EFSA's approach on Public Consultations on scientific outputs

1. Executive summary

EFSA's approach on public consultation described in this document reflects EFSA's commitment to transparency, accountability, high scientific quality and efficiency. It will foster the already elaborated interaction between EFSA, EU citizens, consumers, and all relevant stakeholders.

The present document reflects the importance of consultation in shaping EFSA's vision and priorities to meet its mission. It is striving for a comprehensive and integrated approach on public consultations to ensure that this process follows common criteria that allows public involvement in a transparent, coherent and timely manner.

The criteria for consultation are considered from the following perspectives:
- why consult,
- what issues are relevant for public and/or focused consultations,
- who should be consulted,
- which is the most appropriate means of consultation,
- how to follow up on the input received.

These criteria are assessed alongside the general principles of EFSA consultation approach:
- clarity around the consultation (definition of the scope and the subject, clarification of the type of consultation and the reasons behind the need to consult the public on the specific issue),
- adequate consultation in terms of timing, representativeness, balanced engagement and electronic alert system (e.g. specific mails sent only to relevant stakeholders),
- careful process through clear and structured steps taking into account the issue of consultation fatigue (do consult, but do not over consult).

The document aims at describing the criteria and tools of public consultation on scientific outputs. It therefore:
- Provides criteria for the identification of the need for a public consultation on a scientific output,

- Identifies the nature of scientific output on which public consultations can be performed and where they cannot,
- Identifies the methods to be used to ensure the effectiveness of public consultation,
- Establishes the means to report on the outcome of the consultation processes.

In addition practical internal implementation measures in form of standard operating procedures have been established at EFSA[1].

2. Introduction

The importance of public consultations is set out in EFSA's Founding Regulation[2]. It is widely acknowledged that EFSA has been created *inter alia* in order to regain consumer confidence in the EU food safety system[3]. Under EFSA's Founding Regulation this is attained through the implementation of two main principles that underline EFSA's daily obligations, namely transparency and scientific excellence[4].

The importance of public consultations to ensure that EFSA is seen, and perceived, as a glass house is apparent and inherent to the concept of transparency. It is not by coincidence that Article 42 of EFSA's Founding Regulation also explicitly mentions the interaction between EFSA and the public.

In addition, consulting on draft scientific outputs are also important in gathering views, data sources and comments that should in turn ensure the completeness, the clarity and the effective respect of those outputs. Against this background, EFSA's Management Board of June 2006 adopted several recommendations aimed at developing such interaction.[5] The same importance to the involvement of third parties is driving the Guidance Document endorsed in April 2006 by the Scientific Committee on "*transparency in risk assessment carried out by EFSA*"[6].

It should furthermore be noted that the ability of EFSA to publicly consult must be viewed in the context of the applicable legal framework. Hence, public consultations will be carried out by EFSA when, and in a manner which is, compatible with the procedures and deadlines laid down in the relevant EU legislation or required by the risk managers.

Since its foundation EFSA has placed great emphasis on public consultations and has now conducted over 30 consultations since 2005. Based on the experience gathered during this period EFSA is now in the position to set out its approach on public consultations, with the contribution of the Stakeholder Consultative Platform.

3. Defining public consultation

Public consultation on scientific outputs according to this document means the creation of an effective exchange on a draft scientific output based on a decision of EFSA to seek comments from the public, namely the non-institutional stakeholders[7], which include academics, NGOs, industry and all other potentially interested and affected parties.

In addition to public consultation, EFSA also regularly consults with institutional partners on many different levels in different *fora* based on diverging legal bases. This document does therefore not address the input of **institutional partners**[8] in the context of the different sectoral legislation or the exchanges with EFSA's **statutory bodies**[9]**.**

EFSA's role is to assess and communicate on all risks associated with the food chain. Accordingly, EFSA's advice frequently supports the risk management and policy-making

processes. These may involve the process of adopting or revising European legislation on food or feed safety, deciding whether to approve regulated substances such as pesticides and food additives, or, developing new regulatory frameworks and policies for instance in the field of nutrition.

