

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

SUMMARY

The Scientific Committee was asked by the European Food Safety Authority to provide guidance that would ensure transparency in the risk assessments carried out by EFSA's Scientific Committee and Panels. In discussing the terms of reference, two main categories of issue emerged - procedural and scientific. This Guidance Document addresses all the process-related issues. It was prepared by a working group made up of members of the Scientific Committee and of several EFSA departments including the Science, Legal, Institutional and International Relations and Communication Departments. The science-related issues will be covered in a separate guidance document.

The Guidance Document highlights several procedural aspects related to risk assessment that can be considered beneficial for improved transparency, including: (i) selecting qualified scientists to participate in EFSA's activities and ensuring their independence; (ii) overall handling by EFSA of requests for scientific opinions; (iii) scientific opinions and other types of EFSA document; (iv) ensuring the availability of relevant data; (v) information exchange between the Scientific Committee, the Panels and the originator of the request; (vi) involvement of other stakeholders; (vii) dealing with diverging scientific opinions; (viii) adoption of scientific opinions; (ix) dissemination of documents and underlying data; (x) confidentiality aspects; and (xi) revising and updating scientific opinions. In doing so, this Guidance Document addresses the many important procedures already laid down - either in Regulation EC 178/2002 (EC, 2002a) known as The EFSA Founding Regulation - or in various internal EFSA documents, such as the Decision concerning the establishment and operations of the Scientific Committee and Panels.

Key words: transparency, procedural aspects, risk assessment

TABLE OF CONTENTS

SUMMARY	1
BACKGROUND	3
TERMS OF REFERENCE.....	3
TRANSPARENCY IN RISK ASSESSMENTS	4
1. Introduction	4
2. Process-related considerations	4
2.1. Selecting qualified scientists to participate in EFSA’s activities and making sure of their independence.....	4
2.2. Overall handling by EFSA of requests for a scientific opinion or for technical and scientific assistance	6
2.3. Scientific opinions and other types of EFSA documents.....	6
2.4. Ensuring availability of relevant data including those from literature.....	8
2.5. Information exchange between Scientific Committee or Panel and the originator of the request.....	9
2.6. Involvement of stakeholders other than the European Commission, the European Parliament and the Member States.....	10
2.7. Dealing with diverging scientific opinions among different bodies.....	11
2.8. Adoption of scientific opinions	11
2.9. Dissemination of scientific opinions, other documents and access to underlying data	12
2.10. Confidentiality	12
2.11. Revision and update of scientific opinions	12
CONCLUSIONS	13
REFERENCES	14
SCIENTIFIC COMMITTEE MEMBERS	15
ACKNOWLEDGMENT.....	15
ANNEX	16

BACKGROUND

Increasing consumer confidence in risk and safety assessment (hereafter referred to as risk assessment) and ensuring a clear separation between risk assessment and risk management in particular was one of the main reasons for establishing the European Food Safety Authority (EFSA). The EFSA Founding Regulation (EC, 2002a) states that risk assessments should be undertaken in an independent, objective and transparent manner on the basis of the available scientific information and data. As the advice provided by EFSA is a main basis for decision making in the food and feed sector, risk managers and consumers need to get a deep understanding of the procedure through which the risks have been assessed and of the validity and limitations of the outcome and of all the associated implications.

A clear formulation of the scientific request to EFSA in the form of detailed 'terms of reference' is an important step that must be taken before a risk assessment can be carried out. These 'terms of reference' should include a clear definition of the mandate/request and a plan for characterising and assessing the risk.

Comprehensive and reliable human or animal exposure-effect data are rarely available. Therefore, risk assessment is often confronted with incomplete data generated in experimental systems including laboratory animals, *in vitro* and *in silico* approaches or data from case reports and epidemiological studies in human beings and animals. The information generated in this manner has to be combined with available human or animal exposure data in order to estimate the risk. Inherent to such an assessment is the involvement of varying degrees of uncertainty, for example uncertainties related to extrapolation from test animals to human beings, variability in the human population, exposure duration, gaps and deficiencies in the database. Therefore, it is important that the strengths and limitations of the data used and the subsequent conclusions are well explained. In addition, the risk assessment should describe the underlying assumptions and uncertainties. Explaining the inclusion criteria as well as exclusion-criteria for specific data sets (e.g. the use of human or animal data for the identification of the most sensitive endpoint as point of departure) is very important for the understanding of the level of certainty or uncertainty of the outcome.

