MEMBER STATE EXPERT GROUP ON GFL

MEETING ON

FITNESS CHECK OF REGULATION (EU) №178/2002

(THE 'GENERAL FOOD LAW')

Centre Borschette, meeting room AB-1D

10.00h – 18.00h

16 January 2015

FCEC working document

This document is addressed to participants of the Member State Expert Group meeting on the Fitness Check of Regulation (EU) №178/2002 (the 'General Food law' – GFL), 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 four 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** is highly encouraged during and after the Expert Group meeting, and in particular:

- **During the meeting**: you will have the opportunity to contribute your comments through a **discussion** in the sections that follow the FCEC presentation;
- **After the meeting**: 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 in the follow up discussions. The deadline for submitting your contact details to the FCEC is set at **30 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, you will have the opportunity to contribute in writing your feedback on the various issues. The deadline for submitting your contributions to the FCEC is set at **28 February 2015**.
    - Any literature, including studies and reports conducted by your services or in your Member State, which are relevant to the GFL evaluation and the specific issues under discussion in this Working Document.

You are welcome to submit your contact details and contributions on the various topics raised, by email to the FCEC at:

anne.marechal@ceasc.com

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 risk analysis

Background

One of the key principles introduced by the GFL is the scientific basis to food law (Article 6), except where a risk to life or health exists but scientific uncertainty persists measures can be taken on a precautionary basis (Article 7). This principle is in line with international obligations and *Codex Alimentarius* provisions. Article 6 foresees that in order to achieve a high level of protection of human health and life, measures adopted by the Member States and the Union governing food and feed ('food law') should generally be based on risk analysis (except where this is not appropriate to the circumstances or the nature of the measure). The recourse to risk analysis prior to the adoption of such measures also aims to avoid any unjustified barriers to the free movement of feed/food products.

There are three interconnected components to risk analysis (Article 3): **risk assessment, risk management and risk communication**. These components together provide a systematic methodology for the determination of effective, proportionate and targeted measures or other actions to protect health.

Risk analysis is to be carried out according to a two-step process:

- **Risk assessment** (Article 6(2)) means a scientifically based process consisting of four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation. Risk assessment should be undertaken in an independent, objective and transparent manner, on the basis of the available scientific information and data.
- **Risk management** (Article 6(3)) means the process of weighing policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors, and, if need be, selecting appropriate prevention and control options. It is recognised that scientific risk assessment alone cannot, in some cases, provide all the grounds on which a risk management decision can be based, and that other relevant factors should legitimately be taken into account including societal, economic, traditional, ethical and environmental considerations and the feasibility of controls.

In parallel, and throughout the risk analysis process, **risk communication** should be continuous, i.e. there should be an interactive exchange of information and opinions among all interested parties (as defined in Article 3).

Finally, in those specific circumstances where the possibility on harmful effects on health is identified but scientific uncertainty persists **the precautionary principle** (Article 7) may be invoked. In those cases, Article 7 provides a mechanism for determining risk management measures or other actions, on a precautionary basis, in order to ensure a high level of health protection in the EU.

The purpose of the study with regard to the risk analysis provisions and principles is to analyse the impacts (positive and negative) of Art. 6 and 7 provisions, including their implementation in secondary legislation, the extent to which they have been of added value/benefit, whether or not positive impacts outweigh negative impacts, and the overall sufficiency and effectiveness of the provisions for ensuring food and feed safety and public health. In doing this, the analysis is seeking a description of how risk analysis principles and procedures have evolved following the introduction of this requirement by the GFL.

The identified sectors of secondary legislation on which this case study will focus are: food contact materials, food additives, feed additives and contaminants.

Questions

We would like to receive inputs from the Member State Competent Authorities on the following aspects - **focussing on your Member State but also highlighting differences from approaches of other member States where possible**[1]:

Article 6 (Risk analysis)

