APPENDIX 5 – THE GENERAL GFL STUDY

ANNEX 5A

On-line survey questionnaire to stakeholders



Evaluation of Regulation (EC) No 178/2002, the General Food Law

On-line survey questionnaire to stakeholders

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Introduction

The evaluation of Regulation (EC) No 178/2002, the "General Food Law" (GFL), forms part of the Commission's Regulatory Fitness and Performance Programme (REFIT)¹, in particular the fitness check of the General Food Law. This study is being carried out for the European Commission by the Food Chain Evaluation Consortium (FCEC) and is managed by Agra CEAS Consulting.

The ultimate aim of this survey is to collect data to feed into the analysis of the evaluation questions as outlined in the Terms of Reference (ToR) for the evaluation of the GFL. The purpose of the evaluation is to assess whether the regulatory framework established by the GFL (Regulation (EC) No 178/2002) is effective and efficient and provides added value to stakeholders, so as to establish whether the GFL continues to be 'fit for purpose'. The information and assessments provided in your responses to this questionnaire will be crucial in assessing the relevance, effectiveness, efficiency, coherence and added value of this regulatory framework and in informing the EU policy process. For this reason we highly appreciate you taking the time to respond to this survey.

This questionnaire is targeted at key stakeholders involved in the GFL, including organisations representing business operators of the entire feed and food supply chains from 'farm to table', other sectors of relevance, international organisations, relevant government bodies in third countries and consumer organisations, both at EU and national level. Please note that a separate complementary survey, using a similar questionnaire, will be carried out at the level of Member State Competent Authorities. In your answers, please express **your expert opinion based on the actual experience** with the GFL of the organisation/s that you represent. EU-level stakeholders should refer to the situation across the EU, and note any limitations in geographic coverage in the comment fields if needed. National stakeholders should refer to the situation in their own country, unless otherwise asked by the question.

A distinction is made between the GFL as such and secondary legislation that is based on the GFL. 'Secondary legislation' means all legislative (or non-legislative) texts that are enshrined in the scope of the GFL. The present study is an evaluation of the General Food Law (Regulation (EC) No 178/2002); it is not an evaluation of the entire food and feed law or of individual areas of secondary legislation. However, this Regulation is a framework and as such it contains general provisions and definitions, general principles, general obligations and general requirements. Some Articles stand alone because they provide for requirements directly imposed on food/feed business operators (FBOs), in particular the provisions relating to traceability (Article 18) and requirements for recalls/withdrawals (Article 19). Where the principles and general requirements set out in the GFL only become effective through implementation via secondary legislation, the relevant parts of this secondary legislation will be examined within the scope of this evaluation. The general objectives and principles such as the risk analysis (Article

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¹ http://ec.europa.eu/smart-regulation/refit/index_en.htm

6), the precautionary principle (Article 7) and the principles of transparency (Articles 9 and 10) form a general framework to be followed when measures are taken by EU and national Competent Authorities (Article 4(2)). Indicatively, in application of the risk analysis principle, subsequent secondary EU food and feed legislation had to include specific procedures ensuring a prior independent scientific assessment of the relevant risks (*e.g.* authorisation procedures).

Some of the general obligations foreseen by the GFL, such as the general obligation of food/feed safety (Articles 14 and 15) and the responsibility of business operators at all stages of the supply chain to ensure that food/feed complies with the requirements of food law and to verify that such requirements are met (Article 17.1) are also a basis for subsequent secondary EU food/feed legislation (e.g. HACCP requirement introduced by Regulation (EC) No 852/2004 on the hygiene of foodstuffs).

A number of questions thus refer to **secondary legislation** stemming from the GFL. Key areas of secondary legislation relevant to the purposes of this evaluation are the following:

- Food hygiene
- GMOs
- Novel foods
- Food for specific groups (foods for infants and young children, total diet replacement for weight control, foods for medical purposes)
- Addition of vitamins, minerals and other substances to foods
- Irradiation
- Food labelling
- Contaminants
- Food improvement agents (food additives, flavourings and enzymes)
- Food contact materials
- Maximum residue limits for plant protection products
- Feed hygiene
- Feed additives
- Feed labelling

In this questionnaire, where reference is made to a specific article of the GFL, please consult the GFL Regulation in the link below:

http://eur-

lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:031:0001:0024:EN:PDF

Please consult the Commission's guidance on the implementation of Articles 11, 12, 14, 17, 18, 19 and 20 of Regulation (EC) No 178/2002 on general food law.

http://ec.europa.eu/food/food/foodlaw/guidance/docs/guidance_rev_8_en.pdf

Similarly, please refer to the DG SANTE website for any reference to the EU legislative texts applicable in the various areas of secondary legislation:

http://ec.europa.eu/food/food/index_en.htm

The scope of this evaluation is limited to Articles 1-21 of the GFL. It excludes the Articles covering the European Food Safety Authority (Articles 22-49; EFSA has already been evaluated), and the Rapid Alert System for Food and Feed (RASFF) and crisis management procedures (Articles 50-57) which are being evaluated in parallel in a <u>separate</u> study also mandated by DG SANTE.

The GFL evaluation will coordinate closely to avoid any potential overlap with these two studies. This is facilitated by the fact that these studies are also being carried out by the Food Chain Evaluation Consortium under the management of different FCEC partners.

The **time period** covered by the evaluation of the General Food Law is **2002-2013**. Please keep this timeframe in mind when answering any of the questions of this survey.

Please submit the completed questionnaire on line, no later than 27 March 2015.