Harmonised transparent approaches are a prerequisite when risks are assessed by the Scientific Committee and Panels of EFSA.

TERMS OF REFERENCE

The Scientific Committee was requested by the European Food Safety Authority to provide guidance on relevant information to be included in EFSA's opinions to ensure the transparency of the risk assessments carried out by EFSA's Scientific Committee and Panels. Such guidance should result in:

- process-related considerations, e.g. appropriate stakeholder involvement prior and during the risk assessment, handling, justification or explanation of minority opinion;
- consistent and harmonised documentation;
- a sufficiently detailed description of the strengths, robustness and limitations of the data used for the risk assessment;
- a clear description of the underlying assumptions and uncertainties providing the reasoning for decisions;
- a list of criteria for inclusion or exclusion of available scientific information for a given risk assessment, e.g. criteria for selection of pivotal studies and data, being part of the risk assessment;
- structured and stepwise approaches in hazard and risk assessment, e.g. science-based decisions for the need of additional studies based on previous studies in a stepwise approach, resulting in an optimal set of toxicity tests (conceptual framework with decision points).

In discussing the terms of reference, it was decided to divide the request into two parts. This Guidance Document would address all process-related issues and the science-related issues would be covered in a separate guidance document. It was also decided that this document would be prepared jointly by a

working group consisting of members of the Scientific Committee and several EFSA departments (composition of the working group is given in the acknowledgement).

TRANSPARENCY IN RISK ASSESSMENTS

1. Introduction

Article 38 of The EFSA Founding Regulation (EC, 2002a) highlights the importance for EFSA of ensuring a high level of transparency when carrying out its activities. According to Article 38 (1), EFSA should make public without delay, in particular: (a) agendas and minutes of the Scientific Committee and Panels; (b) the opinions of the Scientific Committee and Panels immediately after adoption, including minority opinions (if any); (c) the information on which opinions are based; (d) the annual declarations of interest made by selected people participating in its work; (e) the results of its studies; (f) the annual report of its activities; and (g) requests from the European Commission, the European Parliament or a Member State for scientific opinions which have been refused or modified and the underlying justifications'. Finally, according to Article 38 paragraph 3, EFSA shall lay down in its internal rules the practical arrangements for implementing the transparency rules referred above. A list of documents related to EFSA's internal rules to improve transparency is provided in the Annex.

2. Process-related considerations

The processes for establishing EFSA's Scientific Committee and Panels are laid down in Article 28 of The EFSA Founding Regulation (EC, 2002a). In Article 28 (9) it is stated that the procedures for the operation and cooperation of the Scientific Committee and Panels shall be laid down in the Authority's internal rules. In 2002, the EFSA Management Board adopted a 'Decision concerning the establishment and operations of the Scientific Committee and Panels' (EFSA, 2002). Inter alia, the following items are set out in this document: Confidentiality and independence of experts; appointment of members of the Scientific Committee and Panels and their terms of office; election of the chairs and vice-chairs of the Scientific Committee and Panels; role of working groups and external experts; planning of meetings; coordination of the work of the Scientific Panels; designation and role of rapporteurs; access to meetings and confidentiality of individual views of participants; technical hearings; request for scientific opinions; adoption of scientific opinions including accelerated procedure and minority opinions. In this document some of these items will be more explicitly described.

2.1. Selecting qualified scientists to participate in EFSA's activities and making sure of their independence

2.1.1. Selection of applicants who expressed an interest in becoming a member of the Scientific Committee or Panels

An essential component for building up and maintaining the confidence of the European Institutions and the public, is to ensure that the experts who participate in EFSA's activities must be of a high scientific quality. To ensure this aim, EFSA applies the following procedure for selecting the members of the Scientific Committee and Panels. First, the Authority launches calls for expression of interest in membership of the Scientific Committee and Panels. These calls, addressed to scientists, are published in the Official Journal of the European Communities, on the Authority's website and in various European scientific journals and magazines. Applicants for the Scientific Committee should have extensive expertise in the assessment of risks both in areas within the fields of competence of the Authority and, also, in related non-food areas, together with a proven capacity to handle multidisciplinary and horizontal scientific questions in relation to the safety of the whole food chain.

As stated in the official texts of the calls, candidates who have applied in response to the call are assessed in two stages by EFSA's scientific staff. Step one of the assessment looks for the following selection criteria in the applicants. They should have:

- experience in carrying out scientific risk assessment and/or providing scientific advice in fields related to food and feed safety in general and, in particular in the areas of competence and expertise of the Scientific Committee or Panel of interest to the applicant;
- experience in peer reviewing scientific work and publications, preferably in fields related to the area covered by the Scientific Committee or Panel of interest to the applicant;
- ability to analyse complex information and dossiers, often from a wide range of scientific disciplines and sources and to prepare draft scientific opinions and reports;
- proven scientific excellence in one, or preferably several fields linked to the area covered by the Scientific Committee or Panel of interest to the applicant;
- professional experience in a multidisciplinary environment, preferably in an international context;
- managerial skills, particularly in regard to chairing and leading working groups.

EFSA's Director of Science appoints a group of high level external scientists - who are not applicants - to audit the quality of this first step of the selection process.

In the second step, other considerations are taken into account for establishing a provisional list of candidates such as expertise, gender and geographical balance to establish a provisional list of candidates in which the experts are listed in alphabetical order but have not yet been assigned to a specific Scientific Panel or Committee. The provisional list is shared with the members of the Advisory Forum who may provide feedback and comment on the listed scientists. The Executive Director of EFSA completes the procedure with a proposal for the EFSA Management Board on the composition of the Scientific Committee and Panels for appointment.

2.1.2. Ensuring the independence of selected experts

The EFSA Founding Regulation (EC, 2002a) stresses the importance of ensuring that the Community institutions, the general public and interested parties should have confidence in EFSA. It is crucial for the reputation and success of the Authority that the integrity and high standards of professional conduct of all those involved in the activities of the EFSA should be beyond reproach. To that effect, EFSA is strongly committed to ensuring the independence of all the experts that participate in the work of the Scientific Committee and Panels and in their working groups.

Members of the Scientific Committee, Panels and their working groups must provide information on direct or indirect interests that might have relevance to the mission of the EFSA. These declarations of interests are published on the EFSA website. Moreover at each meeting participants are asked to declare any interest which might be considered prejudicial to their independence in relation to the items on the agenda. Declarations of interests must be updated at least annually or whenever an update is required for any new situation arising. A declared interest does not mean automatically a conflict of interest and there are essentially four categories of interests, as laid down in the Guidance on Declarations of Interest (EFSA, 2004a):

- financial interests;
- work carried out for food, feed and animal production-related business;
- other links with the food, feed and animal production-related business;
- intellectual interests.

On the basis of the type and nature of the declared interests of the members of the Scientific Committee and Panels and their working groups, the chairperson in consultation with EFSA staff must decide whether the member in question:

- has a fundamental incompatibility with membership of the group;
- should be temporarily excluded from the meeting;
- be allowed passive participation in the meeting;

- be allowed active participation in the meeting.

Experience indicates that there is an ongoing need for guidance addressed to experts on how to declare their interests.

It is noted that there is a need for more guidance for the experts on how to declare their relevant interests.

2.2. Overall handling by EFSA of requests for a scientific opinion or for technical and scientific assistance

An internal document entitled 'Procedure for the handling of requests for scientific opinions' (EFSA, 2006) lays down a set of common principles that apply also to the way incoming requests are registered and which procedural steps are taken before EFSA decides to formally accept or reject the request. The document is based on legislative, administrative and scientific criteria for the handling of requests (The EFSA Founding Regulation (EC, 2002a); Commission Regulation 1304/2003 (EC, 2003a)).

The documentation backing up each eligible request is included in the Register of Requested Opinions which is accessible on the EFSA website (http://www.efsa.eu.int/register/qr_panels_en.html).

It is important to distinguish between questions asked to EFSA under the provisions of Article 29 of The EFSA Founding Regulation (EC, 2002a) (*scientific opinions*), which are generally for the Scientific Committee and Panels, and those asked under the provisions of Article 31 (*technical and scientific assistance*), which are generally intended for EFSA staff. It is to be noted that only the European Commission can ask questions under the provision of Article 31.

Examples of Article 31 are the coordination of the Community summary report on zoonoses, or the pesticides risk assessment peer review. These activities are co-ordinated by EFSA in collaboration with Member States and/or working groups and generally without any formal involvement of the Scientific Committee and Panels. However, when additional expertise beyond EFSA staff and Member States is required, a question may be raised to the Scientific Committee or Panel for an opinion under the provision of Article 29.

Moreover, the Scientific Committee and Panels periodically review whether there are any aspects relevant for their missions, which might need to be addressed, e.g. development of new methodologies for risk assessment, or elaboration of a guidance document for carrying out specific tasks. Based on this review, yearly work plans are agreed upon and proposed to the EFSA Executive Director who decides on the inclusion in the work programme of the EFSA. This procedure is generally referred to as self-tasking or scientific opinions on the Authority's own initiative.

It is noted that some requests currently asked under Article 29, of The EFSA Founding Regulation (EC, 2002a) e.g. requests for advice under a clear framework, could be satisfactorily dealt with by the EFSA staff or by a working group with the endorsement of the Panel. EFSA should consider, in consultation with the European Commission, when and how such procedures are suitable.

2.3. Scientific opinions and other types of EFSA documents

The procedures for the preparation of a scientific opinion are laid down in the 'Decision concerning the establishment and operations of the Scientific Committee and Panels' (EFSA, 2002). In summary, after a request has been allocated, the Scientific Committee or Panel may ask the EFSA secretariat to clarify a question and/or to supply additional information. The Scientific Committee and Panels can establish working groups whenever they are deemed necessary. In many cases other experts with particular scientific and relevant expertise may be invited to contribute to working groups. These experts are invited by EFSA in consultation with the Scientific Committee or Panel and are also subject to the rules covering independence and confidentiality. The working group may be asked to undertake all the necessary preparatory work towards forming a draft opinion to be presented to the

Scientific Committee or Panel for discussion and possible adoption. EFSA is currently establishing a pan-European expert database, which will be a reliable source for an efficient searching of recognised national experts to serve in working groups of the Scientific Committee or Panel.

EFSA can also entrust certain tasks to specific organisations, e.g. under Article 36 of The EFSA Founding Regulation (EC, 2002a), or through a call for tender. The process for establishing networking under Article 36 is ongoing.

Common principles should be developed on how to incorporate the input of organisations or individuals entrusted by EFSA to undertake specific tasks.

In its second plenary meeting of 27-28 August 2003, the Scientific Committee agreed on the main components which should be included in scientific opinions (EFSA, 2004b):

- A summary (with keywords), informative for the technical and non-technical reader, summarising which questions were addressed, which information was evaluated, the key issues that resulted to the opinion and the conclusions and, if any, recommendations based on the assessment;
- The background and terms of reference as provided by the originator of the request, which can be either 1) the European Commission, 2) the European Parliament, 3) a Member State or 4) the EFSA itself (self tasking);
- The assessment, i.e. the actual risk assessment section, addressing the questions posed, how the information was evaluated and which issues were considered of key-relevance for the opinion;
- Conclusions and recommendations;
- Statement on minority opinion(s) (if any);
- A list of the references and documentation both made available to EFSA and wider sources of information on which the opinion is based, including an indication when data collection was stopped.
- A list of the names of the Scientific Panel/Committee members in alphabetical order and the names of members who declare an interest which excludes them from adoption of the opinion to be indicated with an asterisk;
- If applicable, an acknowledgement with the names of the working group/external experts who prepared (or made contributions to) the draft opinion.

The general format of the opinion is still in place but in the meantime further considerations were given to the assessment part and the summary.

Regarding the assessment part, it was noted that the aspects to be addressed in an opinion can vary between the various Panels. Depending on the question to be answered, a common assessment format for all EFSA's opinions is not always possible or useful. However, if applicable, the opinion should include the basic elements of the generally accepted risk assessment frameworks, i.e. Codex Alimentarius framework for chemical and microbiological risk assessment and World Organisation for Animal Health (OIE) framework for risk assessment of animal diseases.

Regarding the summary, the concept of a text equally informative for technical and not technical readers has proven to be difficult to put in practice. The prevailing current concept is that the Scientific Panel/Committee shall prepare and adopt a summary embedded in the scientific opinions which, in comparison to what has been agreed in 2003, should be a technical summary reflecting the content of the opinion.

Where considered appropriate from a communication point-of-view, a so called 'explanatory note', separate from the opinion, should accompany the publication of the scientific opinion on EFSA's website. The explanatory note presents the opinion in non-technical language and puts the opinion into context so that consumers, media and stakeholders will understand it better. EFSA's Communication

Department is responsible for the preparation of the explanatory note in collaboration with the scientific secretariat and the chair of the respective Scientific Committee or Panel or a delegated member of the Scientific Committee or Panel. It is noted that a guidance document is currently under preparation which will include criteria for the need for an explanatory note, its content and the way of presentation.

In addition to scientific opinions there are several other types of documents which are issued by EFSA, e.g. reports which have to be prepared under a specific legislation¹, other scientific reports², scientific advice³, scientific statements⁴ and guidance documents⁵. The terms 'reports', 'statements' and 'guidance documents' are used in a less formalised way than 'scientific opinion'.

It is noted that there is a need for more guidance and, if applicable, harmonisation on the types of documents issued by EFSA including procedural aspects, e.g. endorsement or adoption.

2.4. Ensuring availability of relevant data including those from literature

A sound risk assessment can only be carried out on chemical substances, biological agents or technological processes when adequate data are available for the identification and characterisation of the hazard, for the exposure assessment and its associated health impacts.

Responsibilities

It is of paramount importance to clearly identify responsibilities and approaches to ensure that all the relevant data, available in the open or grey literature or from other sources (e.g. food manufacturing companies), are brought to the attention of risk assessors. To this end, it is important to consider the following frameworks in which risk assessments take place.

For the assessments and periodic re-assessments carried out by EFSA under a regulatory framework clearly identifying an applicant who has the duty to provide specific data sets together with the application, it is crucial that applicants have performed a comprehensive data search, retrieval and scrutiny of relevant literature data, and data sets should be provided in accordance with the appropriate EFSA guidance document. The information should be provided in English.

For the assessments carried out by EFSA on request of the European Commission, the European Parliament or a Member State or its own initiative, the request should be accompanied not only by background information explaining the scientific issue to be addressed, but also by the relevant data available to the originator of the request. In addition the EFSA scientific secretariat should ensure the retrieval of relevant data in collaboration with the Scientific Committee and Panels and their working groups.

It is also an EFSA responsibility to be aware of any upcoming scientific information which may have an impact on human or animal health within its remit, e.g. emerging risks or need for an update of an earlier opinion.

EFSA should strengthen its managerial policy in the area of data collection to help the Scientific Committee and Panels in searching for and retrieving data including those from the literature.

¹ e.g. Annual Summary report on Zoonoses based on EC Directive 2003/99 (EC, 2003b) (http://www.efsa.eu.int/science/monitoring_zoonoses/reports/1277_en.html)

² e.g. Report of the CONTAM Panel on provisional findings on furan in food (http://www.efsa.eu.int/science/contam/contam_documents/760/contam_furan_report7-11-051.pdf)

³ e.g. Advice of the CONTAM Panel related to relevant chemical compounds in the group of brominated flame retardants for monitoring in feed and food (http://www.efsa.eu.int/science/contam/contam_documents/1380/contam_advice_ej328_bfr_en1.pdf)

⁴ e.g. Statement of the AFC Panel on the possibility of allocating a group-TDI for certain phthalates (http://www.efsa.eu.int/science/afc/afc_documents/1147/phthalategroup_minutes_statement1.pdf)

⁵ e.g. Guidance document of the GMO Panel for the risk assessment of genetically modified plants and derived food and feed (http://www.efsa.eu.int/science/gmo/gmo_guidance/660/guidance_docfinal1.pdf)

Approaches

A number of actions should be carried out by EFSA to meet the needs mentioned above, such as:

- networking with competent institutions in Member States, taking advantage of the procedure provided for by Article 36 of The EFSA Founding Regulation (EC, 2002a);
- networking with international organizations (e.g. WHO and FAO) and with the three non-food Scientific Committees of DG SANCO;
- establishing a list of European organisations/institutions in different sectors that could be called upon to help in data retrieval;
- implementing case-by-case agreements with institutions in Member States, European scientific associations and, when possible, other partners for carrying out literature surveys on specific subjects;
- issuing open calls for available relevant data;
- Information exchange with the EFSA Advisory Forum on emerging food-related issues; and
- ensuring that a key role is played by scientists participating in the work of EFSA by encouraging and supporting them to take a pro-active role in keeping EFSA informed about relevant data they become aware of during their daily work.

The developments mentioned above should be effectively promoted also through the establishment within EFSA of a documentation service.

Moreover it is noted that there are many existing and continuously evolving data bases, data banks and information systems and that literature data surveys relevant for EFSA's activities are carried out by a number of different subjects and in different times and contexts.

It is proposed that EFSA, based on a review of the available relevant guidelines, considers the development of a guidance document for literature data surveys to be complied with when producing data dossiers for risk assessment at EFSA or when carrying out literature follow up surveys on EFSA's risk assessments.

2.5. Information exchange between Scientific Committee or Panel and the originator of the request (i.e. European Commission, European Parliament and the Member States)

In order to preserve risk assessment independence, The EFSA Founding Regulation (EC, 2002a) provides for a clear distinction between risk assessment and risk management, but an efficient and transparent mechanism of interaction is obviously needed to ensure that appropriate exchanges may satisfactorily take place, particularly in more complex cases.