1. To what extent was risk analysis applied in your Member State, **prior to the application of the GFL**, on the basis of the risk analysis principles of Article 6? In particular:
    a. To what extent was risk assessment based on available, independent scientific evidence?
    b. If not, on which factors was it based?
    c. To what extent was risk management based on the results of risk assessment as identified above?
    d. Were other legitimate factors taken into account in the risk management process? What were the key legitimate factors that were considered in addition to risk assessment?
    e. Did the risk analysis process involve a continuous interactive exchange of information and opinions among all interested parties (risk communication processors)? Which were the parties that were mostly involved in risk communication (risk assessors, risk managers, consumers, feed/food businesses, the academic community, NGOs, etc.)?
    f. To what extent did this interactive exchange of information provide an explanation of risk assessment findings and the basis of risk management decisions?
    g. Did you separate risk assessment and risk management prior to the GFL? In what way?
    h. Was risk assessment/risk management applied across all the different sectors of food law (with reference to secondary legislation)?
    i. If not, did it apply in specific sectors (secondary legislation)? Which ones? *Please highlight key sectors of secondary legislation where risk assessment/risk management was applied.*

2. How has risk analysis, as laid down in Article 6, been applied in practice in your Member State **after the GFL**? *If providing a global overview is not possible, please highlight key patterns of application of Article 6 and any adjustments that were required.* In particular:
    a. To what extent has risk assessment/risk management been integrated in existing administrative structures, systems and procedures?
    b. To what extent have you had to adapt existing structures, systems and procedures in order to integrate the risk analysis?
    c. After the establishment of EFSA, has it reduces the need for risk assessment

[1] Without naming particular Member States, but simply by indicating e.g. in Member State *A* the approach is different ... when compared to that followed in our Member State, or in Member State *B*.

activities at national level?
   d. Have you had to develop (other) new structures?
   e. Have you established an independent risk assessment body following the adoption of the GFL?
   f. Are there rules/guidance governing the undertaking of risk assessment in your country?
   g. Is risk assessment/risk management applied across all the different sectors of food law (with reference to secondary legislation)?
   h. If not, does it apply in specific sectors (secondary legislation)? Which ones? *Please highlight key sectors of secondary legislation where risk assessment/risk management was applied.*

3. What have been the main constraints and difficulties encountered in the application of risk analysis in line with Article 6? *Please provide evidence highlighting key issues and reasons why.*

4. What has been the impact (positive or negative) of having the risk analysis principle as laid down in Article 6: i) at EU level/at national level; ii) amongst the different elements of risk analysis: risk assessment, risk management and risk communication; iii) on international trade? *Please highlight the main positive/negative impacts and reasons why. Please note that positive impacts (benefits) are explored further in questions 6-8.* In particular:
   a. Has it increased/decreased the incidence of unjustified barriers to the free movement of feed/food products within the EU? *Please provide evidence of specific cases highlighting whether unjustified barriers have increased/ decreased.*
   b. What has been the impact, positive or negative, on innovation?
   c. Has it increased/decreased the level of protection of human health and life?

5. Which sectors (EU secondary legislation) have been impacted the most (whether positively, or negatively) from the introduction of the Article 6 provisions, in terms of the change in the i) risk assessment and ii) risk management process, compared to the situation prior to the GFL? *Please provide evidence of specific cases highlighting different approach to risk analysis before/after the GFL (before the GFL: see Question 1) and positive/negative impacts. Please note that positive impacts (benefits) are explored further in questions 6-8.*

6. What have been, overall, the benefits of having the risk analysis principles laid down in Article 6? *Identify the key benefits of the Article 6 approach, in comparison also to the situation before the GFL (see Question 1). Please provide evidence of the benefits, to the extent possible also in quantitative terms, from specific cases.* The following might be some of the benefits of the risk analysis provisions of Article 6:
   a. Has it improved the scientific basis of measures adopted by i) the Member States and ii) the Union on food and feed?
   b. Has it contributed to more proportionate risk management measures?
   c. Has it improved transparency and accuracy/clarity of the information exchange with all interested parties? *E.g. cases where this has occurred vs cases where this has not occurred and resulting impact on consumer trust/confidence.*
   d. Other benefits? (*please identify*)

7. Which sectors (EU secondary legislation) have benefitted the most from the introduction of the Article 6 provisions, in terms of the above benefits? *Please provide evidence of specific cases highlighting the benefits achieved and reasons why.*

8. Where any of the above benefits have not been achieved, what were the implicating factors that constrained achievement? Which part of the risk analysis process is mostly affected by the identified factors: risk assessment; risk management; risk communication? *Please provide evidence highlighting cases (e.g. sectoral legislation) where benefits have not been achieved, key issues blocking achievement and reasons why, distinguishing between issues affecting risk assessment, risk management, and risk communication (your answer could be combined with Question 3).*

9. To what extent do the positive impacts of risk analysis (as laid down in Article 6) outweigh negative impacts? *If providing a global overview of the balance of positive vs negative impacts is not possible, please provide ad hoc evidence of specific cases where positive outweigh negative impacts, and vice versa.*

10. What has been the added value of having EU-wide risk analysis principles laid down in Article 6 compared to what could be achieved by Member States at national and/or regional level? *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.* In particular:
    a. Has Article 6 resulted, in practice, in a more consistent approach regarding risk assessment and risk management approaches across Member States?
    b. Has Article 6 resulted, in practice, in a more consistent approach regarding risk assessment and risk management approaches across the different sectors of food law (secondary legislation)? Is such a consistency possible/desirable (in view of the different context and technical elements of secondary legislation)?

11. In terms of the balance between the positive and negative impacts of Article 6, 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 be achievable without the GFL? *Please provide evidence highlighting specific cases and reasons why.*

12. How has the separation and the interface between risk assessors and risk managers **at EU level** been functioning in practice? How has this evolved since the introduction of the GFL and the establishment of EFSA? *Please provide evidence highlighting specific cases of differential approaches, if any, in specific sectors.* In particular:
    a. To what extent is risk assessment at EU level applied in an independent, objective and transparent manner?
    b. To what extent is the balance between science and other legitimate factors in risk management decisions transparent in all cases?
    c. To what extent is the balance between science and other legitimate factors in risk management decisions consistent amongst sectors of EU food law?
    d. To what extent is the foreseen process of interactive exchange of information and opinions among all interested parties consistently applied at EU level?

13. Are there differences in **Member State interpretation** of the principles of Article 6? *Please provide evidence highlighting specific cases of differential approaches amongst Member States.* In particular:
    a. To what extent is risk assessment applied in an independent, objective and transparent manner at national level?
    b. What is the trigger for the application of Article 6 (risk assessment/ risk management) at national level? To what extent is the balance between science and other legitimate factors in risk management decisions transparent in all cases at national level?
    c. To what extent is the balance between science basis and other legitimate factors in risk management decisions consistent amongst Member States/amongst sectors of national food law?
    d. To what extent is the foreseen process of interactive exchange of information and opinions among all interested parties consistently applied amongst Member States at national level?

14. If there are differences in approaches, …
    a. Are these differences in interpretation between the EU and Member States, or in interpretation amongst Member States?
    b. Are these due to differences in administrative structures/cultures, in the overall national legislative framework, or other factors? *Please identify key factors underpinning differences in approaches.*
    c. Are the GFL provisions on risk analysis (Article 6) sufficient to ensure a more harmonised approach? Generally speaking, if you have experienced deviations in interpretation of Article 6 amongst Member States, 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.* Should the GFL provisions be clarified/ more prescriptive?
    d. What are the impacts/consequences of different approaches amongst Member States regarding risk analysis? *Please provide concrete cases highlighting the impacts of differences in approaches to risk assessment, risk management and risk communication amongst Member States.*

15. In which cases (e.g. in which circumstances or areas), do you consider it necessary to have national risk assessments? *Please specify examples and reasons why.*

16. In cases where there have been national risk assessments, did it result in **national** risk management decisions? *Please specify measures taken on this basis*

17. Are there any gaps/problems in the current provisions of Article 6? *Please provide evidence highlighting specific cases and reasons why.*

18. Is the current framework of risk analysis, as laid down in Article 6, sufficient? Has it enabled, over time, ensuring a high level of feed/food safety and public health protection? *If current risk analysis framework is/is not sufficient, please provide evidence highlighting specific cases where this has/has not proven to suffice in ensuring a high level of feed/food safety and public health protection and reasons why.*

Article 7 (precautionary principle)

19. To what extent was the concept of the precautionary principle applied in your Member State, **prior to the application of the GFL**? How was it defined in your Member State **prior to the GFL**?

20. To what extent has the precautionary principle, as laid down in Article 7, been applied in practice in your Member State **after the GFL**? Are there rules/guidance governing the use of the precautionary principle in your country?
If providing a global overview is not possible, please highlight key patterns of application of Article 7 and any adjustments that were required.

