APPENDIX 5 – THE GENERAL GFL STUDY

ANNEX 5D

Advisory Group on the Food Chain, Animal and Plant Health
Working Group meeting on
Fitness Check of Regulation (EC) No 178/2002
19 December 2014

ADVISORY GROUP ON THE FOOD CHAIN, ANIMAL AND PLANT HEALTH

WORKING GROUP MEETING ON

FITNESS CHECK OF REGULATION (EC) №178/2002

(THE 'GENERAL FOOD LAW')

Centre Borschette, meeting room 1B

10.00h – 18.00h

19 December 2014

FCEC working document

This document is addressed to participants of the Working Group meeting on the Fitness Check of Regulation (EC) №178/2002) the 'General Food law' – GFL), of the Advisory Group on the food chain, animal health and plant health, in the context of the independent study on the evaluation of the GFL, which is carried out for the European Commission by the Food Chain Evaluation Consortium (FCEC). The study is being led by Agra CEAS Consulting.

The document has been prepared by the FCEC and does not necessarily present the views of the Commission.

Contents

Background to the meeting

Regulation (EC) No 178/2002, known as "the General Food Law Regulation" (GFL), establishes the fundamental principles, requirements, objectives and definitions of food/feed policy, which underpin all legal measures undertaken at EU and national level.

A study on the evaluation of GFL is undertaken for the Directorate General for Health and Consumers (DG SANCO) of the European Commission, in the context of a Fitness Check on GFL. The study is led by Agra CEAS Consulting of the Food Chain Evaluation Consortium (FCEC).

The evaluation aims at analysing the effectiveness, efficiency, coherence, relevance and EU added value of the legislative framework introduced by GFL (**Annex 1**). It should assess whether the fundamental objectives have been efficiently achieved and whether the provided tools have been consistently implemented via secondary legislation and have fully delivered. In addition, the assessment aims at focusing on potential for simplification and on reduction of regulatory costs and burdens.

The study involves collection of data and information through desk research, an on-line survey of organisations representing operators along the feed and food supply chain ('from farm to fork'), an on-line survey of MS Competent Authorities (CAs), consultation of SMEs through the EEN SME Panel, and five thematic case studies on key areas covered by the GFL. The latter will involve interviews of MS CAs and stakeholders, at both EU and MS level. The FCEC had also set up a Food Law Expert Advisory Panel of five senior food law academics, with the objective of drawing on their independent expert advice for guidance and to ensure the scientific quality of the evaluation.

The study was launched in late September and the main phase of the consultation process has just started. The purpose of this WG meeting of the Advisory Group is to present the issues to be considered by the study and to invite stakeholders to provide their views and inputs (data) concerning the various issues under review.

In particular, the objective of the meeting is to give the opportunity to the FCEC to present the objectives and scope of the evaluation, gather initial feedback on key issues of common, collective interest and GFL problem areas, provide clarifications and encourage concrete inputs and contribution to the on-line survey consultation and case studies.

Objectives of the discussion sessions

This Working Document aims to facilitate this discussion, by providing an overview of the issues considered by the study and the qualitative and quantitative data needed to assess the impact of the GFL, so that participants can prepare in advance and thus allow for a more complete response to the on-line survey and a more productive exchange in the context of the case studies.

Your **contribution as stakeholders** is highly encouraged during and after the WG meeting, and in particular:

- **During the meeting**: as participants you will have the opportunity to contribute your comments through a **discussion** in the sections that follow the FCEC presentation; - **After the meeting**: as participants you are kindly invited to contribute **in writing**:
    - Your contact details and to indicate, where applicable, in which areas you would be able to contribute. To this end, you will be invited to indicate, where possible, specific contacts of your member organisations at national level with whom it would be useful for the FCEC to follow up discussions. The deadline for submitting your contact details to the FCEC is set at **15 January 2015**. *Please note that, with some of you, follow up interview meetings will be organised by the FCEC during the main phase of the study, in the context of the case studies.*
    - During the main phase of the study, participants will have the opportunity to contribute in writing their feedback on the various issues. The deadline for submitting your contributions to the FCEC is set at **28 February 2015**.

