



The EFSA stakeholders challenge – working with civil society

“Following a series of food scares in the 1990s (eg BSE, dioxins...) which undermined consumer confidence in the safety of the food chain, the European Union concluded that it needed to establish a new scientific body charged with providing independent and objective advice on food safety issues associated with the food chain. Its primary objective as set out in the White Paper on Food Safety would be to: “...contribute to a high level of consumer health protection in the area of food safety, through which consumer confidence can be restored and maintained.” The result was the European Food Safety Authority (EFSA).” (EFSA website)

The EFSA has been up and running since 2002 and has produced dozens of scientific opinions on a wide number of food and feed-related issues. It has, however, not escaped criticism and has so far failed to achieve broad support from some representatives of the civil society, especially some environmental groups. One of the most controversial issues has been the EFSA’s work on genetically modified organisms (GMOs) which has attracted most of the criticism, in particular for its handling of new technologies, scientific uncertainty and poor quality research from industry. Within this criticism EFSA’s much-vaunted independence – the keystone to being trusted by the public in Europe - was also questioned.

The above organisations welcome the establishment of the Stakeholders Platform and hope this will address some of the deficiencies identified within EFSA. Our participation to the Stakeholders Platform should not be interpreted as an acceptance of the methods and procedures applied by the GMO panel, or as legitimising EFSA’s opinions. We have outlined

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below some of the key elements which need to be properly implemented. We believe that some inappropriate practices can be easily rectified if the political will is there amongst those who work for EFSA. We hope that this paper therefore provides the start of a healthy debate within the Platform and the EFSA.

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1. The Stakeholder Platform

In order for the Stakeholder Platform to be open, transparent and functional we believe the EFSA should:

- ensure open and transparent consultation to decide agenda items of future Platform meetings;
- ensure circulation of the agenda and papers at least 60 days before the meeting in order to give participants adequate time to identify the right representative/s and to get prepared;
- allow stakeholders to have at least two representatives;
- ensure that the Platform is balanced so that each stakeholder has the same number of delegates
- ensure the participation of EFSA officials, members of scientific panels and other relevant Commission officials where appropriate;
- confirm that the organisations that require financial support in order to attend meetings do not have to re-apply for funding for each meeting, and, following the Commission's practice, provide for a daily allowance for such groups.

2. EFSA's legal requirements related to science

2.1 Long term safety

The EU has a comprehensive legislative framework to protect consumers and the environment. A key aspect is the legal requirement to consider the long-term effects of a particular food and probable combination effects. This is particularly relevant for new technologies such as genetic modification and allows us to learn the lessons of past mistakes eg pesticides. Approval of pesticide products were given without knowing what the long term implications would be. Some important consequences up to adulthood, during aging and for the next generation, of *in utero* exposure are still not assessed, even for each individual

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active substance. The legal obligation for this can be found in article 14.4 of the EU's 178/2002 regulation.

“In determining whether any food is injurious to health, regard shall be had:

- (a) not only to the probable immediate and/or short-term and/or long-term effects of that food on the health of a person consuming it, but also on subsequent generations;*
- (b) to the probable cumulative toxic effects;*
- (c) to the particular health sensitivities of a specific category of consumers where the food is intended for that category of consumers.”*

This article is self-explanatory but is often omitted particularly when it comes to EFSA's opinions on new foods, such as GMOs. In addition other legislation such as Directive 2001/18 also call for the assessment of long term environmental effects.

Challenge 1: EFSA must consider article 14.4 of Regulation 178/2002 when judging the safety of all food products, including GMOs, and other legislation that requires an assessment of any long term human or environmental effects.

2.2 Diverging scientific opinions

The EFSA has a legal requirement to address differences in scientific opinions in the EU. For some issues such as pesticides and GMOs substantial differences can be found between member states and the EFSA opinions. Article 30.4 of 178/2002 states that:

“Where a substantive divergence over scientific issues has been identified and the body in question is a Member State body, the Authority and the national body shall be obliged to cooperate with a view to either resolving the divergence or preparing a joint document clarifying the contentious scientific issues and identifying the relevant uncertainties in the data. This document shall be made public.”

