that led to the adoption of the GFL show a lot of similarities.

<sup>477</sup> See Impact Assessment of Animal Health Law] at p. 103 where it is stated that "*AHL shall include general principles, similar to the ones set out in a general food law (Regulation (EC) No. 178/2002).*"

<sup>478</sup> According to recital 15 of Animal Health Law, "*[t]he risk assessment on the basis of which the measures under this Regulation are taken should be based on the available scientific evidence and undertaken in an independent, objective and transparent manner. Due account should also be taken of the opinions of the European Food Safety Authority (EFSA) established by Article 22(1) of Regulation (EC) No 178/2002 of the European Parliament and of the Council*".

<sup>479</sup> See also General GFL study, at pp. 186-187.

<sup>480</sup> Article 113(2) of Regulation (EU) 2017/625 on official controls and other official activities.

<sup>481</sup> Initiative to Improve the Food Supply Chain – Consultation Strategy, July 2017, European Commission, to be found at: [https://ec.europa.eu/info/sites/info/files/2017\\_07\\_31\\_consultation\\_strategy\\_en.pdf](https://ec.europa.eu/info/sites/info/files/2017_07_31_consultation_strategy_en.pdf); Inception Impact Assessment (IIA) on an initiative to "Improve the Functioning of the Food Supply Chain", European Commission, published on 26 July 2017, to be found at: [https://ec.europa.eu/info/news/inception-impact-assessment-food-supply-chain-published\\_en](https://ec.europa.eu/info/news/inception-impact-assessment-food-supply-chain-published_en). See also Commission Work Programme 2017, Delivering a Europe that protects, empowers and defends, COM(2016) 710 final, dated 24.10.2016, to be found at: [https://ec.europa.eu/info/sites/info/files/cwp\\_2017\\_en.pdf](https://ec.europa.eu/info/sites/info/files/cwp_2017_en.pdf).