Furthermore, you are invited to **distribute this working document to your member organisations at national level as well as private companies**; we would welcome any direct feedback these organisations may wish to provide on the topics of discussion.

Please consult both the present document and the ToR of the GFL evaluation ahead of the workshop meeting.

THE FCEC THANKS YOU IN ADVANCE FOR YOUR COOPERATION

1. Discussion on traceability

Background

The traceability requirement is laid down in Article 18 of the GFL Regulation. Although traceability pre-existed in the food chain, with the adoption of the GFL in 2002 the traceability obligation for all feed and food business operators was explicitly stipulated in a horizontal EU legal text. Consequently, Article 18 created a new general obligation for feed and food business operators. Traceability rules apply since 1 January 2005. EU guidance (2010) on the implementation of the GFL[1] provides more detailed advice to operators on the implementation of the traceability requirements in their business.

Article 18 establishes **mandatory *'one step back-one step forward'* traceability**. This requirement is meant to provide a comprehensive system allowing to trace food/feed products throughout the supply chain. Each business is responsible for its own activities within a chain, but there is a joint responsibility throughout the chain. As such, traceability should enable targeted withdrawals as well as providing targeted and accurate information concerning implicated products to consumers or to control officials in case of investigation. In this sense, the traceability obligation aims at avoiding unnecessary wider disruption in the internal market in the event of food safety incidents.

The traceability requirement applies to business operators at all stages of the food/feed chain, from primary production (food producing animals, harvests), food/feed processing to distribution and supply, including brokers, regardless of whether they take physical possession of the food/feed in question. Food and feed business operators must be able to identify the immediate supplier and the immediate subsequent recipient of a food, feed, a food-producing animal or any substance to be incorporated into a food or feed they place on the market, with the exemption of retailers to final consumers. EU importers also have the obligation to be able to identify at least the business from which the imported food, feed, animals or substance have been supplied.

Article 18 requires food and feed operators to have in place systems and procedures to ensure the traceability of their products; as indicated in the Guidance document, although the Article does not provide any details about these systems, the use of terms '*systems'* and '*procedures'* implies a structured mechanism able to deliver the needed information upon request from the competent authorities.

The purpose of the study with regard to the traceability requirement is to analyse the extent to which Art. 18 has been of added value/benefit to business operators, the sufficiency of the provisions for ensuring food and feed safety, the regulatory costs that these provisions have implied for the supply chain including in terms of its implementation in secondary legislation, and the cost:benefit ratio of the traceability requirement. In doing this, the analysis will provide a description of how traceability systems and procedures in place to allow for traceability information to be made available to Member State Competent Authorities have evolved, following the introduction of this requirement by the GFL. The impact on SMEs is particularly important here.

[1] Guidance on the implementation of Articles 11, 12, 14, 17, 18, 19 and 20 of Regulation (EC) N° 178/2002 on General Food Law. Conclusions of the Standing Committee on the Food Chain and Animal Health. Jan. 2010.

Questions

We would like to receive inputs from the supply chain stakeholders on the following aspects - **focusing on the sector of activity that your organisation represents**:

1. To what extent was *'one step back-one step forward'* traceability implemented, in the different sectors across the supply chain, prior to the application of the GFL traceability obligation in Article 18?
    - Can you estimate the rate of application of '*one step back-one step forward'* traceability prior to the introduction of the GFL, e.g. as a % of the number of companies in your sector practising this level of traceability, or % of output covered by traceability? *If providing a global estimate is not possible, ad hoc evidence of specific cases can be highlighted.*

2. How was Article 18 applied in practice?
    - Was the traceability requirement integrated in existing structures, such as bookkeeping systems?
    - If so, to what extent did companies in your sector have to adapt existing structures, in order to integrate the traceability requirement?
    - Did companies in your sector have to develop new structures?

    If providing a global overview for your sector is not possible, please highlight key patterns of application of Article 18 and any adjustments that were required.