Despite the differences in scientific opinion between European Member States and the EFSA there is no evidence that the EFSA has fulfilled its obligations under this article.

Challenge 2: EFSA must address the differences in scientific opinion across the EU on controversial products such as pesticides and GMOs and meet the requirements set down in article 30.4 of Regulation 178/2002.

2.3 Scientific uncertainty

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In many issues that EFSA has to address, and particularly when considering new technologies, scientific uncertainties exist. However EFSA opinions often do not state where the uncertainties arise even though this is a long-established scientific practice, and is sometimes even legally binding to do so. For example, when considering the release of GMOs into the environment, the Commission Decision 2002/623 explicitly states:

“Overall uncertainty for each identified risk has to be described, possibly including documentation relating to:

- assumptions and extrapolations made at various levels in the ERA,*
- different scientific assessments and viewpoints,*
- uncertainties,*
- the known limits of mitigation measures,*
- conclusions that can be derived from the data.”*

Although this legal obligation is quite clearly set out, EFSA has only given scant regard to uncertainties in any of their opinions for GMO products under 2001/18.

An assessment of the scientific uncertainties in an EFSA opinion is crucial to enable risk managers (eg the Commission and Member States) to make judgements in the public interest. It also avoids abuse of EFSA opinions by risk managers who can claim that a product is safe just because EFSA said so.

Challenge 3: EFSA must fully address the scientific uncertainties in all of its opinions and, as a consequence, consider the precautionary principle.

3. Independence and neutrality

3.1. Selection of ad hoc experts

Being independent of vested interests and being seen to be independent, is key to building trust in EFSA’s opinions. In 2004 Friends of the Earth published a report questioning the relationship between a significant number of influential members of the EFSA GMO Panel (including the chair) and the biotechnology industry. A key *ad hoc* expert was also someone who works closely with the industry.

Some scientific panels contain scientists that are also involved in the national regulatory or approval process for the same issue or even product. The EFSA Management Board has decided this is not a conflict interest. This has led to the inappropriate situation whereby

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scientists take part in EFSA discussions that review their own previous decisions.

Challenge 4 – EFSA must review the make-up of its scientific panels and their use of *ad hoc* experts, with a view to making them impartial and absent of direct and indirect industry links. Moreover, scientists involved in national advisory committees or competent authorities should not sit on an EFSA panel of the same issue.

3.2. Declarations of interests

The declarations of interest offer the possibility for the public and the Member States to know whether the scientists involved in producing an opinion have an impartial position. They therefore play a key role in the acceptance of EFSA opinions.

Declaration of interests by members of the scientific panels are legally binding by European law. Article 37.2 of Regulation 178/2002 states:

“The members of the Scientific Committee and the Scientific Panels shall undertake to act independently of any external influence.

For this purpose, they shall make a declaration of commitment and a declaration of interests indicating either the absence of any interests which might be considered prejudicial to their independence or any direct or indirect interests which might be considered prejudicial to their independence. Those declarations shall be made annually in writing.”

EFSA itself states in the introduction of its Guidance of Declaration of Interest (M.B. 16-12-2004) that: *“Integrity and high standards of professional conduct by all those involved in the activities of the European Food Safety ... are therefore crucial for its independence and for its reputation... One aspect of integrity is to demonstrate that those involved in the work of EFSA act independently of any external influence related to the subject of the activity.”*

In its comprehensive guidance for its staff and scientific panels, the EFSA Management Board has clarified what constitutes an interest that needs to be declared. In particular, this statutory text states that members of panels who have worked for a food company or have had links with the food industry in the past 5 years need to declare this as an interest. An interest is not just restricted to a direct financial interest but also includes intellectual and indirect interests, the latter defined as, *“ Other interests that may have some influence over the individual’s behaviour and therefore have to be neutralised.”*

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Whilst these are welcome measures, evidence strongly suggests that individual members of the scientific panels are failing to adhere to them.

Challenge 5: The Management Board should insist that all interests are declared and declaration of interests published on its web site, in line with their guidance. Failure to declare interests should result in dismissal of the individual.

4. Transparency

The EFSA is legally obliged to carry out its activities with a high level of transparency. There are however a number of areas where the EFSA could substantially improve its transparency.

