European Food Safety Authority

Management Board Meeting

14 September 2004

EVALUATION – ARTICLE 61 OF REGULATION 178/2002

Whereas,

1. The initial views concerning the evaluation of the Authority was communicated to the Board at the 22 June 2004 Management Board. The initial paper has now been refined in close co-operation with the Commission services for what concerns the methodology and draw up of the terms of reference.
2. The proposed time frame for the exercise is the following :
   - End August - Draft of Terms of reference for Management Board consideration.
   - September - December 2004 - finalisation of the Terms of Reference with Commission upon comments of the Board on the draft. Launch of a call for tender for the selection of independent consultant or use of the AMI list available. The Commission will be associated to the selection of the contractor.
   - November/December - Formal approval of the Board
   - January 2005 - Appointment of contractor
   - June 2005 - Interim report detailing the progress of the work
   - October 2005 - Final report from the contractor, for consideration by the Board
   - January 2006 - Recommendations from the Authority to the European Commission (report from the Management Board acting on a proposal from the Executive Director), to be made public. Report to be forwarded to European Parliament and Council.

EFSA EVALUATION - DRAFT TERMS OF REFERENCE

Content

1. Justification, purpose and objectives for EFSA's evaluation

1.1. It is current practice, within the EU institutional environment, to proceed with evaluations of programmes or activities which entail public spending. In this context, an evaluation is defined as an assessment, as systematic and objective as possible, of on-going and completed programmes or organisations, as regards their design, implementation and results.

1.2. In line with this general principle, the obligation to evaluate the Authority is enshrined in Article 61 paragraph 1 of its founding Regulation. This article states:

> *Before 1 January 2005 and every six years thereafter, the Authority, in collaboration with the Commission, shall commission an independent external evaluation of its achievements on the basis of the terms of reference issued by the Management Board in agreement with the Commission. The evaluation will assess the working practices and the impact of the Authority. The evaluation will take into account the views of the stakeholders, at both Community and national level. The Management Board of the Authority shall examine the conclusions of the evaluation and issue to the Commission such recommendations as may be necessary regarding changes in the Authority and its working practices. The evaluation reports and the recommendations shall be forwarded to the Council and the European Parliament and shall be made public.*

1.3. The purpose of the evaluation is to present, in an independent way, the achievements of EFSA as compared to the established objectives, possible shortcomings or possible improvements necessary to its structures and working practices. It should in principle lead to a series of operational changes and possibly also to changes to the Authority's legal framework.

1.4. Full account should be taken of the relatively short time span during which EFSA has been operational at the beginning of the evaluation (roughly 1 1/2 year since the establishment of the scientific committee and panels). It follows that the Review will have to be flexible in that new experience will be acquired in the course of the evaluation.

1.5. The objectives of EFSA evaluation are firstly to improve present and future design, mission and tasks of the organisation and secondly to provide transparency and accountability in reporting results of its activities and impacts to European citizens.

1.6. It is geared to evaluate and compare the implementation of EFSA's mission and tasks to the outcomes and results by analysing their:

- relevance - to objectives
- Added value - to possible alternatives for conducting the mission and tasks
- efficiency - in providing outputs promptly and at least cost
- effectiveness - in achieving planned results and project purpose
- impact - on overall objectives to which the project purpose should contribute

2. Description of the activity to be evaluated

2.1. EFSA provides independent scientific advice on all matters linked to food and feed safety - including animal health and welfare and plant protection - and provides scientific advice on nutrition in relation to Community legislation. The Authority communicates to the public in an open and transparent way on all matters within its remit. EFSA's risk assessments provide risk managers (consisting of EU institutions with political accountability, i.e. European Commission, European Parliament and Council) with a sound scientific basis for defining policy driven legislative or regulatory measures required to ensure a high level of consumer protection with regards to food safety.

2.2. EFSA was legally established by Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 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"). Regulation 178/2002 provides the mission and tasks of EFSA as well as the structure of its organisation, Advisory forum, scientific committee and scientific panels. It also specifies the duties of EFSA in the fields of data collection, networking with the Member States and organisations operating in the fields within EFSA's mission, identification of emerging risks and rapid alert system.

