



OPENNESS, TRANSPARENCY AND CONFIDENTIALITY.

INTRODUCTION

1. Openness and transparency are fundamental aspects of the European Food Safety Authority (EFSA) and are enshrined as concepts in EFSA's regulatory framework¹ and in the overall Community policies on governance. EFSA is keen to embrace these concepts as they are essential for:
 - (i) providing a framework in which consumers can have confidence;
 - (ii) meeting the legitimate needs of stakeholders (including the food industry) as to the basis for risk assessment and the subsequent risk management decisions which are taken in response;
 - (iii) allowing an informed debate, both among experts and in the media, on sensitive and important scientific issues within the remit of EFSA.
2. It should be noted that this paper is not meant to be seen as the definitive description of EFSA's objectives in relation to openness and transparency. As the Authority grows, it will be able to develop a more comprehensive policy than at present i.e. it will develop the capability to organise and manage open meetings, consultations and build a proactive approach to stakeholder and public involvement. However, it should be noted that EFSA has from the outset given priority to building openness and transparency into all aspects of its work.
3. Unless there are precise and legitimate reasons for doing otherwise, EFSA will conduct its activities on the broad presumption that it must be open and transparent.
4. There is however a need to be clear as to how EFSA intends to operate these principles in practice and in particular to clarify those circumstances in which information may be sought from EFSA but will not or not immediately be made

¹ See Annex 1

available. Openness on this point, including the need for confidentiality, is in itself an essential point of building trust with stakeholders.

INFORMATION NOT FOR DISCLOSURE OR IMMEDIATE DISCLOSURE BY EFSA

5. EFSA will publish its opinions and other findings as quickly and in as accessible a manner as possible. It will ensure that information is made available by the most effective means to stakeholders and the public. This will be through its website, publications and, where appropriate, through direct contacts with stakeholders, the press and other media. The work of its Management Board, Advisory Forum and Scientific Panels and Committee will in principle be made available through the publication of agendas, papers, minutes and, in appropriate cases, through public consultation. However, it should be noted that there are specific cases where publication cannot be justified and it is important to highlight here what these are and indicate how EFSA can manage its policy on openness in a responsible manner.
6. European Union legislation prevents EFSA from disclosing to the public information which is commercially sensitive. This is clearly a proper device for protecting companies' commercial interests, but care must be taken to ensure that this is not made a pretext for withholding information of legitimate public interest. EFSA proposes to discuss openly with companies how to interpret in a proportionate and balanced manner the concept of commercially sensitive information and is ready to take a challenging approach to issues in the public interest.
7. There is also generally recognised to be a need to preserve confidentiality in two areas regarding the presentation of scientific advice as will be undertaken by EFSA:-
 - (i) Confidentiality needs to be allowed for internal scientific debate on issues to ensure that those participating feel free to challenge any view put forward from any perspective. Full openness for such a debate would be likely to inhibit discussion in a way which would be damaging to consumers' interests and reduce the likelihood of a high quality final (public) opinion. EFSA's regulations already recognise this by requiring members of the Scientific Committee and Panels not to disclose such discussion, whilst equally requiring that each member indicates their position on the final opinion. Discussions on how to develop greater openness in the scientific risk assessment process itself are on-going and will be the subject of the Ostende Colloque.

MB 16.09.2003 – 13 – Agreed

- (ii) Achieving the best method of risk communication requires a similar level of confidential internal discussion and challenge to ensure that the best means is found to communicate scientific issues to the public in a way which is proportionate to their risk and sets that in a proper context. It may require further discussion with the risk assessors as well as with expert communicators. To make this process public whilst it is underway is inherently to give rise to incomplete and ill managed communications, which are likely to mislead the public and give rise to actions which are not proportionate, whether as ‘unnecessary’ food scares or the ‘too ready’ dismissal of a risk in the media.
8. The issues set out above need to be considered in the specific context of the Advisory Forum. A major part of the Forum’s remit is to share intelligence on issues which are subject to either 7(i) or (ii) above. Whilst all such information, provided it has ultimately a meaningful outcome, will rightly be made public in due course, Member States will not wish to share emerging findings from ongoing risk assessments or possible alternative means of risk communication without the option of confidentiality where this is needed. Yet such sharing of information is vital if EFSA is to achieve its twin purposes of building greater scientific consensus across Europe on key issues and providing the basis for more effective and consistent EU-wide communication of risk.
 9. The Advisory Forum differs from both the Management Board and Scientific Committee and Panels in that it is not a decision making body. Although it is not required to publish its agendas, the Management Board has agreed to the Executive Director’s proposal to publish agendas and minutes on the web. In addition, working papers produced by EFSA for the Forum’s discussions will be published prior to the meeting. The only exceptions to this general principle will be on the grounds set out in the previous paragraph.