4.1 Publication of minutes

EU law makes it clear that the EFSA must make information, such as minutes of meetings, public “*without delay*” (article 38. 1 of Regulation 178/2002). In practice however, such documents are only made public after several months.

Challenge 6: Draft minutes of all meetings should be published within one week and final minutes within 3 weeks.

4.2 Access to Panels

Civil society groups have a broad level of expertise on a wide range of issues covered by the EFSA. Currently the only way for NGOs to write to or communicate with a scientific panel is via the Chief Executive. This is an unnecessary and cumbersome way of conducting business.

Challenge 7: All stakeholders should be able to write directly to scientific panels. In the name of transparency the EFSA should publish all correspondence on their website.

4.3 Access to documents

Under EC law free access to information and free access to documents is considered a fundamental right of each citizen. Exceptions to this rule are construed narrowly and applied restrictively. The EC legal framework regulating access to documents is considered to provide

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for a fair balance of the interest of secrecy/confidentiality on the one hand and the interest of transparency and participation on the other hand.

This right to access to documents, explicitly enshrined in Art. 255 EC Treaty and implemented by Regulation No. 1049/2001 regarding public access to European Parliament, Council and Commission documents, can be strengthened through more specific EC legislation on access to documents for particular sectors. This specific balance of interests between transparency and confidentiality is reflected for example in Art. 25 of the Directive 2001/18/EC on deliberate release of GMOs , in article 10 of Regulation N° 258/97 concerning novel food and novel food ingredients and in article 1 and 2 of the related Commission Regulation 1852/2001 laying down detailed rules for making certain information available to the public and for the protection of information pursuant to Regulation N° 258/97.

In addition Article 41 of Regulation (EC) 178/2002 states:

“Access to documents

- 1. The Authority shall ensure wide access to the documents which it possesses.*
- 2. The Management Board, acting on a proposal from the Executive Director, shall adopt the provisions applicable to access to the documents referred to in paragraph 1, taking full account of the general principles and conditions governing the right of access to the Community institutions' documents.”*

In order to increase transparency and meet its legal obligations, the EFSA should make it easier for the public to access information. A guide for the public to where they can get the full information that they are legally entitled to should be a key aspect of the EFSA website.

In addition, if sections of (for example) an application for a new GMO are to be withheld the EFSA should confirm that:

- a) the applicant has requested those specific sections to remain confidential;
- b) the applicant has demonstrated that disclosure of those specific sections would significantly harm its competitive position;
- c) the EFSA has assessed this claim and agrees with it.

Challenge 8: The EFSA must make documents that the public are legally entitled to obtain easily available on the EFSA website. If parts of documents are to be withheld then the

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EFSA must show that the information would have caused the applicant significant harm to its competitive position. More specific legislation must also be taken into account for access to documents

4.4 Sources of information and criteria used in opinions

The results of research can sometimes be open to interpretation and require judgements by EFSA as to whether observed effects are of concern or not. In order to increase transparency, it should be made clear in advance of applications when observed significant differences are considered not to be of concern.

In addition, Article 38.1.c of Regulation 2002/178 states that the EFSA must make public the information on which its opinions are based. This is important so that stakeholders and member states can understand why EFSA has come to a certain conclusion, which bibliography it has used, and to determine whether this position stands up to scientific scrutiny. Many of the issues dealt with by EFSA are complex and can be controversial so this aspect of transparency is particularly important.

Challenge 9: In advance of all applications the EFSA must define values/thresholds that clearly state when observed significant differences are to be considered as of concern or meaningful or significant with citation of scientific references to support such positions and all papers and bibliography on which opinions are based on.

5. The EFSA code of good administration behaviour

Relationship between EFSA and a number of NGOs, particularly those from the environmental movement have to be improved. It is hoped that the Stakeholder Platform will be a step towards changing this situation according to its code of good administrative behaviour (article 8) stating that *“the agents or other servants of the Authority shall be impartial and independent. They shall abstain from any arbitrary action adversely affecting members of the public as well as any preferential treatment of any ground whatsoever”*.

Challenge 10: The EFSA must take steps to improve the relationship with NGOs including by applying provisions of its code of good administrative behaviour and in particular its article 8 concerning impartiality and independence.