2.3. The Management Board is responsible for overseeing the work of the European Food Safety Authority. Its main duty is to ensure the Authority functions effectively and efficiently and that it fully delivers its mandate as defined in the founding Regulation. The Board provides a strategic overview and direction for the growth of EFSA, providing guidance to the Authority as it seeks to ensure that the expectations of European and national institutions, stakeholders and the public at large are met.

2.4. The Advisory Forum is composed of representatives from competent bodies in the Member States which undertake tasks similar to those of the Authority. It constitutes a mechanism for exchange of information on potential risks and the pooling of knowledge. It equally ensures close cooperation between the Authority and the competent bodies in the Member States.

2.5. EFSA developed during 2003 into a fully-fledged independent European agency with the establishment of its Scientific Committee and Panels. Scientific experts from all over Europe and beyond were appointed to eight Panels, covering everything from food additives to animal health, and to a Scientific Committee with oversight of these panels.

2.6. EFSA is now dealing principally with requests for risk assessments from the European Commission with a number of questions coming from the European Parliament and Member States. Notwithstanding the important needs of its key customers, EFSA is already undertaking its own work in order to look ahead and address broader issues of importance to its mandate. For example, through such "self-tasking", the Authority's Scientific Committee has initiated work in relation to the identification of emerging food safety issues.

Five principal objectives underlie EFSA's scientific activities:

1. To provide scientific opinions and advice in response to questions related to food safety issues formally addressed to the Authority by the European Commission, the European Parliament, the Member States or by the Authority itself (i.e. through "self-tasking).

2. To assess the risk of, and as appropriate, propose risk-related factors for specific groups of regulated substances, following notification procedures and time schedules defined by legislation (e.g. food additives, food flavourings, feed additives including medicinal products, pesticides, GMOs and novel food ingredients).

3. To monitor specific risk factors and diseases and provide scientific opinions on tests and other tools to control these risk factors and diseases (for instance, the geographical BSE risk assessment or the monitoring of zoonoses and other food-borne zoonotic agents).

4. To prepare work for the future evaluation of health claims made for food products. Depending on the final text of the legislation currently being discussed in Council and Parliament, this could include the development of proposals for and guidance on nutritional profiles which must be respected or on the nature and extent of scientific data required to substantiate a given claim.

5. To apply and promote new and harmonized scientific approaches and methodologies for hazard and risk assessment of food and feed.

EFSA's risk assessments are carried out by its Scientific Committee and eight Scientific Panels specialized in the following areas:

- Panel on food additives, flavourings, processing aids and materials in contact with food (AFC)
- Panel on additives and products or substances used in animal feed (FEEDAP)
- Panel on plant health, plant protection products and their residues (PPR)
- Panel on genetically modified organisms (GMO)
- Panel on dietetic products, nutrition and allergies (NDA)
- Panel on biological hazards
- Panel on contaminants in the food chain (CONTAM)
- Panel on animal health and welfare (AHAW)

The Scientific Committee and Scientific Panels are supported by EFSA's own scientific staff.

The Authority is also building up scientific networks involving Community institutions, national food safety authorities and scientific institutions in and outside the EU as well as international organisations in order to: facilitate exchange of information and expertise; evaluate possible collaboration in areas of mutual interest and continuously improve its own scientific knowledge and expertise.

Risk communication plays a key role in the achievement of EFSA's overall aim to contribute to improved safety of the European food chain and to build public confidence in the risk assessment process. EFSA's mission in the area or risk communication is to provide appropriate, consistent, accurate and timely communication on issues relating to food and feed safety, based on the Authority's risk assessments and own scientific expertise. A critical success factor in achieving this goal will lie in EFSA's ability to establish itself as an authoritative and trusted voice with regard to safety issues concerning the food chain both among its stakeholders and the public at large.

Finally, EFSA provides to the public and any interested parties objective, reliable and easily accessible information, in particular with regard to the results of its work.

3. Scope of the evaluation

3.1. Beyond the objectives of the evaluation as previously mentioned, the scope of the evaluation will equally address the needs in terms of decision-making of the risk management institutions, be it at general or specific levels.

3.2. The evaluation will also examine whether the changing legal and policy frameworks require any readjustments of the scope, mission and tasks of EFSA established in Regulation 178/2002.