3. What are currently the costs of providing *'one step back-one step forward'* traceability according to Article 18? *Please provide evidence of the annual operational costs typically involved (including staff training), as a % of total production costs. The calculation should exclude: any capital investment; any costs you would have incurred in any case (business-as-usual costs[2]); and those costs stemming from private contractual obligations that require traceability beyond the requirements of Article 18. If costs depend on business size, extent of cross-border trading and sector of activity (see Question 5), please provide evidence highlighting range of costs and reasons why.*

4. What were the main constraints and difficulties encountered in the application of traceability systems in line with Article 18? *Please provide evidence highlighting key issues and reasons why.*

5. Which sectors/businesses have been impacted the most from the introduction of the Article 18 traceability provisions, in terms of the required adjustment in their production, administrative and business operations, and resulting costs? Is there a relationship between the rate of uptake of *'one step back-one step forward'* traceability and … :

    - Company/plant size? Has the impact been greater for SMEs compared to larger businesses?

[2] *Business-as-usual (BAU) costs*: the costs stemming from the normal execution of standard functional operations within an organisation, in contrast to those costs stemming from regulatory obligations which might introduce changes to an organisation's standard functional operations.

- Cross border trading? Has the impact been greater for those businesses engaged in intra-EU cross-border trading compared to businesses trading within national markets?
- Sector of activity? Has the impact been greater for businesses in some product sectors? E.g. food vs feed; short supply chains vs long supply chains; etc.
- Different stages of the feed/food supply chain? E.g. raw material producers, manufacturers, retailers, importers etc.
- Other factors? (*please identify*)

For all the above: Please provide evidence of specific cases highlighting differential impacts/costs (see also Question 3) and reasons why.

6. What have been the benefits of having the traceability obligation for all food/feed business operators and the full supply chain? *Identify the key benefits of the Article 18 approach. Please provide evidence of the benefits, to the extent possible also in quantitative terms, from specific cases.* As intended in the GFL, the benefits of the traceability provisions of Article 18 should be identified in terms of:
   - Targeted withdrawals? *e.g. costs of targeted withdrawals vs costs of nontargeted withdrawals.*
   - Avoiding unnecessary disruption of trade? *e.g. costs of a disruption that resulted from effective/efficient traceability versus costs of a disruption where traceability has not proved effective/efficient.*
   - Enabling consumers to be provided with accurate information concerning implicated products thereby helping to maintain consumer trust and confidence? *e.g. cases where this has occurred vs, cases where this has not occurred and resulting impact on consumer trust/confidence.*
   - Other benefits? (*please identify*)

7. Which sectors/businesses (product sectors or businesses at different stages of the feed/food supply chain) have benefitted the most from the introduction of the Article 18 traceability provisions, in terms of the above benefits? Is there a relationship between who benefits the most and the costs of traceability (Question 3)? Is this linear - are those who benefit the most those that incur the highest costs? *If benefits depend on business size, extent of cross-border trading and sector of activity (see Question 5), please provide evidence highlighting specific cases and reasons why.*

8. What has been the impact (positive or negative) of having stricter sector-specific traceability rules in some sectors, e.g. food of animal origin, electronic animal identification, feed traceability and labelling, GMOs? *Please provide evidence highlighting specific cases and reasons why.*

9. To what extent do the benefits of traceability outweigh costs longer term? *Please estimate the extent to which the benefits of traceability exceed the costs of setting up and operating traceability systems. If providing a global estimate of cost:benefit is not possible, ad hoc evidence of specific cases can be highlighted. If the cost:benefit ratio depends on business size, extent of cross-border trading and sector of activity (see Questions 5 and 7), please provide evidence highlighting differential impacts and reasons why.*

10. What has been the added value of having an EU-wide traceability obligation for all food/feed business operators and the full EU supply chain? *Identify the key benefits of the EU approach compared to what could be achieved by Member States at national and/or regional level. Please provide evidence highlighting specific cases, benefits of the EU approach in quantitative terms (to the extent possible), and reasons why.*

11. In terms of the cost:benefit ratio, to what extent do you consider the situation would have been better/worse without the GFL? Could any of the benefits identified under Question 6 been achievable without the GFL? *Please provide evidence highlighting specific cases and reasons why.*

12. Are there additional traceability requirements (i.e. additional information) imposed on feed/food business operators by their customers? Do business operators understand the difference between legal requirements as part of the GFL traceability obligation and those traceability requirements imposed by their customers? Do quality assurance schemes or specific food management accreditation schemes (e.g. ISO) require a stricter documentation for traceability *(e.g. fixing record keeping periods?; Additional information on e.g. nature of the products?)? Please provide evidence highlighting specific cases and reasons why.*

13. Are there differences in Member State interpretation of the requirements of Article 18? To what extent is internal traceability applied and/or considered a legal requirement in the different Member States? Do Member States apply different internal traceability rules amongst sectors? Should the GFL rules be clarified on this point? *Please provide evidence highlighting specific cases and reasons why.*

14. Is *'one step back-one step forward'* traceability sufficient? Has it enabled ensuring a high level of feed/food safety and consumer protection? Would a more extended traceability requirement be necessary: ○ In specific product sectors?
    - Horizontally across all sectors of the feed/food supply chain?

    If current traceability is sufficient, please provide evidence highlighting specific cases where this has proven to suffice in *ensuring a high level of feed/food safety and consumer protection. If a more extended traceability is necessary, please provide evidence highlighting specific cases and reasons why.*

15. Are there any gaps/problems in the current provisions of Article 18 on traceability? *Please provide evidence highlighting specific cases and reasons why.*

16. To what extent have guidelines been issued on Article 18? Have these been necessary/useful?
    - Have the guidelines issued at EU level been clear/useful/comprehensive?
    - Have national authorities/sectoral organisations issued guidelines? Are these useful? If not useful, why?
    - Have guidelines addressed the particular requirements in some sectors where specific traceability rules apply– e.g. meat?
    - Are more guidelines necessary? At what level: EU; national; product sector?

17. Are there elements in the guidelines which should be better placed in the GFL?

Generally speaking, if you have experienced deviations in interpretation of Article 18 rules, is this due to the lack of more prescriptive provisions in the GFL as such or to broader issues of interpretation/enforcement? *Please provide evidence highlighting specific cases and reasons why.*

2. Discussion on responsibilities of feed/food businesses operators

Background

Article 17.1 of the GFL defines the role of food/feed business operators. Operators have the **primary responsibility for food safety**. They must also 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 food safety and consumers' interests (such as food/feed labelling).

This section refers to the following **core requirements/responsibilities** set out in the GFL for feed/food business operators:

- 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 law (EU/national provisions) (Article 17.1);
- *establish 'one step back - one step forward' traceability**
- withdraw/recall food/feed at risk (Article 19.1, 19.2, 20.1 and 20.2) ;
- notify public authorities in case food/feed is 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).

* *Note: the requirement for operators to establish 'one step back - one step forward' traceability at all stages of production, processing and distribution (Article 18) is covered in a separate case study, as presented in the previous section of this working document.*

Article 17.1 does not introduce a Union regime regulating the allocation of liability among the different links of the feed and food chain, which is a complex matter that depends very much on the structure of the different national legal systems.

In discussing the allocation of responsibility along the supply chain, it is important to take into account the fact that interactions between producers, manufacturers and distributors of feed/food have become increasingly complex and intertwined. The links along the chain are important, as each business is responsible for taking the measures necessary to ensure compliance with food law requirements within the context of its own specific activities (by applying HACCP-type principles[3] and other similar instruments), while there is a joint responsibility throughout the chain. Where a product is found failing food law requirements, the liability of each link in the chain should be reviewed according to whether or not it has properly fulfilled its own specific responsibilities.

The purpose of the study with regard to the requirements of Article 17.1 is to analyse the sufficiency of the provisions for ensuring feed and food safety, the regulatory costs that these

[3] The requirement for food business operators, except primary producers, to put in place and implement procedures based on HACCP (Hazard Analysis and Critical Control Point) principles is introduced in secondary legislation (Art. 5 of Regulation (EC) No 852/2004 on food hygiene).

provisions have implied for the supply chain including in terms of its implementation in secondary legislation, the extent to which this has been of added value/benefit to business operators, and the potential for simplification and reduction in the current regulatory burden.

Questions

We would like to receive inputs from the supply chain stakeholders on the following aspects - **focusing on the sector of activity that your organisation represents**:

1. How do operators ensure that they meet the responsibilities laid down in Article 17.1? *Please indicate the procedures and/or instruments that are mainly used by companies in your sector, both to ensure compliance with the requirements of (EU/national) food law and to verify that such requirements are met:*
    - What are the main procedures and/or instruments that are applied by operators to ensure compliance with the requirements of (EU/national) food law?
    - To what extent operators perform their own verification controls?
    - To what extent operators perform verifications to their suppliers?

2. To what extent did companies in your sector have such procedures and/or instruments in place prior to the application of responsibilities for feed and food business operators in Article 17.1? *If providing a global overview is not possible, ad hoc evidence of specific cases can be highlighted.*

3. How was Article 17.1 applied in practice?
    - Were requirements integrated in existing structures, such as verification controls of suppliers/customers or contractual obligations?
    - If so, to what extent did companies in your sector have to adapt existing structures?
    - Did companies in your sector have to develop new structures?

    If providing a global overview for your sector is not possible, please highlight key patterns of application of Article 17.1 and any adjustments that were required.

4. What were the main constraints and difficulties encountered in the application of Article 17.1? *Please provide evidence highlighting key issues and reasons why.*

5. Does secondary legislation provide sufficient detail to enable you to meet your responsibilities as laid down in Article 17.1? In which cases is there sufficient detail in secondary legislation? Are there cases where secondary legislation creates overlaps or contradictions that make it difficult for you to meet your responsibilities? *Please provide evidence highlighting key (positive and negative) issues with the implementation of Article 17.1 in secondary legislation and reasons why.*

6. What are currently the costs for feed/food operators that are associated with meeting the requirements of Article 17.1? *Please provide evidence of the annual operational costs typically involved (including staff training), as a % of total production costs. The calculation should exclude: any capital investment; any costs you would have*

incurred in any case (business-as-usual costs[4]);and those costs stemming from private contractual obligations that go beyond the requirements of Article 17.1. If costs depend on business size, extent of cross-border trading and sector of activity (see Question 7), please provide evidence highlighting range of costs and reasons why.

7. Which sectors/businesses have been impacted the most from the introduction of the Article 17.1 provisions, in terms of the required adjustment in their production, administrative and business operations, and resulting costs? Is there a relationship between impact and … :
   - Company/plant size? Has the impact been greater for SMEs compared to larger businesses?
   - Cross border trading? Has the impact been greater for those businesses engaged in intra-EU cross-border trading compared to businesses trading within national markets?
   - Sector of activity? Has the impact been greater for businesses in some product sectors? E.g. food vs feed; short supply chains vs long supply chains; etc.
   - Different stages of the feed/food supply chain? E.g. raw material producers, manufacturers, retailers, importers etc.
   - Other factors? (*please identify*)

   For all the above: Please provide evidence of specific cases highlighting differential impacts/costs (see also Question 6) and reasons why.

8. How are the costs emanating from the requirements of Article 17.1, as also implemented through secondary legislation, distributed in terms of the following elements? *Please provide a broad estimate of the percentage (%) share of each of the following elements in total costs (as identified in Question 6):*
   - Own verification controls?
   - Verification controls of suppliers?
   - Official controls of Member State Competent Authorities?
   - Providing evidence to customers?
   - Other elements? (*please identify*)

   If costs depend on business size, extent of cross-border trading and sector of activity (Question 7), please provide evidence highlighting range of costs and reasons why.

9. To what extent does HACCP contribute to fulfilling the general requirement of the GFL that the FBO carries primary responsibility (Art. 17.1) for placing safe food on the market (Art 14 and 15)? Are there any gaps/problems? What are these? *Please provide evidence highlighting specific cases and reasons why.*

10. Has Article 17.1 provided the lowest cost solution for ensuring food safety and consumer protection, as also implemented in secondary legislation? *Please provide evidence highlighting specific cases and reasons why:*
    - Has flexibility been applied, as intended in secondary legislation (e.g. simplified HACCP for smaller businesses, traditional products and non-food producing establishments)?