21. What have been the main constraints and difficulties encountered in the application of the precautionary principle in line with Article 7? *Please provide evidence highlighting key issues and reasons why.*

22. What has been the impact (positive or negative) of having the precautionary principle as laid down in Article 7? *Please highlight the main positive/negative impacts and reasons why.* In terms of the potential impacts, please consider:
    a. Has it increased/decreased the incidence of unjustified barriers to the free movement of feed/food products within the EU? *Please provide evidence of specific cases*
    b. Has it increased/decreased the level of protection of human health and life?
    c. What has been the impact, positive or negative, on innovation and why?
    d. Other benefits? (*please identify*)

23. Which sectors (EU secondary legislation) have been impacted the most (whether positively, or negatively) from the introduction of the Article 7, in terms of the application of the precautionary principle, compared to the situation prior to the GFL? *Please provide evidence of specific cases highlighting different approach to risk analysis, by taking the precautionary principle into account, before/after the GFL and positive/negative impacts.*

24. What has been the added value of having EU-wide precautionary principle laid down in Article 7 compared to what could be achieved by Member States at national and/or regional level? *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.* In particular:
    a. Has Article 7 resulted, in practice, in a more consistent approach regarding the precautionary principle approaches across the different sectors of EU food law (EU secondary legislation)?
    b. Has the adoption of a uniform basis throughout the EU enabled limiting barriers to the free movement of food and feed?

25. In terms of the balance between the positive and negative impacts of Article 7, to what extent do you consider the situation would have been better/worse without the GFL? Could have any of the benefits identified been achievable without the GFL?

Please provide evidence highlighting specific cases and reasons why.

26. Are there differences in interpretation of the principles of Article 7? Is Article 7 applied correctly? *Please provide evidence highlighting specific cases of differential approaches at EU level, between EU and MS, amongst Member States?* In particular:
    a. Are there issues with the understanding of 'scientific uncertainty'? *Please provide evidence highlighting specific cases of differential approaches, if any, in specific sectors.*
    b. What is the trigger for the application of Article 7? Have you defined in your country a level of scientific uncertainty threshold under which Article 7 applies (or should apply)? *Please provide evidence highlighting specific cases*
    c. To what extent is the precautionary principle at EU or national level applied in an independent, objective and transparent manner?

27. Is the current framework for the precautionary principle applicable to food law, as laid down in Article 7, sufficient? Has it enabled, over time, ensuring a high level of feed/food safety and public health protection? *If current risk analysis framework is/is not sufficient, please provide evidence highlighting specific cases where this has/has not proven to suffice in ensuring a high level of feed/food safety and public health protection and reasons why.*

2. Discussion on transparency provisions

Background

Transparency (public consultation and public information) is a fundamental principle of the GFL:

- Article 9 foresees that *"There shall be open and transparent public consultation, directly or through representative bodies, during the preparation, evaluation and revision of food law, except where the urgency of the matter does not allow it."*
- Article 10 foresees that *"Where there are reasonable grounds to suspect that a food or feed may present a risk for human or animal health, then, depending on the nature, seriousness and extent of that risk, public authorities shall take appropriate steps to inform the general public of the nature of the risk to health, identifying to the fullest extent possible the food or feed, or type of food or feed, the risk that it may present, and the measures which are taken or about to be taken to prevent, reduce or eliminate that risk."*

As such, Article 9 pertains to the application of transparency during the legislative and decision-making process in peace time, while Article 10 pertains to transparency during times of important risks.

These provisions aim to ensure that consumer confidence and the confidence of stakeholders and trading partners through the open and transparent development of food law (Article 9), and through public authorities taking the appropriate steps to inform the public where there are reasonable grounds to suspect that a food may present a risk to health (Article 10). This is necessary in view of the growing concern in food safety and the protection of consumer's interests, of the general public, non-governmental organisations, professional associations, international trading partners and trade organisations.

The purpose of the study with regard to the transparency principle is to analyse the impacts (positive and negative) of Art. 9 and 10 provisions, including their implementation in secondary legislation, the extent to which they have been of added value/benefit, whether or not positive impacts outweigh negative impacts, and the overall sufficiency and effectiveness of the provisions for ensuring the open, balanced and transparent development of food law as well as in crisis situations, and ultimately, ensuring consumer trust and confidence of all interested parties. In doing this, the analysis is seeking a description of how transparency principles and procedures have evolved following the introduction of these provisions in Articles 9 and 10 of the GFL.

Questions

We would like to receive inputs from the Member State Competent Authorities on the following aspects - **focussing on your Member State but also highlighting differences from approaches of other Member States where possible**[2]:

1. To what extent was transparency ensured in your Member State, **prior to the application of the GFL**, on the basis of the principles of Articles 9 and 10? In particular:

   Article 9:

   a. Was there public consultation for EU/national feed/food legislation, during the various phases of its development? *Please distinguish between the various phases of legislative development (preparation; evaluation; and, revision).*
   b. Did consultation cover all of the main interest groups, or was it focussed on some groups, and which ones? *Please specific which interest groups tended to be mostly involved (farmers; food processors; distribution/retail; importers/exporters; SMEs; consumers; NGOs etc.).*
   c. Was public consultation carried out across all the different sectors of food law (with reference to secondary legislation)?
   d. How did the consultation process was conducted? *Please specify which elements were typically involved in the consultation process (consultation groups of stakeholders (were these ad hoc or permanent?); internet consultations; workshops; invitations for comments/positions; feasibility/ impact/evaluation studies; cost-benefit analysis; etc.).*
   e. If not, was it applied in specific sectors (secondary legislation)? Which ones? *Please highlight key sectors of secondary legislation where public consultation was applied.*

   Article 10:

   f. What was the trigger points and/or modalities for informing the general public on a potential food/feed safety risk? *Please specify whether public information tended to be: 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; only once notified to the Commission; only once measures were taken; where relevant, after confirmatory testing; as soon as there were reasonable grounds to suspect risk; other (please specify).*
   g. What information was communicated to the general public in the different risk situations? *For example, in the case of recalls, did the information tend to cover: product details; producer; lot numbers; other (please specify).*
   h. Did there exist standard procedures/protocols to be followed on the provision of information to the public in different situations of risk, including on the type of information to be provided?

2. How has transparency, as laid down in Article 9 (public consultation) and Article 10 (public information), been applied in practice in your Member State **after the GFL**? *If providing a global overview is not possible, please highlight key patterns of application of Articles 9 and 10, any adjustments that were required, distinguishing*

[2] Without naming particular Member States, but simply by indicating e.g. in Member State *A* the approach is different … when compared to that followed in our Member State, or in Member State *B*.

between the implementation of Article 9 (public consultation) and of Article 10 (public information). In particular:

a. Has public consultation/public information requirements of the GFL been integrated in existing administrative structures, systems and procedures?
b. If so, to what extent have you had to adapt existing structures, systems and procedures in order to integrate the public consultation/public information requirements of the GFL?
c. Have you had to develop (other) new structures?
d. Are there rules/guidance governing the undertaking of public consultation/public information in your country?

3. What have been the main constraints and difficulties encountered in the application of the transparency principles in line with Articles 9 and 10? *Please provide evidence highlighting key issues and reasons why, distinguishing between the implementation of Article 9 (public consultation) and of Article 10 (public information).*

4. What has been the impact (positive or negative) of applying the transparency principles as laid down in Articles 9 and 10? *Please highlight the main positive/negative impacts and reasons why, distinguishing between the implementation of Article 9 (public consultation) and of Article 10 (public information). Please note that positive impacts (benefits) are explored further in questions 6-8.* In particular:

Article 9:

a. Has it increased/decreased the level of consumer confidence/trust in the legislative process? *E.g. cases where this has occurred vs cases where this has not occurred and resulting impact on consumer trust/confidence.*
b. Has it increased/decreased the level of confidence/trust of other stakeholders/interest groups in the legislative process? *E.g. cases where this has occurred vs cases where this has not occurred and resulting impact on trust/confidence.*

Article 10:

c. Has it increased/decreased the level of consumer confidence/trust in the actions taken by public authorities to address the risks involved? *E.g. cases where this has occurred vs cases where this has not occurred and resulting impact on consumer trust/confidence.*
d. Has it increased/decreased the level of confidence/trust of other stakeholders/interest groups in the legislative process? *E.g. cases where this has occurred vs cases where this has not occurred and resulting impact on trust/confidence.*

5. Which sectors (EU secondary legislation) have been impacted the most (whether positively, or negatively) from the introduction of the Article 9 and 10 provisions, in terms of the change in the public consultation/public information requirements, compared to the situation prior to the GFL? *Please provide evidence of specific cases highlighting different approach to public consultation/public information before/after the GFL (before the GFL: see Question 1) and positive/negative impacts. Please note that positive impacts (benefits) are explored further in questions 6-8.*