3.3. The change in the scope of tasks in function of newly created bodies, new areas of concern and recommendations ensuing from the results of the evaluation are part of the scope of evaluation.

4. Evaluation Questions

4.1. The White Paper on Food Safety and the Regulation establishing EFSA provide the source of the Authority's objectives, activities, expected outcomes and results on which the evaluation questions are based.

4.2. Be it at general or operational level, the evaluation questions therefore derived from the positioning, mission and tasks (intervention logic) which was designed for EFSA in the Regulation. They will then be associated with their expected effects measured by success criteria and quantitative or qualitative indicators for each success criterion, so as to be able to measure to what extent the expected result has been achieved.

4.3. Given that the main focus of the evaluation is on the results generated by EFSA's activities, its intervention logic gives rise to the setting up of specific [objectives-success criteria-indicators] subsets. For instance:

Objectives - Evaluation Questions	Success criteria	Indicators
Establishment as independent centre of scientific excellence	Recognition by stakeholders as trusty and reliable risk assessment body	Spreading of attendees to stakeholders events
	Recognition by third parties	Number of scientific opinions challenged

4.4. The indicators will then be assessed against expected target levels and/or baselines, so as to be able to assess whether objectives / activities were successful or not.

4.5. Upon validation of the evaluation questions - success criteria – indicators, the evaluation calendar under section 6. will be finalised.

Relevance

Q1: **To what extent is EFSA in line with the missions and tasks given to it in Article 22 and 23 of the Regulation?**

Are EFSA's tasks and responsibilities as laid down in Regulation 178/2002 adequate and do they correspond to the requirements of the beneficiaries and stakeholders? Are there areas where its remit should be clarified or changed?

Is the overall legal framework appropriqte for the Authority given the changing legal and policy objectives of the European Community ?

The answers to these evaluation questions will be derived from the comparison between the results of the ex-ante evaluation done in preparation to the legal basis of EFSA and the results of the present evaluation.

Added value

Q2: **To what extent does outsourcing of the risk assessment issues to EFSA provide added value compared to possible alternative options of implementing the activities in question (e.g. through the Commission Services themselves, the contracting out of individual tasks, etc.).**

What are the improvements or shortcomings compared to the previous system of scientific and technical support within the European Commission?

List of success criteria:

a. Enhanced specialised expertise and know-how;

b. Timely and high-quality response given to questions or inquiries made by EU institutions or other stakeholders;

c. Credibility of EFSA's outputs enhanced as a result of greater independence;

d. More effective stakeholder involvement (e.g., Consumer organisations, European Food Industry, other interested bodies ….);

e. Setting up of comprehensive networks for the gathering and exchange of information;

f. Cost/saving assessment of EFSA's activities on the budgetary framework of the European Union as a whole;

g. Flexibility in the implementation of outsourced tasks achieved.

Coherence, complementarity, synergy

Q3: **To what extent are the elements of EFSA's intervention logically complementary, mutually supportive and non-contradictory?**

To what extent do the objectives and activities of EFSA support or contradict those of other public interventions?

How has the interface between risk assessment and risk management been managed?

To what extent tasks conducted by EFSA might more appropriately be given to other bodies created subsequently?

How successful is the networking between EFSA and the national competent authorities in the specific policy area and how could it be improved?

To what extent EFSA's actions contribute to enhance coherence in policy making by providing independent scientific advice?

To what extent has EFSA be successful in developing a coherent approach to food safety assessments so as to enable a more consistency in decision making in the other institutions?

How successful has EFSA been in bringing together the different national organisations so as to enhance approaches and coherence?

How successful has EFSA been in promoting the necessary coherence in the risk communication process in collaboration with the European Commission and Member States (cf Article 40)

List of success criteria:

a. Coherence ensured with regard to the overall strategic objectives at Community level (Strategic Planning and Programming);

b. Consistency ensured with regard key objectives in the Community policy areas to which EFSA pertains;

c. Internally coherent hierarchy of objectives established (from the Regulation down to the Annual Work Programme);

d. Consistency ensured between high-level objectives in the Regulation and the resources, responsibilities and competences entrusted to EFSA;

e. Complementary nature of the objectives of EFSA with those of other public interventions, in particular those of the EP, Council, European Commission and national agencies in the specific policy area as it appears in their policies/legislation/documents;

f. Complementary nature of the activities of EFSA with those deployed by other public interventions, in particular those of the EP, Council and European Commission and relevant national agencies active in the specific policy area;

g. Effective mechanisms are in place in order to ensure co-operation and networking with the Commission Services, where relevant, other Community Agencies and the national agencies and international organisations concerned;

h. Effective mechanisms are in place to facilitate information sharing and exchange with regards to risk communication;

i. Effective strategies are in place to ensure the consistent dissemination of risk communication messages throughout the Community following risk assessments published by EFSA.