The main objective of these interactions is to ensure that:

- the questions (terms of reference) asked to EFSA are clearly drafted and documented by risk managers so that they can be well understood by the Scientific Committee and Panels and if different risk management scenarios have been identified on which a risk assessment is requested, the scenarios should be described;
- the opinions provided by EFSA are clearly formulated with the underlying science, including the uncertainties in the assessment, so that the information given in the opinion can be well understood and used by the originator of the request.

It is recommended that an effective and efficient dialogue is ensured between EFSA and the originator of the request from the initial stage of the process to achieve these objectives. Possible obstacles for performing an adequate assessment (e.g. insufficient available information) should be identified as of the initial dialogue.

It is to be noted that Article 28 (8) of The EFSA Founding Regulation (EC, 2002a) states that the representatives of the European Commission departments are entitled to be present in the meetings of

the Scientific Committee, Panels and their working groups. The Scientific Committee or Panel in charge of carrying out the risk assessment should effectively interact with the manager(s). The preferred way [of working] is that the risk manager who is familiar with the question should follow the scientific work of the Scientific Committee, Panels and working groups on the particular subject of interest. In this context he/she takes part in the discussion along the whole preparation of an opinion for the purpose of further clarification or information without influencing the outcome of the discussion and resulting opinion. Participation of risk managers should also be facilitated by use of available communication tools (e.g. video- or telephone conferencing).

It is noted that an adequate information exchange between the Scientific Committee or Panel and the other originators of a request, i.e. the European Parliament or the Member States, should be facilitated and preferably in compliance with a similar procedure to the one applicable to the European Commission.

2.6. Involvement of stakeholders other than the European Commission, the European Parliament and the Member States

‘Stakeholder’ or ‘interested party’ is understood by EFSA to describe an individual or group that is concerned or stands to be affected – directly or indirectly - by the outcome of a specific procedure, or that represents the general interest of groups concerned by such outcome.

In EFSA’s dealings with stakeholders, a distinction is made between ‘institutional stakeholders’ and ‘civil society stakeholders’. The first category refers to those to whom EFSA has a legal obligation under Community rules, e.g. the European Commission, the European Parliament and the Member States. The second category is composed of interested parties who have a legitimate interest in the work of EFSA and those are or might be affected by EFSA’s scientific work, e.g. consumer groups, NGOs, market operators such as farmers, distributors or processors.

Since its establishment EFSA has attached great importance to the involvement of interested parties in its areas of competence and has acknowledged the importance of close collaboration with stakeholders by encouraging dialogue in this respect. To this end EFSA has taken a series of initiatives intended to involve stakeholder participation in its work, such as annual colloques, public consultations, technical hearings, scientific colloquia, and the establishment in 2005 of the Stakeholder Consultative Platform⁶.

The possible mechanisms for involving interested parties should operate in a diversity of circumstances and therefore the ‘one-size-fits-all approach’ is not advisable or may already be pre-defined by the legal framework. Equally, it is of crucial importance to define at what stage of the work stakeholders should be involved. Decisions on involvement of stakeholders, on the topics for consultation as well as the stage at which stakeholders should be involved should be based on pre-defined criteria.

In order to ensure the widest level of participation, effective consultations and involvement of stakeholders in its work and decisions, it is recommended that EFSA should develop criteria for consultation with interested parties. Some of the considerations which should be taken into account are as follows:

- legal framework, e.g., fixed deadlines and strict procedures set out by law;
- involvement of stakeholders in a coherent and transparent manner including clear communication;
- identification of topics of public interest eligible for fruitful consultations;
- identification of the target stakeholders;
- definition of the nature of the input by stakeholders and its integration into the overall process;

⁶ http://www.efsa.eu.int/stakeholder_stakeholder_consultative_platform/catindex_en.html

- choice of optimal tools, i.e. public consultations, technical hearings, technical meetings, bilateral stakeholder meetings, scientific colloquia, consultative platform for each specific situation;
- evaluation of the effectiveness of different consultation processes.

It is recommended that EFSA should develop criteria for stakeholder involvement jointly with the EFSA scientific experts and staff, experts in the fields of social and communication sciences and the interested parties, taking into account the considerations mentioned above.

