USDA Foreign Agricultural Service
GAIN Report
Global Agricultural Information Network

Voluntary _ Public

Date: 2/3/2011
GAIN Report Number: E60005

Belgium EU-27

Post: Brussels USEU

The European Food Safety Authority

Report Categories:
Biotechnology
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Report Highlights:
This report aims to describe the background to and role and structure of the European Food Safety Authority (EFSA). The report also explains the steps associated with the biotechnology approval system in the EU and EFSA's contribution to that system.

General Information:

In response to a series of food crises in the late 1990s, the European Food Safety Authority (EFSA) was set up in January 2002 as part of a comprehensive program to improve EU food safety, ensure a high level of consumer protection and restore and maintain consumer confidence in the EU food supply. The European Commission's White Paper on Food Safety of January 2002 asserts: ' *The Commission believes that major structural changes are necessary in the way food safety issues are handled, having regard to the experience over the last few years and the generally accepted need functionally to separate risk assessment and risk management. The establishment of a new* (European Food Safety) *Authority will provide the most effective instrument in achieving the changes required to protect public health and to restore consumer confidence. It is clear therefore that the primary focus of such an Authority will be in the public interest'.*

EFSA was legally established by European Parliament and Council Regulation (EC) No 178/2002 *laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.* The Regulation stipulates that EFSA should be an independent scientific source of advice, information and risk communication in the areas of food and feed safety. A further requirement was to set up a network enabling close collaboration with similar bodies in the European Union's Member States.

Role

In the EU food safety system, risk assessment is undertaken independently from risk management. As the risk assessor, EFSA produces scientific opinions and advice to:

- provide a foundation for EU policies and legislation, and,
- support the European Commission, European Parliament and EU Member States in taking risk management decisions.

More specifically, EFSA's remit covers food and feed safety, nutrition, animal health and welfare, plant protection and plant health. Its role is to assess and communicate on all risks associated with the food chain. Since EFSA's advice serves to inform policies and decisions of risk managers, a large part of EFSA's work is undertaken in response to specific requests for scientific advice. Requests for scientific assessments are received from the European Commission, the European Parliament and EU Member States. EFSA also undertakes scientific work on its own initiative. As such, EFSA's advice frequently supports the risk management and policy-making process, involving:

- the adoption or revisions of EU legislation on food or feed safety,
- deciding whether to approve regulated substances such as pesticides and food additives,
- developing new regulatory frameworks and policies in, for example, the field of nutrition.

EFSA is not involved in these management processes, but its independent advice provides them with a scientific foundation.

Through its risk communications activities, EFSA seeks to raise awareness and further explain the implications of its scientific work. EFSA aims to provide appropriate, consistent, accurate and timely communications on food

and feed safety issues to all stakeholders and the public at large, based on the Authority's risk assessment and scientific expertise. EFSA aims to achieve this by:

- analyzing public perception of risks linked to food,
- explaining and contextualizing risk,
- working with actors including national authorities, stakeholders and media to develop messages suited to the needs of different audiences,
- ensuring consistency by co-coordinating communications with other risk assessment bodies and risk managers including the European Commission and EU Member States.

Structure

EFSA is an EU-funded Agency based in Parma, Italy. It is governed by a Management Board whose members are appointed to act in the public interest and do not represent any government, organization or sector. The Board sets EFSA's budget, approves the annual work program and ensures that EFSA works effectively and co-operatively with partner organizations across the EU and beyond. It also appoints EFSA's Executive Director and members of the Scientific Committee and Panels.

The **Management Board** comprises fifteen Board members. One (currently Paola Testori Coggi) represents the European Commission, while fourteen (including the chair and two deputies) are selected on the basis of their expertise, knowledge and experience following a call for expressions of interest. Candidates are proposed by the European Commission and are appointed for four years by Decision of the EU Council of Ministers in consultation with the European Parliament.

Board meetings usually take place at least four times a year and are open to the public. All may be viewed live or on demand on the EFSA website.

EFSA's current Executive Director, Catherine Geslain-Lanéelle, was appointed in July 2006 for a five year term. She is responsible for all operational matters, staffing issues and drawing up the annual work program in consultation with the European Commission, European Parliament and EU Member States.

EFSA's Scientific Committee and Panels undertake EFSA's scientific risk assessment work. They are composed of appropriately qualified European risk assessment experts with a range of relevant expertise. All members are appointed through an open selection procedure. Appointments are made by the Management Board for three year terms which may be renewed.

The Scientific Committee prepares scientific advice in the area of new and harmonized approaches for risk assessment of food and feed, and provides strategic advice to the Executive Director. The Committee supports the work of EFSA's Scientific Panels on horizontal scientific matters. It also prepares advice on scientific co-operation and networking with scientific experts and research organizations nationally and internationally. The Committee is composed of the Chairs of each of the Panels plus six independent scientists.

The Scientific Panels carry out risk assessment work in their respective specialized fields as follows:

Animal health and welfare
Food additives and nutrient sources added to food
Biological hazards , including BSE-TSE-related risks
Food contact materials, enzymes, flavorings and processing aids
Contaminants in the food chain
Additives and products or substances used in animal feed
Genetically modified organisms (Genetic engineering, biotechnology)
Dietetic products, nutrition and allergies

Plant protection products and their residues
Plant health
Working Groups involving external scientists with relevant expertise are regularly set up by the Panels to deal with specific issues and to help produce scientific opinions.
The experts on EFSA's Scientific Committee and Panels are supported by EFSA's own scientific staff in the Risk Assessment Directorate.
The Scientific Cooperation and Assistance Directorate supports EFSA's risk assessment activities and manages projects in the following areas:

- scientific co-operation with Member States,
- data collection,
- emerging risks, and,
- assessment methodology.

It also deals with specific risk issues by directly involving experts from EU Member States in:

- zoonoses data collection,
- pesticide data collection, and,
- pesticide risk assessment peer review.

EFSA's Advisory Forum connects EFSA with the national food safety authorities in all 27 EU Member States. The Forum's members represent each national body responsible for risk assessment in the EU (plus observers from Norway, Iceland, Switzerland and the European Commission). It is chaired by EFSA's Executive Director. The aim of the Forum is to allow EFSA and the Member States to jointly address European risk assessment and risk communication issues. EFSA also uses the Forum to consult Member States on scientific matters and its work program and to identify and address emerging risk issues as early as possible.

Biotechnology – approval system in the EU

Biotech events [1] , either for placing on the market or for release into the environment, are subject to the following approval system:
Authorization for placing on the market of biotech events for food or feed use [2]
An authorization is required for the placing on the EU market (import, distribution, processing) of biotech events.
An application [3] is sent to the appropriate national competent authority of a Member State. That competent authority acknowledges receipt of the application in writing to the applicant within 14 days of its receipt, and transmits the application to EFSA without delay.

1. EFSA informs the other Member States and the European Commission of the application without delay, and makes it available to them. EFSA also makes the summary of the dossier available to the public by placing it on the internet.

2. EFSA "***shall endeavor to respect***"' a time limit of six months from its receipt of a valid application to give its opinion. This six-month limit is extended whenever EFSA (or a national competent authority through EFSA) requests supplementary information from the applicant.

3. EFSA forwards its opinion on the application to the European Commission, the Member State and the applicant. EFSA also makes its opinion available for public comment within 30 days from publication.

4. Within three months after receiving the opinion from EFSA, the European Commission presents a draft Decision reflecting EFSA's opinion to the '*Standing Committee on the food chain and animal health*' (composed of representatives of the Member States and chaired by the Commission). The Standing Committee votes on the draft Decision. In the case of no qualified majority (qualified majority being 255 votes out of 345) in favor of the draft Decision, the European Commission submits it to the Council of the European Union (typically the Agriculture and Fisheries Council meeting) without delay. If the Council has neither adopted the draft Decision nor opposed it by qualified majority within three months from the date of referral, it is adopted by the European Commission. *Note: this procedure is currently under revision as a function of the implementation of the Lisbon Treaty*.

5. Authorizations granted are valid throughout the EU for a period of ten years. They are renewable for ten-year periods on application to the European Commission by the authorization holder at the latest one year before the expiry date of the authorization. This application for renewal of authorization must include *inter alia* any new information which has become available regarding the evaluation of safety and risks to the consumer or the environment. Where no decision is taken on the renewal before the authorization's expiry date, the period of authorization is automatically extended until a decision is taken.

<u>Authorization for deliberate release into the environment of biotech events [4]</u>

The standard authorization procedure requires written consent of the appropriate competent authority to be given before the deliberate release into the environment (cultivation for which no specific containment measures are used) of a biotech event. The following is necessary to obtain written consent.

1. The person wishing to undertake the release must submit a notification [5] to the appropriate national competent authority of the Member State within whose territory the release is to take place.

2. The national competent authority acknowledges the date of receipt of the notification.

3. The national competent authority sends to the European Commission, within 30 days of receipt, a scientific opinion on each notification received.

4. The European Commission, at the latest 30 days following receipt, forwards the opinion to the other MS which may, within 30 days, present observations through the Commission or directly.

5. The national competent authority has 45 days to evaluate the MS' observations. If these observations are in line with the national competent authority's scientific opinion, that opinion in sent to the European Commission which, in turn, presents a draft Decision reflecting the opinion to its '*Committee for the adaption to technical progress and implementation of the Directive on the deliberate release into the environment of genetically modified organisms.*' The Committee votes on the draft decision. In the case of no qualified majority in favor of the draft Decision, the European Commission submits it to the Council of the European Union (typically the Environment Council meeting) without delay. If the Council has neither adopted the draft Decision nor opposed it by qualified majority within three months from the date of referral, it is adopted by the European Commission. *Note: this procedure is currently under revision as a function of the implementation of the Lisbon Treaty*.

6. If, on the other hand, the Member States' observations are not in line with the national competent authority's scientific opinion, the matter is passed to EFSA for its scientific opinion. EFSA's opinion is

then sent to the European Commission which presents a draft Decision reflecting EFSA's opinion to the '*Committee for the adaption to technical progress and implementation of the Directive on the deliberate release into the environment of genetically modified organisms*'. As in point 5, above, the Committee votes on the draft Decision. In the case of no qualified majority in favor of the draft Decision, the European Commission submits it to the Council of the European Union (typically the Environment Council meeting) without delay. If the Council has neither adopted the draft Decision nor opposed it by qualified majority within three months from the date of referral, it is adopted by the European Commission. *Note: this procedure is currently under revision as a function of the implementation of the Lisbon Treaty*.

Note: A proposed revision to the legislation governing the cultivation of biotech crops is currently being considered by the Council and European Parliament. If adopted, the revision would allow Member States to prohibit the cultivation of approved biotech crops on part or all of their respective territories for reasons not based on science.

[1] In the EU commonly referred to as Genetically Modified Organisms (GMOs)

[2] Regulation (EC) No 1829/2003 of the European Parliament and of the Council

[3] The application is accompanied by *inter alia*:

- name and address of the applicant;
- designation of the food, and its specification, including the transformation event(s) used;
- a copy of the studies which have been carried out and any other available material to demonstrate no adverse effects on human or animal health or the environment;
- methods for detection, sampling and identification of the event;
- samples of the food;
- where appropriate, a proposal for post market monitoring;
- a summary of the dossier in standardized form.

A complete list of accompanying information is provided in Article 5 (3) for food use, and Article 17 (3) for feed use of Regulation (EC) No 1829/2003.

[4] Directive 2001/18/EC of the European Parliament and of the Council

[5] The notification includes *inter alia*:

- a technical dossier supplying the information necessary for carrying out an environmental risk assessment;
- the environmental risk assessment and the conclusions, together with any bibliographical reference and indications of the methods used.

Complete details are provided in Article 6 (2) of Directive 2001/18/EC.