EFSA can launch a public consultation during the following stages of developing a scientific output:

i) At the beginning of the process in the case of self-tasking (to define the scope and major principles),
ii) At a preliminary step in the assessment process, not long after EFSA's scientific experts or staff have started to work on the output. In these cases, event, EFSA is usually seeking information, data, views and sources available on a specific topic, at the beginning of the work in order to have the best data possible and/or approach proposed for the scientific output,
iii) When a draft scientific output is available outlining EFSA's initial position in relation to the scientific issue. As a rule, the goal of these consultations is to ensure the clarity, completeness and soundness of the draft scientific output.

4. Objectives

The main objective of this document is to provide for a corporate coordinated approach to public consultations on scientific outputs by:

1. Providing criteria for the identification of the need for a public consultation on a scientific output,
2. Identifying the types of scientific output on which public consultations can be performed,
3. Identifying the methods to ensure the effectiveness of public consultation,
4. Establishing a means to report on the outcome of the consultation processes.

4.1 Criteria for public consultation

Identifying the need for a consultation must be based on coherent and clear criteria. The following criteria provide guidance for the circumstances where EFSA will consider the need to publicly consult:

(1) New type of questions: in areas where EFSA has not issued opinions previously and where a public consultation would ensure that the knowledge on different types of approach and information is available for risk assessment or developing risk assessment methodologies.

(2) Complex/emerging scientific issues: in case EFSA is dealing with particular issues where science has progressed substantially in the past or which includes novel technologies where information and approaches in risk assessment are still to be developed.

(3) Risk assessment methodologies/principles/processes: documents of horizontal nature or risk assessment approaches where a broad range of comments sought will support the clarity and effective respect of the scientific output.

4.2 The nature of the documents

In line with EFSA's mission, EFSA is committed to make use of public consultations in a broad way.

However, the public consultation process must be undertaken within the relevant legal framework regulating the respective domain. The ability of EFSA to consult could be limited *inter alia* by:

a) the need to comply with strict legal or negotiated deadlines set for developing scientific outputs,
b) the particular urgency of a question,
c) the fact that certain regulatory procedures already foresee public consultations,
d) the confidential nature of certain data or information contained within an output,
e) the protection of personal and "regulatory" data.

4.3 Outputs viable for public consultations

In view of the criteria outlined above under 4.1, and considering the categories of scientific outputs[10] of EFSA according to its decision, EFSA may organize public consultations on the following:

a. Scientific opinions of the Scientific Committee and/or Panels[11]
b. Statements of the Scientific Committee and/or Panels
c. Statements of EFSA
d. Guidance documents of the Scientific Committee and/or Panels
e. EFSA guidance documents
f. Scientific or technical reports of EFSA
g. EFSA self-task outputs.

4.4 Outputs not viable for public consultations

Considering the same criteria outlined above, EFSA is not in a position to organize public consultations on the following outputs:

a. Scientific opinions of the Scientific Committee and/or Panels on the so called regulated substances, where the legal framework limits EFSA's ability to consult with the public (e.g. opinions on applications)[12]. In addition, the other limitations listed under 4.2. may need to be taken into consideration.
b. Statements of the Scientific Committee and/or Panels: where they are adopted in response to an urgent request or under emergency situations.

c. Conclusions from the Pesticides Peer Review process[13] and Reasoned opinion on maximum residue levels[14]: where only institutional consultations are foreseen.

4.5 The effectiveness of a public consultation

Public consultation should be an iterative process, not a single event or a series of single events to ensure good quality engagement of external stakeholders into EFSA's work.

It is necessary to have good process management with clear milestones (who consult, when, under which framework, with what follow up, with what expected results) to ensure the effectiveness and transparency of the consultations.

Effectiveness will be based on clear timelines, feedback and responsiveness. In order to have a successful and meaningful public consultation and to keep the consultation an iterative process, clear information must be provided and the right target groups must be informed in a timely manner.

Public consultations are addressed to the public and stakeholders and will as a rule, be processed via the EFSA web page. In this context it is important that the explanatory texts clarify the essential background information regarding the consultation. This includes the relevant deadlines, a clear indication that comments submitted will be published on EFSA's website, and a foreseen timetable and process for further developments. The consultation will also need to clarify the consultation target audiences, the nature of relevant information and further operational details e.g. comments which do not relate to the contents of the document or contain information on individual cases or are related to policy or risk management aspects, which is out of the scope of EFSA's activity, will not be taken into account.