CURRENT EFSA INITIATIVES ON OPENNESS AND TRANSPARENCY

10. The Board agreed at its meeting in March 2003, at the suggestion of the Executive Director, that Papers for meetings should be published in advance on the website. This has the advantage of making it easier for the audience to follow the webstream and also introduces greater clarity should the Board choose to take a different view from the advice put to it.
11. A number of steps are underway to increase openness and transparency with regard to the operation of the Scientific Committee and Panels:-

MB 16.09.2003 – 13 – Agreed

- (i) Members have been asked to consider what steps they would believe appropriate to their area in enabling stakeholder participation, such as the holding of stakeholder meetings and consultations whilst the risk assessments are underway and circulation of risk assessments in draft;
 - (ii) It is intended to publish in draft national safety assessments, for example, those carried out in the area of plant health, plant protection products and their residues, before their consideration by the PPR Panel itself.
 - (iii) EFSA proposes to provide, via the website, timetables for the consideration of particular issues/applications. This should help stakeholders, whether consumer organisations or industry, who have complained that in the past they could not establish when progress would be made on a question. Representations will in consequence be able to be made in a timely manner to the secretariat (we wish to avoid individual lobbying of members).
 - (iv) The website will provide potted biographies of all members of the Scientific Committee and Panels and information concerning working group members. It is intended to extend this facility to individual members of EFSA staff with whom stakeholders are likely to have contact.
12. The ‘Colloque’ with stakeholders scheduled for this autumn will provide the basis for further discussions on stakeholder involvement in EFSA, including openness and transparency. Particular issues already identified from EFSA’s side concern possible stakeholder involvement in preparing both questions for risk assessment and issues for risk communication, as well as further identifying stakeholder information needs from EFSA.
13. The issue of openness and transparency has already been raised in the Advisory Forum and as part of their on-going work, it is the intention, particularly in relation to communication, to develop their views on this matter. In line with the views of the Management Board, the issue will also be brought to the attention of the Scientific Committee for their input.

RECOMMENDATIONS

14. The EFSA Board:
- (i) Agreed to the overall direction outlined above, recognising that there is a general presumption for openness and transparency
 - (ii) Agreed the criteria on issues not for disclosure or immediate disclosure as set out in paragraph 8;

MB 16.09.2003 – 13 – Agreed

- (iii) Noted the steps outlined in paras 10 - 13 above, already underway to increase openness and transparency and the further action proposed in the context of the 'Colloque'.

Agreed at Brussels, on 16th September 2003

Dr Stuart Slorach
Chair

Annex 1

Article 38
Transparency

The Authority shall ensure that it carries out its activities with a high level of transparency. It shall in particular make public without delay:

- (a) agendas and minutes of the Scientific Committee and the Scientific Panels;
- (b) the opinions of the Scientific Committee and the Scientific Panels immediately after adoption, minority opinions always being included;
- (c) without prejudice to Articles 39 and 41, the information on which its opinions are based;
- (d) the annual declarations of interest made by members of the Management Board, the Executive Director, members of the Advisory Forum and members of the Scientific Committee and Scientific Panels, as well as the declarations of interest made in relation to items on the agendas of meetings;
- (e) the results of its scientific studies;
- (f) the annual report of its activities;
- (g) requests from the European Parliament, the Commission or a Member State for scientific opinions which have been refused or modified and the justifications for the refusal or modification.

2. The Management Board shall hold its meetings in public unless, acting on a proposal from the Executive Director, it decides otherwise for specific administrative points of its agenda, and may authorise consumer representatives or other interested parties to observe the proceedings of some of the Authority's activities.

3. The Authority shall lay down in its internal rules the practical arrangements for implementing the transparency rules referred to in paragraphs 1 and 2.

Article 39
Confidentiality

1. By way of derogation from Article 38, the Authority shall not divulge to third parties confidential information that it receives for which confidential treatment has been requested and justified, except for information which must be made public if circumstances so require, in order to protect public health.

2. Members of the Management Board, the Executive Director, members of the Scientific Committee and Scientific Panels as well as external experts participating in their working groups, members of the Advisory Forum and members of the staff of the Authority, even after their duties have ceased, shall

be subject to the requirements of confidentiality pursuant to Article 287 of the Treaty.

3. The conclusions of the scientific opinions delivered by the Authority relating to foreseeable health effects shall on no account be kept confidential.

4. The Authority shall lay down in its internal rules the practical arrangements for implementing the confidentiality rules referred to in paragraphs 1 and 2. The Authority shall publish all opinions issued by it in accordance with Article 38.