2.7. Dealing with diverging scientific opinions among different bodies

Article 30 of The EFSA Founding Regulation (EC, 2002a) address diverging opinions between EFSA and Community agencies, the European Commission's Scientific Committees and Member State bodies. Where a substantive divergence over scientific issues has been identified, the bodies concerned should cooperate to explain and either resolve the differences or present a joint document to the European Commission clarifying the contentious scientific issues and identifying the relevant uncertainties in the data. This document shall be made public.

EFSA is currently preparing a document laying down procedures for the identification and management of potential conflict over scientific opinions and contributing to achieve – as a start- a consensus on this issue with European Agencies.

For possible diverging opinions between EFSA and international bodies which cannot be resolved, the contentious scientific issues should be clearly stated and argued in the opinion.

2.8. Adoption of scientific opinions

Once a draft opinion has been prepared, it is placed on the agenda of the next meeting of the Scientific Committee and Panels for discussion and possible adoption. The Scientific Committee and Panels adopt opinions generally by unanimity, either during a meeting or through a written procedure. According to 'Decision concerning the establishment and operations of the Scientific Committee and Panels' (EFSA, 2002), a quorum of at least two thirds of the members of the Scientific Committee and Panels must be physically present in order for the meeting to adopt an opinion. The written procedure is used, amongst others, for urgent questions, cases where substantial changes are discussed and agreed upon at the meeting but still need to be included in the draft opinion. It is noted that alternative techniques (e.g. video conference) should be explored for adoption of scientific opinions.

In a case where there is no unanimity for adoption of the opinion, the opinion should also include any minority opinions, attributed to their authors and with supporting arguments.

For overlapping requests, involving more than one Scientific Panel, there are several options for adoption and the most suitable modus operandi for adoption should be agreed preferably when assigning the question or during the assessment.

Options for adoption of scientific opinions dealing with overlapping questions include:

- adoption by one Panel (but with input provided by other Panel members normally through expert participation in the working group);
- co-adoption by relevant Panels;
- adoption by the Scientific Committee (for multi-sectoral issues);
- adoption of separate opinions (dividing mandate);

It is considered that all the options for adoption of overlapping requests are in principle useful and practicable but the decision has to be taken on a case-by-case basis. It would be helpful to develop criteria as a basis for such decisions.

2.9. Dissemination of scientific opinions, other documents and access to underlying data

After adoption, opinions and other documents such as reports, statements and guidance documents will be made publicly available on the EFSA website. In addition, where more clarification through active communication is required, EFSA may issue explanatory notes, press statements or press releases, accompanied by press briefings when appropriate. For opinions which might require prompt response at the national level and for publication of opinions supported by communication activities, the members of the Advisory Forum are informed under embargo usually 48 hours before the opinion and related communication material is made publicly available. All opinions and related press releases are formulated in English; the summary of the opinion and the related press releases are translated into the three languages of the EFSA's website, German, French and Italian.

Data underlying all the documents mentioned above can be made available upon request unless confidentiality rules apply (see chapter 2.10).

2.10. Confidentiality

EFSA applies a high level of transparency when processing information unless a clear regulatory requirement exists for a defined level of confidentiality. Transparency is the rule and confidentiality the exception.

The legal framework for EFSA provides for transparency rules, i.e. on active disclosure⁷ or on providing access on request⁸, often in combination with confidentiality rules⁹. EFSA has developed internal rules (EFSA, 2005) in regard to the principles of confidentiality and transparency to implement these rules and they are applicable horizontally to any activities undertaken by EFSA.

The balance between transparency and confidentiality rules is determined by the approach that the maximum amount of information linked to EFSA's activities is to be disclosed or made accessible to the public and that only the essential minimum shall be kept confidential. This needs to be duly justified. It means any decision against disclosure needs to be based on a rule of law that grants confidentiality to the specific information and only those parts which are justified as confidential may be retained. It should be stressed that several regulations give the European Commission the exclusive competence to accept/reject confidentiality claims of third parties. In these cases EFSA is bound by the outcome of such decisions by the European Commission¹⁰. In this context the horizontal principles established by Regulation 1049/2001 (EC, 2001) on access to documents play an exemplary role.

Possible justifications for confidentiality include:

- commercial interests of a natural or legal person, including intellectual property;
- serious harm to the decision-making processes;
- protection of privacy and the integrity of the individual.

The confidentiality level is maintained throughout EFSA's operations by ensuring that all individuals involved in these operations have committed themselves to confidentiality undertakings. Therefore, members of the Scientific Committee and Panels, their working groups and all EFSA staff sign an individual declaration concerning confidentiality.