In addition to reaching the public via its website EFSA may also use a more targeted approach to support the consultation process:

a) The Stakeholder Consultative Platform composed of EU-wide organisations operating in the food chain plays an important role in ensuring that consultations reach the relevant parties. The platform could help to identify the stakeholders with relevant expertise and those who will be genuinely affected by the scientific output (producers, users) and those that have a general interest. In addition to using the direct contact established in the stakeholder platform for the focused dissemination of consultations, the network between the stakeholders can be used to collect comments from additional third parties, giving the Stakeholder Platform the role of spokesperson of wider interests and needs, collecting additional inputs on specific sectors within EFSA's remit.

b) The organisation of targeted consultations such as technical meetings or hearings/brainstorming with stakeholders ensures that consultations on specific outputs are reaching the appropriate parties, allowing targeting particular groups or sectors which can be particularly affected by the scientific output. Such meetings are organised with a limited number of stakeholders and allow a focussed dialogue with scientific experts of EFSA.

c) The use of specialist media to divulge the open consultations launched or the organization of specific events (such as workshops or media events) can be an additional tool to help promoting the consultation exercise among interested groups.

5. Means to report on the outcome of the consultation process

In line with the principles of openness and transparency EFSA recognises the importance of providing feedback on the outcome of the consultation. The feedback should be provided during and at the end of the consultation process. Having collected comments submitted during a consultation, EFSA commits to preparing a written report on the comments received addressing how these have been addressed by EFSA.
The report lists the number of comments received, summarises the main areas/themes of concern, specifies how these comments were considered by EFSA and highlights if possible how the comments have been dealt with.

6. Conclusion

This document is part of a continuous dialogue between EFSA and the public. It will be used as "general guidelines" for public consultations on scientific outputs acknowledging the important role public consultation play in the development of scientific outputs.

EFSA plans to review the implementation of these guidelines within 2 years time. The lessons learned from experience will be used for future improvement and the review will look at the practical legal limitations and/or constraints, the level of expertise of comments, the handling of comments not based on science and the overall existing practices.

[1] This document is without prejudice to the forthcoming EFSA data collection strategy and does not address the consultations on non scientific policy documents which will be set out in the forthcoming EFSA Stakeholder policy.
[2] See recitals 55 and 56 of Regulation (EC) n° 178/2002.
[3] See recital 40 of Regulation (EC) n° 178/2002, above.
[4] See recital 32 and 40 and Article 22(7) Regulation (EC) n° 178/2002, above.
[5] (1) Develop active networking and stronger co-operation with Member States (2) Strengthen EFSA's relationship with its institutional partners (EU and international) and stakeholders (3) Enhance EFSA's organisation (4) Enhance the impact and effectiveness of EFSA's communications (5) Develop EFSA's role in nutrition (6) Define EFSA's mediumand long-term vision.
[6] Transparency in risk assessment carried out by EFSA: guidance document on procedural aspects Prepared by a working group consisting of members of the Scientific Committee and various EFSA Departments Request No EFSA-Q-2005-050 Endorsed on 11 April 2006 by the Scientific Committee
[7] Relevant stakeholders include all non-institutional stakeholders. They include (1) those parties who have knowledge or scientific expertise to contribute to a scientific output (2) those who are genuinely impacted (e.g. producers, users) by an output and (3) those parties with a general interest.
[8] Such as MS in the context of authorisation procedures (e.g. Reg.1829/2003).
[9] Such as the European Commission, National Competent Authorities member of EFSA's Advisory Forum, the European Parliament, National Focal Points, organizations listed in the list foreseen in Article 36 of EFSA's Founding Regulation *et cetera.*
[10] EFSA Website lists all EFSA's Scientific Outputs.
[11] Please see below, at 4.4.
[12] In particular, Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition; Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements; Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives; Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97; Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC; Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC; Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients; Regulation (EC) No 1829/2003 of European Parliament and of the Council of 22 September 2003 on the deliberate release into environment of genetically modified organisms, Regulation (EC) No 2065/2003 of the European Parliament and of the Council of of 10 November 2003 on smoke flavourings used or intended for use in or on foods and Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. It should also be noted that under the Better Regulation initiative, the European Commission has committed itself to systematic consultation of the public and of its main stakeholders in order to gather views on its draft legislative proposals: see EUROPEAN COMMISSION, *Towards a reinforced culture of consultation and dialogue - General principles and minimum standards for consultation of interested parties by the Commission*, Commission communication - COM(2002)704.
[13] Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market and implementing Regulations.
[14] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC.