

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

**On-line survey questionnaire  
to Member State Competent Authorities (MS CAs)**

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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)<sup>1</sup>, 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 the 28 EU Member States’ Competent Authorities. Please note that a separate complementary survey, using a similar questionnaire, will be carried out at the level of 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. In your answers, please express **your expert opinion based on the actual experience** with the GFL of the Member State Competent Authority/ies that you represent.

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

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<sup>1</sup> [http://ec.europa.eu/smart-regulation/refit/index\\_en.htm](http://ec.europa.eu/smart-regulation/refit/index_en.htm)

scope of this evaluation. The general objectives and principles such as the risk analysis (Article 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](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](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 evaluation of the European Food Safety Authority (Articles 22-49; EFSA has already been evaluated) and it excludes the Rapid Alert System for Food and Feed (RASFF) and crisis management procedures (Articles 50-57), which are being evaluated in parallel in a *separate* study also mandated by DG SANTE. Finally, please note that a third separate study mandated by DG SANTE is also running in parallel to the GFL and the RASFF evaluations; this is examining the impact on official controls and enforcement actions of the current legal framework applicable to food fraud along the agri-food chain.

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 **fill in the survey on-line only when all replies are ready** 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 administration**, therefore please ensure that you allocate sufficient time to enable this consultation to take place and to prepare your replies. In each of the 28 EU Member States, relevant Member State Competent Authorities are requested to send one coordinated response per Member State, so that aggregate results can take into account **one response per Member State**.

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 administration, prior to filling in the on-line questionnaire. Please note that **your response to this questionnaire needs to be submitted online** (Word versions of the questionnaire will not be accepted).

**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 regard to personal data protection within the **FWC 2013-2017 Framework Contracts for evaluation, impact assessment and related services<sup>2</sup>**.

**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)

This questionnaire is available in English only.

THE FCEC THANKS YOU IN ADVANCE FOR YOUR COOPERATION

If you have any questions on this questionnaire or need any further clarifications of the issues raised and/or the consultation process, please contact us by e-mail at:

**[anne.marechal@ceasc.com](mailto:anne.marechal@ceasc.com)**

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<sup>2</sup> 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. Name of the responding (coordinating) Competent Authority: .....

2. 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

3. 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.*

4. 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.

5.

- (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)*

	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).

6. 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 verifying 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
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						

	1	2	3	4	5	Don't know
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

### 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 food-producing animal if it is unsafe. Feed is unsafe if it has an adverse effect on human or animal health or makes the food derived from food-producing animals unsafe for human consumption.

7. 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?

<b>i. To determine whether FOOD is unsafe</b>	Relevant	Not relevant	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 justify on what basis the above considerations are relevant/not relevant

<b>ii. To determine whether FEED is unsafe</b>	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 (1= have not contributed; 5=fully contributed)*

<b>i. To determine whether FOOD is unsafe</b>	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

<b>ii. To determine whether FEED is unsafe</b>	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

8. The GFL stipulates that food/feed that complies with EU food/feed safety legislation (including provisions laid down in secondary legislation) is deemed safe (Articles 14.7 for food, and 15.4 for feed). In this context, 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
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, please specify						

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

9. Have there been any cases where you restricted the marketing or required the withdrawal/recall of compliant food/feed from the Union market, because there were reasons to suspect that the food/feed was unsafe (Articles 14.8 and 15.5)?

	Yes	No	Don't know
Any cases?			

+ Comment box to highlight cases, reasons why and impacts

### 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.

10. 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

11. 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						
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

### 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 from whom and to whom a food/feed/food-producing animal/any other substance intended to be (or expected to be incorporated into a food/feed has been supplied (“one step back – one step forward” approach) and (b) to have systems and procedures in place that allow this information to be made available to the competent authorities upon request.