2.11. Revision and update of scientific opinions

EFSA has to ensure that an efficient data monitoring system is in place as well as an effective procedure to manage any new information which may have an impact on a previous opinion (see also chapter 2.4). A review of the data by the Scientific Committee and Panels may lead to a decision to update an earlier opinion, or to issue a statement in the minutes about the relevance of the new data

⁷ e.g. Article 6 (7) of Regulation 1829/2003 (EC, 2003c) or Article 38 Regulation 178/2002 (EC, 2002a)

⁸ e.g. Article 4 of Regulation 1049/2001 (EC, 2001) or Article 11 of Regulation 1490/2002 (EC, 2002b)

⁹ It should be noted that from their technical legal nature 'non-disclosure' and 'confidentiality' are not identical but as the interests they protect correspond, they are used under the term confidentiality in this text.

¹⁰ e.g. Regulation 1829/2003 (EC, 2003c) or 1831/2003 (EC, 2003d)

and/or to initiate further investigations of the data which in some cases may lead to a request for more data. In such cases, the originator of the request should be informed. It should be noted that certain pieces of sectoral legislation on regulated substances already provide an explicit legal base for EFSA to issue an opinion on whether an authorisation is still in accordance with the requirements of the respective legal conditions¹¹ on its own initiative or on a request from the European Commission or a Member State.

In addition, new data are taken into consideration when authorisations are subject to renewal obligations¹².

CONCLUSIONS

The present document highlights several procedural aspects related to risk assessment, which would be beneficial for improving transparency. It is suggested that the recommendations provided in this document are implemented by EFSA.

Furthermore, a new working group needs to be established to deal with science related aspects of transparency in risk assessment.

¹¹ As an example Article 11 of Regulation (EC) 2065/2003 (EC, 2003e), Article 22 of Regulation (EC) 1829/2003 (EC, 2003c), Article 12 of Regulation (EC) 1935/2004 (EC, 2004)

¹² As an example Article 12 of Regulation (EC) 2065/2003 (EC, 2003e), Article 23 of Regulation (EC) 1829/2003 (EC, 2003c)

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ACKNOWLEDGMENT

The Scientific Committee wishes to thank the working group members for their contributions. The working group was composed of the following members: EFSA Scientific Committee: Ada Knaap, Harry Kuiper, Pierre le Neindre, Vittorio Silano, Philippe Vannier. EFSA Departments: Dirk Detken (Legal), Lucilla Gregoretti (Science), Juliane Kleiner (Science), Djien Liem, (Science), Irene van Geest (Communication), Victoria Villamar (Institutional and International Relations).

ANNEX

Documents related to EFSA Internal Rules and Decisions with respect to transparency

Decision concerning the establishment and operations of the Scientific Committee and Panels (MB 17.10.2002 – 3 adopted)

http://www.efsa.eu.int/mboard/statutory_texts/internal_rules/409/decision_panels_mb_04_en11.pdf

Guidance on Declaration of Interest (endorsed by the Management Board MB on 16 December 2004)

http://www.efsa.eu.int/mboard/statutory_texts/internal_rules/409/declar_of_interestsmb161204-endorsed1.pdf

Advice from the EFSA Scientific Committee on a general format for scientific opinions of the EFSA (SC document adopted on 17 September 2003)

http://www.efsa.eu.int/science/sc_committee/sc_documents/614_en.html

Decision of the Management Board of the European Food Safety Authority concerning implementing measures of transparency and confidentiality requirements (MB 10.03.2005-10)

http://www.efsa.eu.int/mboard/statutory_texts/internal_rules/409/mb_transparency_confidentiality_requirements1.pdf

Openness, transparency and confidentiality (MB 16.09.2003 -13- agreed)

http://www.efsa.eu.int/mboard/statutory_texts/internal_rules/409/mboard_meeting_010_doc14_adopted_en11.pdf

EFSA code of good administrative behaviour (MB 16.09.2003 -11- adopted)

http://www.efsa.eu.int/mboard/statutory_texts/internal_rules/409/mboard_meeting_010_doc13_adopted_en11.pdf

Report to the European Ombudsman

http://www.efsa.eu.int/mboard/statutory_texts/internal_rules/409/iai_report_european_ombudsman1.pdf

Decision concerning access to documents (MB 16.09.2003-adopted)

http://www.efsa.eu.int/mboard/statutory_texts/internal_rules/409/mboard_meeting_010_doc15_adopted_en11.pdf