[4] *Business-as-usual (BAU) costs*: the costs stemming from the normal execution of standard functional operations within an organisation, in contrast to those costs stemming from regulatory obligations which might introduce changes to an organisation's standard functional operations.

- Is the related documentation and record keeping, which is required by Member State Competent Authorities to demonstrate the effective application of the measures, commensurate with the nature and size of the food business?
- Are there any areas where simplification/reduction in regulatory burden is needed? What would the expected cost saving? *Please provide evidence highlighting specific cases where cost reduction is possible, as a % of current baseline costs (as identified in Question 6).*

11. Is the approach applied by Member State Competent Authorities in taking into account feed/food business operators' own controls in their risk profiling and verification control plans consistent? *Please provide evidence highlighting specific cases and reasons why:*
    - Are official controls on FBOs uniformly applied in terms of considering systems developed on the basis of Article 17.1 (as also implemented via secondary legislation e.g. the requirement to apply HACCP-type principles on food hygiene)?
    - Do companies with multiple locations in a MS benefit from centrally approved self-control and verification procedures? What have been the best practices? What have been the worst practices?
    - Is the situation improving over-time?

12. What have been the benefits of having the obligations for all food/feed business operators and the full supply chain as laid down in Article 17.1? *Identify the key benefits of the Article 17.1 approach. Please provide evidence of the benefits, to the extent possible also in quantitative terms, from specific cases.* As intended in the GFL, the benefits of the provisions of Article 17.1 should be identified in terms of:
    - Better targeted controls?
    - Better targeted withdrawals?
    - Better targeted identification/prevention of potential risks/early response?
    - Comprehensive coverage of the feed/food supply chain?
    - Maintaining consumer trust?
    - Creating a level-playing field?
    - Other benefits? (*please identify*)

13. Which sectors/businesses (product sectors or businesses at different stages of the feed/food supply chain) have benefitted the most from the introduction of the Article 17.1 provisions, in terms of the above benefits? Is there a relationship between who benefits the most and the costs (Question 6)? Is this linear - are those who benefit the most those that incur the highest costs? *If benefits depend on business size, extent of cross-border trading and sector of activity (see Question 7), please provide evidence highlighting specific cases and reasons why.*

14. To what extent do the benefits of Article 17.1 outweigh costs longer term? *Please estimate the extent to which the benefits exceed the costs of setting up and operating procedures and instruments to ensure that the requirements of Article 17.1 are met. If providing a global estimate of cost:benefit is not possible, ad hoc evidence of specific cases can be highlighted. If the cost:benefit ratio depends on business size, extent of cross-border trading and sector of activity (see Questions 7 and 10), please provide*

evidence highlighting differential impacts and reasons why.

15. In terms of the cost:benefit ratio, to what extent do you consider the situation would have been better/worse without the GFL? Could any of the benefits identified under Question 9 been achievable without the GFL? *Please provide evidence highlighting specific cases and reasons why.*

16. What has been the added value of having an EU-wide responsibility obligation for all food/feed business operators and the full EU supply chain? *Identify the key benefits of the EU approach compared to what could be achieved by Member States at national and/or regional level. Please provide evidence highlighting specific cases, benefits of the EU approach in quantitative terms (to the extent possible), and reasons why.*

17. What has been the impact (positive and negative) of not having a strict liability system laid down in EU food law? Does it provide flexibility or does it create uncertainly? *Please provide evidence highlighting specific cases and reasons why.*

18. Are there additional requirements (i.e. additional information) imposed on feed/food business operators by their customers? Do business operators understand the difference between legal requirements as part of the GFL Article 17.1 obligations and those requirements imposed by their customers? Do quality assurance schemes or specific food management accreditation schemes (e.g. ISO) require a stricter documentation for compliance and verification controls? *Please provide evidence highlighting specific cases and reasons why.*

19. Are there differences in Member State interpretation of the requirements of Article 17.1 including where these are implemented through secondary legislation? Should the GFL rules be clarified on this point? *Please provide evidence highlighting specific cases and reasons why.*

20. Are the responsibilities imposed on feed/food business operators by Article 17.1 sufficient? Have they enabled ensuring a high level of feed/food safety and consumer protection? Would a more extended/detailed responsibility requirement be necessary:
    - In specific product sectors?
    - Horizontally across all sectors of the feed/food supply chain?

    If current responsibility allocation is sufficient, please provide evidence highlighting specific cases where this has proven to suffice in *ensuring a high level of feed/food safety and consumer protection.*
    If a more extended responsibility allocation is necessary, please provide evidence highlighting specific cases and reasons why.

21. Are there any gaps/problems in the current provisions of Article 17.1? *Please provide evidence highlighting specific cases and reasons why.*

22. To what extent have guidelines been issued on Article 17.1, as also implemented in secondary legislation? Have these been necessary/useful?
    - Have the guidelines issued at EU level been clear/useful/comprehensive?
    - Have national authorities/sectoral organisations issued guidelines? Are these

useful? If not useful, why?

- Are more guidelines necessary? At what level: EU; national; product sector?

23. Are there elements in the guidelines which should be better placed in the GFL? Generally speaking, if you have experienced deviations in interpretation of Article 17.1 rules, is this due to the lack of prescriptive provisions in the GFL as such or to broader issues of interpretation/enforcement? *Please provide evidence highlighting specific cases and reasons why.*

Annex 1: Acronyms and definitions

The following **abbreviations, acronyms and definitions** are used in this working document:

- Art. : Articles
- BAU: Business-As-Usual (costs)
- CA/s: Competent Authority/ies
- COM: European Commission
- EU: European Union
- FBO/s: Food/feed Business Operator/s (as defined in Article 3 of the GFL)
- 'food law': means law governing any stage of production, processing and distribution of food and feed.
- FCEC : Food Chain Evaluation Consortium
- FVO: Food and Veterinary Office
- GFL: General Food Law (Regulation (EC) No 178/2002)
- HACCP: Hazard Analysis of Critical Control Points
- MS: Member State/s
- MS CAs: Member State Competent Authority/ies
- PAFF: Standing Committee on Plants, Animals, Food and Feed (ex-SCoFCAH)
- RASFF: Rapid Alert System for Food and Feed
- 'Secondary legislation': all legislative (or non-legislative) texts that fall in the scope of the GFL
- SMEs: Small and Medium size Enterprises
- ToR: Terms of Reference of the study on the evaluation of the GFL
- WG: Working Group

The following **evaluation themes** are addressed in the evaluation questions:

- **Relevance.** The extent to which the original objectives of the GFL correspond to current needs. In making this assessment we will need to keep in mind that needs can evolve and so it is possible that recent events, such as the horsemeat scandal, will have resulted in a different set of needs to those apparent at the time the GFL was drafted.
- **European added value.** This term refers to the benefits accruing from establishing the GFL at the EU level rather than allowing Member States to operate national or regional policies. The relationship to international obligations (Codex, OIE) is also important here.
- **Effectiveness.** The extent to which the intervention resulting from the application of the GFL (including the application of its fundamental definitions, principles and requirements in related specific pieces of food law) caused changes in the EU food safety area. This aspect of the evaluation will also examine the extent to which the objectives have been achieved, identify areas where expectations have not been met, identify factors which have hindered their achievement and the role, if any, of policy measures outside the framework of food law as set out in the GFL, in the achievement of observed changes. Because there may be national differences, it will be important to assess effectiveness at both the national and EU level.
- **Efficiency.** The extent to which the costs involved (including the costs generated by the application of its fundamental definitions, principles and requirements in related specific pieces of food law) have been justified given the effects achieved. Actions to reduce regulatory burden, potential alternative policy instruments or mechanisms that could improve cost-effectiveness will need to be assessed.
- **Internal coherence.** The extent to which the GFL has contributed to the internal coherence of EU food law.
- **External coherence.** The extent to which the EU food safety regulatory framework established by the GFL and its implementation works together with other Member State interventions which have similar objectives.
- **Complementarity.** The extent to which the EU food safety policy framework established by the GFL proved complementary to other EU interventions/initiatives in the field of food policy such as the Common Agricultural Policy, environmental policy, etc.
- **Adaptation.** As an outcome of this exercise, the extent to which aspects of the GFL and/or other related specific pieces of food law should be adapted.