Instructions for completing the questionnaire

This questionnaire is comprised of closed, mostly multiple-answer, questions, of two types:

- yes/no questions, where a tick means that you agree with the statement;
- scoring questions, where you are required to score your position on a scale from 1 to 5. In general terms, unless otherwise indicated in the question, the scoring scale is to be interpreted as follows: 1 = not at all/totally negative response, 5 = fully/totally positive response, with 3 = a middle or average position, e.g. more or less achieved/effective/relevant, etc.

While this is the general rule, more detailed instructions are provided for each question to guide your answers. Answers to some questions are compulsory, in which case you will not be able to move on to the next question if answers are missing. A "don't know" answer is available for each question, although we encourage respondents to always provide an actual answer to the extent possible. Most questions are followed by a **comment box** for any specific examples, evidence or comments you may have on the specific issue covered. Comment boxes may also be used to indicate the caveats, if any, related to your answers. Please fill in free text every time you see "+ Comment box". The on-line survey offers comment boxes to provide your free text answers.

Please note that the host platform does not allow you to save your responses and go back to the questionnaire at a later stage. Therefore we strongly recommend that you <u>fill in the survey</u> <u>online only when all replies are ready</u> so that you complete the questionnaire in one session, otherwise you may lose all previous answers.

In addition, most questions are likely to require an **internal consultation within your organisation**, therefore please ensure that you allocate sufficient time to enable this consultation to take place and to prepare your replies.

EU-level organisations are encouraged to distribute this questionnaire to their national members and to organise internally their method of response, i.e. whether they wish to provide a coordinated response on behalf of their members or individual responses from their national members or both; it is noted that **this on-line survey is open only to associations and not individual companies**².

To facilitate your response, we have also provided a Word version of this questionnaire to use in your consultation with the relevant services/departments within your organisation or other relevant organisations, prior to filling in the on-line questionnaire. Please note that <u>your response to this questionnaire needs to be submitted online</u> (Word versions of the questionnaire will not be accepted).

The Food Chain Evaluation Consortium (Agra CEAS Consulting)

² SMEs will be consulted on this evaluation via the Europe Enterprise Network SME Panel.

Data protection: All data collected through the survey will be used by the FCEC for the purposes of statistical analysis for the present study. The confidentiality of your responses and statements is guaranteed in the sense that only aggregated statistical data will be published and that you will not be personally identified as having responded to the questionnaire, unless you explicitly wish your organisation to be identified as such. Please note that in the use of the data collected, we conform to our contractual obligations with regards to personal data protection within the **FWC 2013-2017 Framework Contracts for evaluation, impact assessment and related services**³.

List of acronyms and terminology:

- Art.: Article of the General Food Law (Regulation (EC) No 178/2002)
- EU: European Union
- FBOs: feed/food business operators (as defined in Article 3 of the General Food Law)
- 'food law': means law governing any stage of production, processing and distribution of food and feed.
- FCEC: Food Chain Evaluation Consortium
- GFL: General Food Law (Regulation (EC) No 178/2002)
- HACCP: Hazard Analysis of Critical Control Points
- MS CAs: Member State Competent Authority/ies
- SMEs: Small and Medium Enterprises
- ToR: Terms of Reference of the evaluation of the General Food Law (Regulation (EC) No 178/2002)

THE FCEC THANKS YOU IN ADVANCE FOR YOUR COOPERATION

³ In line with these obligations, after having finalised the analysis of the answers to surveys and interviews and prepared reports, we are instructed to transfer all raw data to the European Commission without personal references. We are requested to erase in all the material the personal data of the respondents collected during the fieldwork, meaning the contact details, names, countries, addresses, and ages. The answers to the surveys and the personal data

potentially contained in the contributions should during the performance of our contractual obligations only be

accessed by the experts listed in our team as part of the staff executing the contract.

Identification data

1	NT C	• ,•	
	Name of v	vour organication:	
1.	1 valifie of	your organisation.	

2. Sector of activities:

Feed	
Food	
Other (e.g. transporters, food contact materials producers) <i>please specify</i>	

3. Stage in the supply chain:

Agricultural input production	
Feed production	
Agricultural production	
Primary processing	
Secondary and further processing stages	
Transport	
Wholesale/Trading/Brokerage/Distribution (B2B)	
Retailer (B2C)	
Consumers	
Other, please specify	

4. Geographical location:

EU-28	
Non-EU	
Austria	
Belgium	
Bulgaria	
Croatia	
Cyprus	
Czech Republic	
Denmark	
Estonia	
Finland	
France	
Germany	
Greece	

Hungary	
Italy	
Ireland	
Latvia	
Lithuania	
Luxemburg	
Malta	
Netherlands	
Poland	
Portugal	
Romania	
Slovenia	
Slovakia	
Spain	
Sweden	
United Kingdom	

1 Objectives of the GFL

5. To what extent has the general horizontal framework introduced by the GFL and its implementation/application at EU/national level contributed to achieving the following core objectives of the GFL? *To score on a scale 1-5 (1=not achieved; 5=fully achieved)*

	1	2	3	4	5	Don't know
Protection of human life/health						
Protection of consumer interests						
Free movement of food in the internal market						
Free movement of feed in the internal market						

⁺ Comment box for justifications

Please fill in free text every time you see "+ Comment box". The on-line survey offers comment boxes to provide your free text answers.

6. To what extent is the general horizontal framework introduced by the GFL adequate to address:

(a) - Other objectives/needs? To score on a scale 1-5 (1=not adequate; 5=fully adequate)

	1	2	3	4	5	Don't know
Innovation potential of the food chain						
Consuming healthier food / nutritional needs of general population						
Competitiveness of the food supply chain						
Other: please specify						

⁺ Comment box, to specify other objectives/needs

(b) - Specific trends of today? *To score on a scale 1-5 (1=not adequate; 5=fully adequate)*

	1	2	3	4	5	Don't know
Sustainability/food waste						
Food quality						
Food availability						
Distance selling, including e-commerce						
Globalisation of trade						
Other: please specify						

⁺ Comment box, to specify other trends of today

2 Scope and definitions

Introduction

This section refers to the scope and definitions of the GFL as laid down in Articles 1 to 4: Articles 1 and 4 provide the scope of the GFL; Article 2 provides the definition of food; Article 3 provides other definitions.

7.

(a) To what extent have the scope and general definitions of the GFL been **sufficiently broad** to ensure an integrated approach to food/feed safety management? *To score on a* scale 1-5 (1= not sufficiently broad; 5=fully sufficiently broad)

(33	1	2	3	4	5	Don't know
Definition of food (Art. 2)						
Food business operator (Art 3.3)						
Definition of feed (Art. 3.4)						
Feed business operator (Art. 3.6)						
Retail (Art. 3.7)						
Placing on the market (Art. 3.8)						
Risk (Art. 3.9)						
Hazard (Art. 3.14)						
Other definitions of Art. 3: please specify						
Scope (Art. 1 and 4)						

⁺ Comment box, to specify cases where it has been/has not been sufficiently broad to ensure an integrated approach to food/feed safety management

(b) To what extent have the scope and general definitions of the GFL been **relevant** to address the objectives of food law (EU/national), *i.e.* high level of protection of human health and consumers' interest and the effective functioning of the internal market? *To score on a scale 1-5 (1= not relevant; 5=fully relevant)*

	1	2	3	4	5	Don't know
Definition of food (Art. 2)						
Food business operator (Art 3.3)						
Definition of feed (Art. 3.4)						
Feed business operator (Art. 3.6)						
Retail (Art. 3.7)						
Placing on the market (Art. 3.8)						
Risk (Art. 3.9)						
Hazard (Art. 3.14)						
Other definitions of Art. 3: please specify						
Scope (Art. 1 and 4)						

+ Comment box, to identify any areas/aspects that are missing. For example, other general definitions that could be included in the GFL to avoid duplication or inconsistencies throughout EU and national food law

3 GFL requirements and responsibilities

3.1 Core requirements and responsibilities for food/feed business operators

Introduction

This section refers to the following **core requirements/responsibilities** set out in the GFL for FBOs to:

- place only safe food/feed on the market (compliant with food/feed safety legislation) (Articles 14, 15) and verify that food/feed is compliant with food/feed law (EU/national provisions) (Article 17.1);
- establish one step back one step forward traceability at all stages of production, processing and distribution (Article 18);
- withdraw/recall food/feed at risk (Article 19.1, 19.2, 20.1 and 20.2);
- notify public authorities in case food/feed considered at risk (Articles 19.3 and 20.3); and,
- collaborate with public authorities on actions taken to avoid or reduce risk (Articles 19.4 and 20.4).
- 8. To what extent have the core requirements/responsibilities imposed by the GFL on food/feed business operators (FBOs) achieved the following outcomes? *To score on a scale 1-5 (1=not achieved; 5=fully achieved)*
 - (a) The requirement to place safe food/feed on the market and verify that food/feed is compliant with food law has ...

	1	2	3	4	5	Don't know
Entailed a fair and proportionate burden on FBOs						
Contributed to improving cooperation between public authorities and FBOs						
Contributed to fit for purpose withdrawals and recalls						
Ensured a high level of protection of consumer's health						
Ensured consumer confidence/trust in food/feed						
Other, please specify						

⁺ Comment box, to provide examples where these outcomes have been/not been achieved

(b) The requirement to establish one step back - one step forward traceability has ...

	1	2	3	4	5	Don't
						know

	1	2	3	4	5	Don't know
Entailed a fair and proportionate burden on FBOs						
Contributed to improving cooperation between public authorities and FBOs						
Contributed to fit for purpose withdrawals and recalls						
Ensured a high level of protection of consumer's health						
Ensured consumer confidence/trust in food/feed						
Other, please specify						

⁺ Comment box, to provide examples where these outcomes have been/not been achieved

(c) The requirements of the GFL on withdrawals/recalls of food/feed at risk have ...

	1	2	3	4	5	Don't know
Entailed a fair and proportionate burden on FBOs						
Contributed to improving cooperation between public authorities and FBOs						
Contributed to fit for purpose withdrawals and recalls						
Ensured a high level of protection of consumer's health						
Ensured consumer confidence/trust in food/feed						
Other, please specify						

⁺ Comment box, to provide examples where these outcomes have been/not been achieved

(d) The requirement to notify public authorities in case food/feed considered at risk has ...

	1	2	3	4	5	Don't know
Entailed a fair and proportionate burden on FBOs						
Contributed to improving cooperation between public authorities and FBOs						
Contributed to fit for purpose withdrawals and recalls						
Ensured a high level of protection of consumer's health						
Ensured consumer confidence/trust in food/feed						
Other, please specify						

⁺ Comment box, to provide examples where these outcomes have been/not been achieved

(e) The requirement to collaborate with public authorities on actions taken to avoid or reduce risk has ...

	1	2	3	4	5	Don't know
Entailed a fair and proportionate burden on FBOs						
Contributed to improving cooperation between public authorities and FBOs						
Contributed to fit for purpose withdrawals and recalls						

Ensured a high level of protection of consumer's health						
	1	2	3	4	5	Don't know
Ensured consumer confidence/trust in food/feed						
Other, please specify						

⁺ Comment box, to provide examples where these outcomes have been/not been achieved

3.2 Food/feed safety requirements

Introduction

Article 14 of the GFL prohibits food being placed on the EU market if it is unsafe. Food is 'unsafe' if it is:

- Injurious to health; or
- Unfit for human consumption.

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

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

- 9. The GFL imposes a general obligation on economic operators to market only food/feed that is safe. For this purpose, it sets out specific basic considerations (see introduction above) for establishing whether a food/feed is safe. In this context:
 - (a) Which of the following considerations have been relevant for protecting consumers' health?

i. To determine whether FOOD is unsafe	Relevant	Not	Don't
		relevant	know
Short- and long-term effects of consuming a specific food			
Probable cumulative toxic effect			
Particular health sensitivities of a specific category of consumers when the food is intended for that category of consumers			
Unacceptability of a food for human consumption			

+ Comment box to justify on what basis the above considerations are relevant/not relevant

ii. To determine whether FEED is unsafe	Relevant	Not relevant	Don't know
Adverse effect of a feed on human or animal health			
Food derived from food-producing animals unsafe for human consumption			

⁺ Comment box to justify on what basis the above considerations are relevant/not relevant

(b) Are there any other considerations that are relevant in protecting consumers' health?

	Yes	No	Don't know
Other considerations?			

⁺ Comment box to specify other potential considerations and justify why these are relevant

(c) To what extent have the following considerations contributed to the effective functioning of the internal market? To score on a scale 1-5 (I = have not contributed; 5 = fully contributed)

i. To determine whether FOOD is unsafe	1	2	3	4	5	Don't know
Short- and long-term effects of consuming a specific food						
Probable cumulative toxic effect						
Particular health sensitivities of a specific category of consumers when the food is intended for that category of consumers						
Unacceptability of a food for human consumption						

⁺ Comment box to provide examples of cases where the above considerations have contributed/not contributed to the effective functioning of the internal market

ii. To determine whether FEED is unsafe	1	2	3	4	5	Don't know
Adverse effect of a feed on human or animal health						
Food derived from food-producing animals unsafe for human consumption						

⁺ Comment box to provide examples of cases where the above considerations have contributed/not contributed to the effective functioning of the internal market

- 10. The GFL stipulates that food/feed that complies with EU food/feed safety legislation (including provisions laid down in secondary legislation) is <u>deemed</u> safe (Articles 14.7 for food, and 15.4 for feed). In this context:
 - (a) To what extent has the presumption that food compliant with EU food/feed legislation is safe proved to be **effective** in protecting consumers' health in the areas listed below? *To score on a scale 1-5 (1= not effective; 5=fully effective)*

1	2	3	4	5	Don't know
1	2	3	4	5	Don't know
	1				

⁺ Comment box to provide examples of cases where the legal presumption has proved/not proved effective in protecting consumers' health

(b) To what extent the presumption that food compliant with EU food/feed legislation is safe increased or decreased **administrative burden** for business operators in the areas listed below? To score on a scale 1-5 (1= burden considerably increased; 3= no change; 5=burden considerably decreased) Note: for definition of administrative burden, please see introduction to Section 7 "Administrative costs and burden".

	1	2	3	4	5	Don't know
Food improvement agents (additives, enzymes and flavourings)						
GMOs						
Addition of vitamins, minerals and other substances to foods						
Feed (feed labelling, feed additives, feed hygiene)						
Novel foods						
Hygiene of foodstuffs						
Foods for specific groups (i.e. foods for infants and young children, total diet replacement for weight control., foods for special medical purposes)						
Other, specify						

⁺ Comment box to provide examples of cases where the legal presumption has increased/decreased administrative burden

3.3 Allocation of responsibilities

Introduction

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

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

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

11. Has the allocation of responsibilities along the food chain as laid down in Article 17 achieved the following outcomes? To score on a scale 1-5 (1=not achieved; 5=fully achieved)

	1	2	3	4	5	Don't know
Contributed to a high level of protection of human health and consumers' interests as regards feed/food products placed on the market						
Facilitated the placing on the market of feed/food products						
Contributed to the effective functioning of the internal market						
Ensured a fair and clear distribution of responsibilities amongst feed/food business operators along the 'farm to table' supply chain						
Ensured a fair and clear distribution of responsibilities between feed/food business operators and Member State Competent Authorities						
Reduced administrative burden (e.g. by avoiding unnecessary repetition of operators' self controls along the 'farm to table' supply chain)						
Freed up resources at Member State Competent Authorities' level to focus on the enforcement of feed/food law						
Strengthened 'trust' along the 'farm to table' supply chain						
Ensured a consistent implementation of the 'farm to table' policy						
Created a level playing field for all feed/food business operators in the EU						

⁺ Comment box, to provide examples

12. To what extent have feed/food business operators at all stages of production, processing and distribution been verifying (e.g. via their own internal controls) that the feed/food law requirements (set out at EU and national level) which are relevant to their activities are met? To score on a scale 1-5 (1=do not verify; 5=fully verify)

	1	2	3	4	5	Don't know
Food/feed business operators at the stage of production						
	1	2	3	4	5	Don't know
Food/feed business operators at the stage of processing						
Food/feed business operators at the stage of distribution						
Importers of food and feed into the EU						
Transporters of food and feed						
Other, please specify						

⁺ Comment box to indicate how operators conduct verification (e.g. via their own internal controls), and reasons why some operators may not conduct verification

13. To what extent have the above benefits resulting from the primary responsibility provisions of the GFL outweighed the costs of meeting this requirement (e.g. via own internal controls)?

	Tick
Benefits have considerably outweighed costs	
Benefits have more or less outweighed costs (break even)	
Benefits have not for the most part outweighed costs	
Don't know	

⁺ Comment box, to identify any data on the annual costs of meeting this requirement (e.g. costs as % of total production costs?), or the estimated cost-benefit ratio

3.4 Traceability requirements

Introduction

Article 18 of GFL establishes rules on traceability for food/feed safety purposes. It requires FBOs (a) to be able to identify <u>from whom</u> and <u>to whom</u> a food/feed/food-producing animal/any other substance intended to be (or expected to be incorporated into a food/feed has been supplied ("<u>one step back – one step forward</u>" approach) and (b) to have <u>systems and procedures</u> in place that allow this information to be made available to the competent authorities upon request.

14. To what extent did your members apply one step back – one step forward traceability, as outlined in Article 18, prior to the introduction of this requirement by the GFL?

	Tick
Yes (always/ in most cases)	
Yes, but not systematically	
Only rarely	
Never	
Don't know	

- + Comment box, to highlight any examples of the application of one step back one step forward traceability prior to the GFL obligation
- 15. To what extent has the requirement to implement one step back one step forward traceability in the supply chain, as outlined in Article 18, improved tracing of food/feed for food/feed safety purposes in the EU, compared to the situation prior to the GFL? *To score on a scale 1-5 (1=not improved; 5=fully improved)*

	1	2	3	4	5	Don't know
Traceability for food safety						
Traceability for feed safety						

- + Comment box, to highlight any examples of improvement of the tracing of food/feed compared to the situation prior to the GFL
- 16. To what extent has the general traceability requirement of Article 18 of GFL ("one step back one step forward" approach and own systems/procedures in place to provide relevant information to the competent authorities) achieved the following outcomes? *To score on a scale 1-5 (1=not achieved; 5=fully achieved)*

	1	2	3	4	5	Don't know
Assists in containing a food/feed safety problem						
Assists in containing/addressing a non-compliance problem with food/feed legislation (not safety-related)						
Ensures fair trading amongst FBOs						
Ensures the reliability of information supplied to consumers for controls purposes (<i>i.e.</i> FBOs have to substantiate their claims to consumers)						
Ensures effective tracing of feed/food across the full 'farm to table' supply chain in the EU						
Ensures efficient (i.e. at lowest possible administrative burden) tracing of						
food/feed across the full supply chain in the EU 'from farm to table'						
Facilitates risk identification						
Ensures effective and efficient targeted withdrawals/ recalls of unsafe food/feed						
Avoids/limits unnecessary disruption of trade						
Contributes to maintain consumer trust and confidence to the safety of a food/feed						
Other, please specify						

⁺ Comment box, to highlight any examples of the achievement of the above outcomes

17. To what extent have the above benefits resulting from the traceability requirement (one step back – one step forward approach) outweighed the costs of setting up and operating traceability systems, as required by the GFL?

	Tick
Benefits have considerably outweighed costs	
Benefits have more or less outweighed costs (break even)	
Benefits have not for the most part outweighed costs	
Don't know	

⁺ Comment box, to identify any data on the annual costs of traceability (e.g. traceability costs as % of total production costs?), or the estimated traceability cost-benefit ratio

3.5 Withdrawals and recalls

Introduction

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

Withdrawal is the process by which a product is removed from the supply chain, with the exception of a production that is in the possession of consumers.

Recall is the process by which consumers are asked to take the product back to the place of purchase or destroy it.

18. Have your members sought assistance from the competent authorities in the case of withdrawals and recalls? Have competent authorities provided your members with the necessary assistance in the case of withdrawals and recalls?

	Yes (always/ in most cases)	Yes, but not systematically	Only rarely	Never	Don't know
Have your members sought assistance from CAs?					
Have CAs provided your members with the necessary assistance?					

⁺ Comment box when this has not been the case

19. To what extent have the combined application of the provisions on determining the safety of feed/food, both in terms of traceability and withdrawals/recalls, achieved the following outcomes: *To score on a scale 1-5 (1=not achieved; 5=fully achieved)*

			, .	-		,
	1	2	3	4	5	Don't know
Ensured targeted withdrawals/recalls of unsafe food/feed						
Resulted in withdrawals/recalls of safe food/feed						
Avoided disruption of trade						

Restored consumer confidence/trust in food						
Ensured a high level of protection of consumers' health						
	1	2	3	4	5	Don't know
Other, please specify						

⁺ Comment box to justify answers

4 International trade

Introduction

Article 11 of GFL requires food and feed <u>imported into the EU</u> to comply with the EU requirements (also to be found in sectoral legislation) or to provisions considered equivalent to those or to requirements contained in specific agreements. Article 12 of GFL requires food/feed <u>exported/re-exported from the EU</u> to a third country to comply with EU requirements or with the requirements of the third country. In other circumstances, except in the case of food injurious to health or unsafe feed, food/feed can only be exported/re-exported if the competent authorities of the third country of destination have expressly agreed.

Note: The following questions refer to the impact of the GFL core responsibilities/requirements as such on the imports of food/feed into the EU and the international competitiveness of EU food/feed.

20. To what extent has the GFL influenced, positively or negatively, the following aspects of EU imports of feed/food from third countries? *To score on a scale 1-5 (1=very negative; 2=negative; 3=neutral; 4=positive; 5=very positive)*

	1	2	3	4	5	Don't know
Quantity of imports						
Quality/safety of imports						
Consumer trust and confidence in imported feed/food						
Business trust and confidence in imported feed/food						
Acceptance/use of EU standards in international trade						
Avoiding/limiting the impact of a feed/food crisis in the EU						
Other (please specify)						

⁺ Comment box, to identify cases where the GFL has influenced, positively or negatively, any of the listed outcomes, and resulting benefits/losses incurred in terms of increased/decreased import value/volume, diversification of sourcing etc. Please report both any positive and any negative impacts of the GFL in terms of EU imports of feed/food from third countries

21. To what extent has the GFL influenced, positively or negatively, the following aspects of EU exports of feed/food to third countries? *To score on a scale 1-5 (1=very negative; 2=negative; 3=neutral; 4=positive; 5=very positive)*

	1	2	3	4	5	Don't know
	1	2	3	4	5	Don't know
	1	2	3	4	5	Don't know
Quantity of exports						
Quality/safety of exports						
Consumer trust and confidence in EU exported feed/food						
Business trust and confidence in exported feed/food						
Acceptance/use of EU standards in international trade						
Avoiding/limiting the impact of a feed/food crisis on international trade						
Competitiveness of EU feed/food exports in international markets						
Other (please specify)						

⁺ Comment box, to identify cases where the GFL has influenced, positively or negatively, any of the listed outcomes, and resulting benefits/losses incurred in terms of increased/decreased export value/volume, geographical presence etc. Please report both any positive and any negative impacts of the GFL in terms of EU exports of feed/food to third countries

5 Risk analysis and precautionary principle

Introduction

The GFL (Article 6) requires that national and EU measures on feed/food should be based on risk analysis, except where this is not appropriate to the circumstances or the nature of the measure. Risk analysis is composed of three elements: (a) risk assessment, which is to be carried out in an independent, objective and transparent manner on the basis of available scientific information and data, (b) risk management which takes into account the risk assessment as well as other legitimate factors and, where relevant, the precautionary principle, and (c) risk communication. The precautionary principle (Article 7) should be triggered in specific circumstances where a risk to life or health exists and there is scientific uncertainty.

22. To what extent have EU measures on feed and food been adopted on the basis of a risk analysis, as laid down in Article 6?

	Tick
Yes (always/ in most cases)	
Yes, but not systematically	
Only rarely	
Never	
Don't know	

⁺ Comment box to identify and provide examples of EU measures that have <u>not</u> been adopted on the basis of a risk analysis

23. To what extent have national (Member State) measures on feed and food been adopted on the basis of a risk analysis, as laid down in Article 6?

	Tick
Yes (always/ in most cases)	
Yes, but not systematically	
Only rarely	
Never	
Don't know	

⁺ Comment box, to identify and provide examples of national measures taken by Member States that have <u>not</u> been adopted on the basis of a risk analysis

24. Where national and EU measures on feed/food have been adopted on the basis of a risk analysis, to what extent have the following outcomes been achieved? *To score on a scale 1-5* (1=not achieved; 5=fully achieved)

(1-noi achievea, 5-juny achievea)						
	1	2	3	4	5	Don't know
Unjustified barriers to the free movement of feed/food have been avoided in the case of EU measures						
EU measures have been effective						
EU measures have been proportionate						
EU measures/actions have been targeted to protect health						
Unjustified barriers to the free movement of feed/food have been avoided in the case of national measures						
National measures have been effective						
National measures have been proportionate						
National measures/actions have been targeted to protect health						
Other (please specify)						

⁺ Comment box to identify and provide examples of cases where EU/national measures that have been adopted on the basis of a risk analysis have achieved or not achieved any of the above outcomes. Please report both any positive and any negative impacts of EU/national measures

25. To what extent has the precautionary principle been applied correctly? *To score on a scale* 1-5 (1=not correctly applied; 5=correctly applied)

		11 /				
	1	2	3	4	5	Don't know
EU level						
National level						

⁺Comment box to identify any cases of national measures taken where the precautionary principle has not been applied correctly

6 Transparency

6.1 Public consultation

- 26. To what extent has there been an open and transparent public consultation for EU feed/food legislation, during the following phases of its development?
 - (a) Open and transparent public consultation during **preparation** of EU legislation

	Tick
Yes (always/ in most cases)	
Yes, but not systematically - Justify your answer	
Only rarely - Justify your answer	
Never - Justify your answer	
Don't know	

⁺ Comment box, to justify negative answers

(b) Open and transparent public consultation during evaluation of EU legislation

	Tick
Yes (always/ in most cases)	
Yes, but not systematically - Justify your answer	
Only rarely - Justify your answer	
Never - Justify your answer	
Don't know	

⁺ Comment box, to justify negative answers

(c) Open and transparent public consultation during **revision** of EU legislation

	Tick
Yes (always/ in most cases)	
Yes, but not systematically - Justify your answer	
Only rarely - Justify your answer	
Never - Justify your answer	
Don't know	

⁺ Comment box, to justify negative answers

27. To what extent has there been an open and transparent public consultation for national feed/food legislation, during the following phases of its development? For national organisations: please reply with regards to measures taken in your Member State.

(a) Open and transparent public consultation during **preparation** of national legislation

	Tick
Yes (always/ in most cases)	

Yes, but not systematically - Justify your answer	
Only rarely - Justify your answer	
Never - Justify your answer	
Don't know	

⁺ Comment box, to justify negative answers

(b) Open and transparent public consultation during evaluation of national legislation

	Tick
Yes (always/ in most cases)	
Yes, but not systematically - Justify your answer	
Only rarely - Justify your answer	
Never - Justify your answer	
Don't know	

⁺ Comment box, to justify negative answers

(c) Open and transparent public consultation during **revision** of national legislation

	Tick
Yes (always/ in most cases)	
Yes, but not systematically - Justify your answer	
Only rarely - Justify your answer	
Never - Justify your answer	
Don't know	

⁺ Comment box, to justify negative answers

28. To what extent have your members been sufficiently consulted by the national CAs during the preparation, evaluation and revision of food/feed legislation at EU or national level? Sufficient = your input has been sought in a structured manner and has been taken into account by the CAs in a balanced way. To score on a scale 1-5 (1=not sufficiently consulted; 5=fully sufficiently consulted)

	1	2	3	4	5	Don't know
Preparation of new legislation						
Evaluation and revision of existing legislation						

⁺ Comment box to identify any cases where feed/food business operators have not been sufficiently consulted

6.2 Public information

Introduction

Article 10 of GFL obliges national authorities to inform the general public where there are reasonable grounds to suspect that a food or feed may present a risk to human or animal health.

29. To what extent has the process of risk information improved over time, in particular taking into account lessons learnt from previous crises (e.g. dioxin, *E. coli*, etc.)?

	Tick
Yes, considerably	
Yes, to some extent	
Only to a limited extent	
Not at all	
Don't know	

⁺ Comment box, to identify cases of continuing failure in risk communication, and impact of these cases

30. In the case of recalls that have occurred in the last five years in your country, to what extent communicating to the public that a food/feed may present a risk for human or animal health has had an impact, positive or negative, in terms of the following aspects? To score on a scale 1-5 (1=very negative; 2=negative; 3=neutral; 4=positive; 5=very positive)

, , ,	_	<u> </u>	_			
	1	2	3	4	5	Don't know
Consumer confidence/trust						
Preventing/managing food and feed crises						
Limiting unnecessary disruption of trade						
Limiting financial damage						
Other (please specify)						

⁺ Comment box to justify the answer given

7 Administrative costs and burden for food/feed business operators

Introduction

Administrative costs are defined as the costs incurred by economic operators in meeting the legal obligations stemming from the GFL, and secondary legislation based on the GFL, to provide information in the context of these obligations, either to public authorities or to private parties. Information is understood in a broad sense, i.e. including labelling, reporting, registration, monitoring and assessment needed to provide the information (see next question on types of information obligations).

In some cases, the information has to be transferred to public authorities or private parties. In others, it only has to be available for inspection or to be supplied on request. These costs include:

- Recurring administrative costs; and,
- Where significant, one-off administrative costs.

The administrative costs include business-as-usual (BAU) costs and administrative burdens. The business-as-usual costs correspond to the costs resulting from collecting and processing information which would be done in any case, even in the absence of the legislation e.g. having a book-keeping system. The administrative burdens stem from the part of the process which is done solely because of a legal obligation stemming from the GFL, e.g. adjusting an existing book-keeping system, or changing the book-keeping system, in order to be able to provide information to meet a legal obligation required by the GFL and secondary legislation based on the GFL. In the questions below, a distinction should be made between costs to provide information that would be collected and processed by businesses even in the absence of the legislation (which generates **BAU costs excluded from the analysis**) and information that is solely collected because of the legal obligation (which generates administrative burdens).

31. What have been, typically, the most burdensome Information Obligations (IOs) stemming from the provisions of EU food law (i.e. the GFL and secondary legislation based on the GFL)?

Please <u>rank the most burdensome IOs</u>, in terms of the administrative actions typically involved to fulfil these obligations and associated administrative costs (excluding BAU costs). Please start by ranking the most burdensome of all IOs (this should rank #1), followed by the second most burdensome (rank #2), and so on.

Information Obligation	Rank
	(based
	on costs)
Notification of (specific) activities or events stemming from the GFL, e.g.	
information on traceability made available to CAs on demand (GFL Art. 18.2	
and 18.3); notifying CAs when reasons to believe food injurious to health (GFL	
Art. 19.3) or feed placed on the market may not satisfy the feed safety	
requirements (GFL Art. 20.3)	
Notification of (specific) activities or events stemming from secondary	
legislation**	
Submission of (recurring) reports**	
Information labelling for third parties	
Information, other than labelling, for third parties	
Application for individual authorisation or exemption**	
Application for general authorisation or exemption	
Registration**	

Information Obligation	Rank
	(based
	on costs)
Certification of products or processes**	
Cooperation with audits and inspection by public authorities (GFL), e.g. ad hoc	
inspections in the context of the GFL Art. 19 and 20	
Cooperation with audits and inspection by public authorities (secondary	
legislation), e.g. regular inspections in the context of secondary legislation on	
official controls (Regulation (EC) 882/2004)**	

Note: The information obligations will imply various administrative actions including: familiarisation with IOs; record keeping; staff training; putting into place ICT systems and equipment etc. The costs associated to these activities should exclude business-as-usual (BAU) costs, i.e. costs that would have been incurred anyway, even in the absence of the information obligation.

- ** There is no direct provision on this in the GFL. This is generated by secondary legislation, e.g. registration of operators in the context of hygiene rules (Hygiene Package).
- + Comment box to provide example or comments on the ranking of Information Obligations
- 32. What have been, typically, the current administrative costs of EU food law (i.e. the GFL and secondary legislation based on the GFL)? Please estimate the costs typically involved, in % of total operational costs and in % of total staff numbers, by size of company, excluding business-as-usual (BAU) costs. In view of the range of companies your organisation may represent, please indicate the typical costs involved, on average, for representative companies in your sector, depending also on their size.

	Micro	Small	Medium	Large
Total annual administrative costs, including training, as % of total operational costs				
Total number of FTEs involved, as % of total number of FTEs				

Note: the survey offers, for each cell in the table above, a drop-down menu to choose between: 0-5%; 5-10%; 10-20%; >20%.

- + Comment box for justifications, evidence and/or to highlight any caveats or constraints related to your answer
- 33. In which of the following key obligations stemming from the GFL is there a potential for (legislative, non-legislative) simplification and reduction of administrative costs and burden?

Yes,	Yes, to some extent/	Only to a	No	Don't
considerable	in some cases	limited extent		know

	Yes, considerable	Yes, to some extent/ in some cases	Only to a limited extent	No	Don't know
Placing safe food/feed on the market)					
Obligation of verification (internal controls)					
Traceability (one step forward one step back)					
Withdrawals and recalls					
Other (please specify)					

⁺ Comment box for cases (analysis of specific areas) where simplification potential exists, including actions taken in the context of ongoing/recent revisions to secondary legislation. In particular, by type of simplification: areas where legislation can be replaced by codes of good practice or guidelines; areas where simplification is possible (but legislation remains essential)

34. To what extent have any of the following tools helped you to save money/work more efficiently in meeting your legal obligations (GFL and secondary legislation)?

	Yes systematically	Yes, to some extent/ in some cases	Only to a limited extent	No	Don't know
EU guidelines					
National guidelines					
Private guidelines					
Private standards					
Private codes of good practice					
Other (please specify)					

⁺ Comment box, to provide examples of best practice cases, e.g. private standards that complement EU food law provisions in the GFL to maximise efficiency

35. To what extent have any of the following tools helped you to meet your legal obligations (GFL and secondary legislation) more effectively?

	Yes systematically	Yes, to some extent/ in some cases	Only to a limited extent	No	Don't know
EU guidelines					
National guidelines					
Private guidelines					
Private standards					

	Yes systematically	Yes, to some extent/ in some cases	Only to a limited extent	No	Don't know
Private codes of good practice					
Other (please specify)					

⁺ Comment box, to provide examples of best practice cases, e.g. private standards that complement EU food law provisions in the GFL to maximise effectiveness

36. In which areas of the EU food law do you see alternative means/measures of ensuring compliance other than law (e.g. guidelines, private standards or codes of good practice)?

1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	Yes	No	Don't know
GFL core areas			
Food hygiene			
GMOs			
Novel foods			
Food for specific groups			
Addition of vitamins, minerals to foods			
Irradiation			
Food labelling			
Contaminants			
Food improvement agents			
Food contact materials			
Maximum residue limits for plant protection products			
Feed hygiene			
Feed labelling			
Feed additives			
Other (please specify)			

⁺ Comment box for indicating which alternative means for which areas

8 Overarching issues

37. To what extent has the legislative framework introduced by the GFL provided any of the benefits highlighted below, compared to what could be achieved, in the absence of a common framework, by Member States at national and/or regional levels or at international level (Codex, OIE)? To score on a scale 1-5 (1=benefit not provided; 5=benefit fully provided)

The GFL has ...

	1	2	3	4	5	Don't know
Provided the basis for a single, uniform framework and principles to develop EU rules in secondary legislation on food/feed safety						
Improved coherence of food safety rules across Member States						
Improved internal coherence of food safety rules between sectors						
Raised the overall level of food safety standards applying across the EU, including the scientific and technical soundness of these standards						
Allowed both EU and third country food/feed supply chains a unique reference to food safety standards applying across the EU						
Provided improved EU product safety recognition worldwide						
Contributed to an improved quality perception in third country markets						
Contributed to an increased demand for EU products in third countries						
Facilitated enforcement of rules across the EU						
Allowed simplification, thus leading to a reduction in administrative costs and burden						
Consistently allocated responsibilities among FBOs along the chain						
Other: please specify						

⁺ Comment box, to justify any of the above benefits stemming from the common framework of the GFL

38. To what extent has each of the core requirements of the GFL had an impact, positive or negative, in terms of ensuring food/feed safety in the EU? *To score on a scale 1-5 (1=very negative; 2=negative; 3=neutral; 4=positive; 5=very positive)*

	1	2	3	4	5	Don't know
Traceability (one step forward one step back)						
FBO responsibility to place safe food/feed on the market						
Withdrawals and recalls						
Obligation of verification (internal controls)						
Penalties						
Other (please specify)						

⁺ Comment box, to explain which areas have had a positive or a negative impact, and reasons why

39. To what extent have the EU guidelines concerning the following areas of the GFL been useful in assisting feed/food operators to comply with their obligations? To score on a scale 1-5 (1=not used/useful; 5=fully used/useful)

	1	2	3	4	5	Don't know
Guidelines on traceability requirements (Article 18)						
	1	2	3	4	5	Don't know
Guidelines on the determination of safe food and food safety requirements (Article 14)						
Guidelines on the allocation of responsibilities between food/feed businesses and control authorities (Article 17)						
Guidelines on recalls/withdrawals of unsafe food (Article 19)						
Guidelines on recalls/withdrawals of unsafe feed (Article 20)						
Guidelines on imports of food/feed (Article 11)						
Guidelines on exports of food/feed (Article 11)						

⁺ Comment box, to explain in which areas guidelines have been/not been useful and reasons why

40. To what extent have there been differences in the implementation/application of the GFL amongst Member States, in any of the following areas?

	Yes systematically	Yes, to some extent/ in some cases	Only to a limited extent	No	Don't know
Definitions of GFL					
Risk analysis					
Application of the precautionary principle					
Imports of feed/food in the EU from third countries					
Exports of EU feed/food to third countries					
Determination of safe food					
Determination of safe feed					
Allocation of responsibilities between food/feed businesses and control authorities					
Traceability					
Requirements regarding recalls/withdrawals of unsafe food					
Requirements regarding recalls/withdrawals of unsafe feed					

- + Comment box, to provide examples of differences in implementation, reasons why, and problems caused
- 41. To what extent has the general framework introduced by the GFL sufficiently taken into account, where appropriate, the following aspects? *To score on a scale 1-5 (1=not taken into account; 5=fully taken into account)*

	1	2	3	4	5	Don't know
Animal welfare						
Animal health						
Plant health						
Environment						

⁺ Comment box to justify why these aspects have been/not been taken into account