6. What have been, overall, the benefits of having the transparency principles laid down in Articles 9 and 10? *Identify the key benefits of the approach laid down in Articles 9*

and 10, in comparison also to the situation before the GFL (see Question 1). Please provide evidence of the benefits, to the extent possible also in quantitative terms, from specific cases, distinguishing between the implementation of Article 9 (public consultation) and of Article 10 (public information). In particular:

Article 9

The following might be some of the benefits of the public consultation provisions of Article 9:

a. Has it improved, overall, the consultation process in your Member State? *Please specify improvements in terms of: i) the various phases of legislative development (preparation; evaluation; and, revision); and ii) elements typically involved in the consultation process (consultation groups of stakeholders: please specify whether these are currently ad hoc or permanent); internet consultations; workshops; invitations for comments/ positions; feasibility/ impact/evaluation studies; cost-benefit analysis; etc.).*
b. Has it ensured a more comprehensive, as well as more balanced, representation of interests in your Member State?
c. Has it improved transparency and accuracy/clarity of the information provided to all interested parties in your Member State?
d. Other benefits? (*please identify*)

Article 10

The following might be some of the benefits of the public consultation provisions of Article 10:

e. Has it improved, overall, the provision of information to the public at times of important risks, in your Member State? *Please specify improvements in terms of: i) trigger points and/or modalities for informing the public on a potential food/feed safety risk; and ii) the information typically communicated to the public in the different situations. For example, in the case of recalls, did the provision of information to the public improve after the application of Art. 10?*
f. Has it ensured a more systematic approach to the provision of information to the public in your Member State? Were standard procedures/protocols set up on the provision of information to the public in different situations of risk, including on the type of information to be provided? If such procedures/protocols pre-existed, did these improve?
g. Has it improved transparency and accuracy/clarity of the information provided to all interested parties in your Member State?
h. Has it helped preventing/managing food and feed crises?
i. Has it helped limiting unnecessary disruption of trade?
j. Has it helped limiting financial damage?
k. Other benefits? (*please identify*)

7. Which sectors (EU secondary legislation) have benefitted the most from the introduction of the provisions of Articles 9 and 10, in terms of the above benefits? *Please provide evidence of specific cases highlighting the benefits achieved and reasons why, distinguishing between the implementation of Article 9 (public consultation) and of Article 10 (public information).*

8. Where any of the above benefits have not been achieved, what were the implicating factors that constrained achievement? Has this affected mostly public consultation or public information? *Please provide evidence highlighting cases (e.g. sectoral legislation) where benefits have not been achieved, key issues blocking achievement*

and reasons why, distinguishing between issues affecting the implementation of Article 9 (public consultation) and of Article 10 (public information) (your answers could be combined with Question 3).

9. To what extent do the positive impacts of transparency (as laid down in Articles 9 and 10) outweigh negative impacts? *If providing a global overview of the balance of positive vs negative impacts is not possible, please provide ad hoc evidence of specific cases where positive outweigh negative impacts, and vice versa. (Please distinguish between the implementation of Article 9 (public consultation) and of Article 10 (public information)).*

10. What has been the added value of having EU-wide transparency principles laid down in Articles 9 and 10 compared to what could be achieved by Member States at national and/or regional level? *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, distinguishing between the implementation of Article 9 (public consultation) and of Article 10 (public information).* In particular:

    Article 9:

    a. Has the consultation process improved, EU-wide, as a result of Article 9 of the GFL?? *Please specify improvements in terms of: i) the various phases of legislative development (preparation; evaluation; and, revision); and ii) elements typically involved in the consultation process (consultation groups of stakeholders (are they currently ad hoc or permanent?); internet consultations; workshops; invitations for comments/positions; feasibility/ impact/evaluation studies; cost-benefit analysis; etc.).*
    b. If not, why?

    Article 10:

    c. Has Article 10 improved, overall, the provision of information to the public at times of important risks at EU-level? *Please specify improvements in terms of: i) trigger points and/or modalities for informing the public on a potential food/feed safety risk; and ii) the information typically communicated to the public in the different situations. For example, in the case of recalls, did the provision of information to the public improve after the application of Art. 10?*
    d. Has Article 10 ensured a more systematic approach to the provision of information to the public at EU-level?
    e. Have the GFL transparency provisions improved transparency and accuracy/clarity of the information provided to all interested parties at EU-level?
    f. Have the GFL transparency provisions resulted, in practice, in a more consistent approach regarding public consultation and public information approaches across Member States?
    g. Have the GFL transparency provisions resulted, in practice, in a more consistent approach regarding public consultation and public information approaches across the different sectors of food law (secondary legislation)? Is such a consistency possible/desirable (in view of the different context and technical elements of secondary legislation)?

11. In terms of the balance between the positive and negative impacts of Articles 9 and

10, 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 be achievable without the GFL? *Please provide evidence highlighting specific cases and reasons why, distinguishing between the implementation of Article 9 (public consultation) and of Article 10 (public information).*

12. Are there differences in **Member State interpretation** of the principles of Articles 9 and 10? *Please provide evidence highlighting specific cases of differential approaches amongst Member States.* In particular:
    a. To what extent is public consultation applied in a comprehensive, balanced and transparent manner across Member States?
    b. To what extent is public information provided in a comprehensive and transparent manner across Member States? To what extent are there differences in the trigger points/ modalities for the provision of information to the public at times of risks?

13. If there are differences in approaches, …
    a. Are these due to differences in administrative structures/cultures, in the overall national legislative framework, or other factors? *Please identify key factors underpinning differences in approaches.*
    b. Are the GFL provisions on public consultation and public information (Articles 9 and 10) sufficient to ensure a more harmonised approach? Generally speaking, if you have experienced deviations in interpretation of Articles 9 and 10 amongst Member States, 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.* Should the GFL provisions be clarified/ more prescriptive?
    c. What are the impacts/consequences of different approaches amongst Member States regarding public consultation and public information? *Please provide concrete cases highlighting the impacts of differences in approaches to public consultation and public information amongst Member States.*

14. Are there any gaps/problems in the current transparency provisions of Articles 9 and 10? *Please provide evidence highlighting specific cases and reasons why, distinguishing between the implementation of Article 9 (public consultation) and of Article 10 (public information).*

15. Is the current framework on transparency, as laid down in Articles 9 and 10, sufficient? Has it enabled, over time, ensuring a high level of trust/confidence of consumers/other interest groups in feed/food law? *If current transparency framework is/is not sufficient, please provide evidence highlighting specific cases where this has/has not proven to suffice* in *ensuring a high level of feed/food safety and public health protection and reasons why.*

3. Other case studies and general questions

There are two more case studies under the GFL evaluation:

- **Traceability** (Article 18);
- **Feed/food business operator (FBO) responsibilities and allocation of responsibilities** along the supply chain, as well as between FBOs and Member State Competent Authorities (Article 17; *Articles 14 and 15; Articles 19/20/21*).

These issues have been discussed in a workshop with the stakeholders involved in the 'farm to table' supply chain, including consumers and NGOs, which was held in Brussels on 19 December 2014 (in the context of the Advisory Group on the Food Chain). The working document that was used for this workshop is attached. Member State Competent Authorities are invited to contribute their feedback on the issues raised by these case studies *(please consult the working document for detailed questions).*

In addition, we would welcome the feedback of Member State Competent Authorities on the following two general evaluation questions:

- **To what extent were differences between Member State markets and cultures taken into account in the GFL and did that improve the efficiency and effectiveness of the law?** This question is particularly pertinent for the new Member States, i.e. those that joined the EU after the adoption of the GFL in 2002.
    a. *Please indicate whether, overall, the GFL has brought about a major change in national approaches to feed/food law, as applied prior and after the introduction of the GFL. Please provide specific examples.*
    b. *Please highlight the extent to which the GFL has improved the effectiveness and efficiency of feed/food law in your Member State. Please provide specific examples.*
    c. *Please highlight the extent to which the GFL has achieved a greater harmonisation of national approaches to feed/food law across the EU, and whether this has led to an improved level of feed/food safety in the period since the GFL was introduced. Please provide specific examples.*

- **To what extent has the EU feed/food safety regulatory framework established by the GFL worked together with other Member States interventions which have similar objectives?**
    a. *Please indicate whether there are other interventions in your Member State that have similar objectives. If yes, please briefly describe these.*
    b. *Please highlight the extent to which these are complementary/conflicting to the GFL and to other EU secondary legislation that is based on the GFL. Please provide specific examples.*

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
- NGOs: Non governmental organisations
- 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.