12. 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

13. 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 ‘ <i>farm to table</i> ’ supply chain in the EU						
Ensures efficient ( <i>i.e.</i> at lowest possible administrative burden) tracing of food/feed across the full supply chain in the EU ‘ <i>from farm to table</i> ’						
Facilitates risk identification						
Ensures effective and efficient targeted withdrawals/ recalls of unsafe food/feed						
Avoids/limits unnecessary disruption of trade						

	1	2	3	4	5	Don't know
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

14. To what extent has full traceability been achieved, in cases where a competent control authority has undertaken an investigation on a specific food/feed?

	<i>Tick</i>
Always/ in most cases	
Yes, but not systematically	
Only rarely	
Never	
Don't know	

+ Comment box to identify cases where it has not

### 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.

15. To what extent have FBOs in your country complied with the following actions in the context of withdrawals and recalls when such actions were necessary (Article 19: food; Article 20: feed)? *To score on a scale 1-5 (1=not complied; 5=fully complied)*

	1	2	3	4	5	Don't know
Have FBOs immediately withdrawn a food/feed from the market when they considered or suspected that it was unsafe (i.e. injurious to health or unfit for human/animal consumption) and had left their immediate control?						
Have FBOs immediately informed the competent authorities of the withdrawal of a food/feed from the market?						
Have FBOs effectively and accurately informed consumers of the withdrawal of unsafe food, when such products might have reached them?						

	1	2	3	4	5	Don't know
Have FBOs recalled unsafe food from consumers when other measures were not sufficient to achieve a high level of health protection?						
Have retailers or distributors withdrawn unsafe food/feed from the market, passed on relevant information necessary to trace unsafe food/feed and cooperated with other relevant FBOs along the food chain?						
Have FBOs always destroyed unsafe feed, unless the competent authority was satisfied otherwise?						
Have FBOs immediately informed the competent authorities when they considered or suspected that a food/feed placed on the market was "injurious to health", regardless if the food/feed was under their immediate control?						
Have FBOs informed the competent authorities of the actions taken to prevent risks to the final consumer when they considered or suspected that a food/feed placed on the market was "injurious to health", regardless if the food/feed was under their immediate control?						
Have FBOs informed the authorities of the action taken to address the potential risk arising from the food/feed? (Art. 19.3)						
Have FBOs prevented or discouraged any person from cooperating with the authorities in the action taken						

+ Comment box to justify answers

16. Have you assisted FBOs, when requested, in the case of withdrawals and recalls?

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

+ Comment box for justification when this has not been the case (reasons for not asking assistance)

17. 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

### 3.6 Penalties and other measures applicable to infringements

#### Introduction

**Article 17.2** of the GFL requires Member States to lay down rules on penalties and other measures applicable to infringements of feed and food law.

18. What types of measures and penalties are applicable in your legal system for infringements relating to the following core obligations imposed on food business operators by the GFL? *Please specify the type of measures/penalties for infringements*

GFL core obligations	Type of measures/ penalties for infringements ( <i>please specify</i> )
Placing only safe food on the market (compliant with food safety legislation)	
Placing only safe feed on the market (compliant with feed safety legislation)	
Establishing one step back – one step forward traceability at all stages of production, processing and distribution	
Notifying public authorities in case of food at risk	
Notifying public authorities in case of feed at risk	
Collaborating with public authorities on actions taken to avoid or reduce risk in food	
Collaborating with public authorities on actions taken to avoid or reduce risk in feed	
Verification that the relevant requirements of food law are met (Article 17(1) of GFL)	

19. What has been the impact of the GFL on your national rules laying down measures other than remedial measures and penalties applicable to infringements of feed and food law? Please consider measures **other than the remedial measures foreseen in the context of Regulation (EC) 882/2004.**

Note: remedial measures are measures implementing Article 54 of Regulation (EC) 882/2004 on official controls

(a) To what extent have new rules been introduced in your Member State on the basis of Article 17.2?

	Rules existed prior to the GFL – no change	Rules existed prior to the GFL – new provisions introduced, on the basis of Art. 17.2	Rules did not exist prior to the GFL – new rules have been adopted on the basis of Art. 17.2	Rules did not exist prior to the GFL – no change	Don't know
Penalties (administrative)					
Penalties (criminal)					
Measures (other than remedial measures), <i>please specify</i>					

+ Comment box, to specify what 'measures' have been introduced, other than the remedial measures foreseen in the context of Regulation (EC) 882/2004

(b) If new rules/provisions have been introduced/changed as a result of the GFL, have they been an effective method to deter feed/food business operators from committing further infringements? *To score on a scale 1-5 (1=not effective; 5=fully effective)*

	1	2	3	4	5	Don't know
Are penalties an effective deterrent?						
Are measures other than remedial measures an effective deterrent?						

+Comment box, to justify the answer and to specify what type of penalties and 'other measures' are most effective

(c) If penalties and measures (other than remedial measures) have not been an effective method to deter feed/food business operators from committing further infringements, is this due to any of following reasons? *Please prioritise your answers, starting from 1=most important.*

	Tick
CA does not have sufficient resources to pursue penalties or other measures on infringements	
The process is too long/complex (e.g. difficulty of allocating liability along the chain, etc.)	
More training for CA staff is necessary e.g. on legal requirements, judicial processes etc.	
National legislation needs updating/improving	
Other (please specify)	
Don't know	

+Comment box, to justify the answer and to provide any other reasons

20. Have you taken measures at national level to implement the provisions of Article 8 of the GFL, in terms of the following aspects?

	Yes	No	Don't know
Prevention of fraudulent/deceptive practices			
Prevention of food adulteration			
Prevention of any other practices which may mislead the consumer: please specify			

+Comment box, to provide further details (legal reference, type of measure, extent to which this provides for administrative/criminal penalties)

21. Article 60 of the GFL sets out a mediation procedure where a Member State considers that a measure taken by another Member State relating to feed/food safety is either incompatible with the GFL or is likely to affect the functioning of the internal market. To what extent, do you consider this procedure relevant? *To score on a scale 1-5 (1=not relevant; 5=fully relevant)*

	1	2	3	4	5	Don't know
Relevance of mediation procedure (Article 60)						

+ Comment box to justify why the procedure is/is not relevant

## 4 International trade

### Introduction

**Article 11** of GFL requires food and feed imported into the EU 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 exported/re-exported from the EU to a third country to comply with EU requirements or with the requirements of the third country. In other circumstances, except in the case of food injurious to health or unsafe feed, food/feed can only be exported/re-exported if the competent authorities of the third country of destination have expressly agreed.

22. To what extent have you implemented restrictions on imports of unsafe feed/food?

	Tick
Yes (always/ in most cases)	
Yes, but not systematically	
Only rarely	

Never	
Don't know	

+ Comment box, to provide key trends of restrictions, if these are systematically recorded, and key reasons why restrictions were imposed

23. To what extent have you taken measures to ban the export to third countries of feed/food injurious to health or unsafe feed/food under Article 12?

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

+ Comment box, to provide key trends of restrictions, if these are systematically recorded, and key reasons why restrictions were imposed

## 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.

24. 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?

	<i>Tick</i>
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 not been adopted on the basis of a risk analysis

25. 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?

	<i>Tick</i>
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 not been adopted on the basis of a risk analysis

26. 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	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

27.

(a) To what extent have 'other legitimate factors' (i.e. factors other than scientific opinions assessing the risk to health) been taken into account when **EU measures** on feed and food have been taken?

	Always	Case by case	Never	Don't know
Economic factors				
Societal factors				

	Always	Case by case	Never	Don't know
Tradition factors				
Environmental impacts				
Ethical factors				
Feasibility of controls				
Other, please specify				

+ Comment box to identify and provide examples of cases where any of the above 'other legitimate factors' have been taken into account when adopting EU measures, and to highlight which were these 'legitimate factors'

(b) To what extent have 'other legitimate factors' (i.e. factors other than scientific opinions assessing the risk to health) been taken into account when **national measures** on feed and food have been taken?

	Always	Case by case	Never	Don't know
Economic factors				
Societal factors				
Tradition factors				
Environmental impacts				
Ethical factors				
Feasibility of controls				
Other: please specify				

+ Comment box to identify and provide examples of cases where any of the above 'other legitimate factors' have been taken into account when adopting national measures, and to highlight which were these 'legitimate factors'

28. Have any provisional risk management measures been taken by Member States at national level on the basis of the precautionary principle (Article 7)?

	Tick
Yes	
No	
Don't know	

29.

(a) If the answer to the previous question is yes, please identify up to three most important cases of measures taken on the basis of the precautionary principle (Article 7), and provide a detailed description

Measure 1	
Measure 2	
Measure 3	

(b) For the three measures taken on the basis of the precautionary principle (Article 7) listed in the previous question, please provide the following information for each measure:

<b>Measure 1:</b>	
Date of adoption?	
How long has this measure been in place?	
Has it been reviewed?	
What were the main drivers for the adoption of this measure? -	Please select amongst the following drivers: - Identification of the possibility of harmful effects on health - Persisting scientific uncertainty - Other, please specify
<b>Measure 2:</b>	
Date of adoption?	
How long has this measure been in place?	
Has it been reviewed?	
What were the main drivers for the adoption of this measure?	Please select amongst the following drivers: - Identification of the possibility of harmful effects on health - Persisting scientific uncertainty - Other, please specify
<b>Measure 3:</b>	
Date of adoption?	
How long has this measure been in place?	
Has it been reviewed?	
What were the main drivers for the adoption of this measure?	Please select amongst the following drivers: - Identification of the possibility of harmful effects on health - Persisting scientific uncertainty - Other, please specify

+ Comment box to identify any other key drivers (not listed above) for the adoption of any of the above identified measures

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

	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

31. 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

	<i>Tick</i>
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

	<i>Tick</i>
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

	<i>Tick</i>
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

32. To what extent has there been an open and transparent public consultation for national feed/food legislation in your Member State during the following phases of its development?

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

	<i>Tick</i>
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

	<i>Tick</i>
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

	<i>Tick</i>
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

33. How often have the following stakeholders been consulted at national level during the preparation, evaluation and revision of food law in your Member State?

	Always	Sometimes	Rarely	Don't know
Farmers				
Food processors				
Distribution/retail				
Importers				

	Always	Sometimes	Rarely	Don't know
Exporters				
SMEs (more specifically)				
Other industry				
Consumers				
Other NGOs				

34. To what extent have the following elements been typically involved in the consultation process?

	Always	Sometimes	Rarely	Don't know
Consultation groups composed of associations representing the different stakeholders of the food chain (specify whether these are permanent or ad hoc groups established by public authorities)				
Internet consultations				
Workshops				
Invitation for comments/positions				
Cost/benefit analysis				
Feasibility/impact/evaluation studies				
Other: please specify				

+ Comment box, to specify other elements of the consultation process

## 6.2 Public information

### Introduction

**Article 10** of the 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.

35. What have typically been the trigger points and/or modalities for communicating to the general public a potential food/feed safety risk? *Please indicate trigger points and/or modalities by level of risk, rather than by level of public perception. The question allows more than one tick per row*

	Low risk	Moderate risk	High risk
In the event of withdrawals of specific feed/food			
In the event of recalls of specific feed/food			
In response to press reports			
Only after completion of inter-services consultation with all competent authorities involved			

	Low risk	Moderate risk	High risk
Only once notified to the Commission/RASFF network			
Only once measures are taken			
As soon as there are reasonable grounds to suspect risk			
Where relevant, only after confirmatory testing			

+ Comment box to provide any data, if systematically collected, on the number of cases in which the public was informed, if possible by level of risk

36. 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

37. 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)*

	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

38. In the case of recalls that have occurred in the last five years in your country, what kind of information have you typically communicated to the general public?

	Tick
Product details	
Producer	
Lot numbers	
Other, please specify	

+ Comment box, to specify other information communicated

## 7 Administrative costs and burden for food/feed business operators

39. 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)?

	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 residues 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

40. 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,						

	1	2	3	4	5	Don't know
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

41. 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.

42. To what extent have the EU guidelines concerning the following areas of the GFL been useful in assisting Member State CAs 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)						
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)						

	1	2	3	4	5	Don't know
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

43. 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

44. 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						

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

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