Efficiency and effectiveness

Evaluators will be asked to identify not only the results of the activities/interventions in question but, wherever possible, also their successful implementation and/or impacts.

Questions pertaining to the efficiency will evaluate key outputs/results of EFSA with the inputs needed to produce them (financial and human resources, legal and administrative framework, etc.). The ratio between administrative and operational expenditure may be an indicator in this context, to be compared to an appropriate benchmark (e.g. other Agencies) or to a baseline to be defined.

Q4: **To what extent has EFSA achieved the objectives set out in the Regulation? In particular:**

A. *To what extent has EFSA contributed to the improvement of food safety in Europe ?*

B. *To what extend has EFSA contributed to rebuilding consumer confidence in the European system of food safety ?*

C. *Has EFSA succeeded in establishing itself as an independent centre of scientific excellence ?*

D. How effective has it been in dealing with complex food safety matters ?

List of success criteria:

a. External recognition that on matters which may have led to a food safety crisis or the perception of one, EFSA has dealt with this in order to reduce any unnecessary disquiet ;

b. Preparedness of EFSA for a crisis, appropriate systems put in place ;

c. Confidence in EFSA to deliver appropriate science which addresses the risks to human health from food feed and other matters dealt with by EFSA ;

d. EFSA's decision making processes concerning priorities take into account overall risk to health ;

e. Recognition by consumer associations and other stakeholder organisations of the importance, independence and excellence of EFSA's work in relation to risk assessment and communication ;

f. Compliance with the legal requirements in terms of openness and transparency and relationship with stakeholders ;

g. Compliance with the legal requirements in terms of openness and transparency and relationship with stakeholders ;

h. Evolution of consumer perception and confidence in food safety issues, recognising that such trends are not specific to EFSA's role per se but rather to the effectiveness of the ability of risk assessors and risk managers to address effectively consumer concerns.

Q5: **To what extent has the Authority timely issued the scientific opinions requested at a reasonable cost in terms of financial and human resources deployed?**

Is there a need to formalise other mechanisms for EFSA to give scientific advices short of the system of scientific opinions formulated by the Scientific Committee and Scientific Panels?

List of success criteria:

a. Quality of scientific opinions issued ;

b. Time frames for issuing scientific opinions and decision making process ;

c. Dialogue between risk assessors and managers on risk analysis issues ;

d. Planning and setting priorities in scientific activities.

Q6: **To what extent has the Authority succeeded in setting up an effective cooperation network with Member States national food bodies, in particular in the exchange of information and communication areas in accordance with its mandate?**

What has been the contribution of this/these Network(s) towards the attainment of the Authority's objectives in these fields?

List of success criteria:

a. Efficiency of the communication network with the Members States and stakeholders;

b. Established cooperation with international organisations and third countries;

c. Integration of EFSA into the EU institutional environment e.g. in view of EFSA's need for more input into legislative proposals which affects it.

[Internal management systems]

Q7: **To what extend do EFSA's management systems and processes contribute to the effectiveness and efficiency of its operations?**

Indicative list of success criteria:

a. Specific, realistic and operational objectives as well as indicators for outputs, results and impacts contained in the work programme;

b. Activities (and resources) of EFSA focused on priority objectives. This criterion relates to the "system" that ensures that activities are prioritised and resources allocated accordingly;

c. Communication and dissemination strategy towards interested parties and public at large is well established between risk assessors and risks managers;

d. Internal communication systems contribute to focusing on core operational objectives and to enhance productivity;

e. Monitoring system allows EFSA to collect relevant data on inputs, outputs, results and impacts (where possible);

f. Monitoring data and evaluation findings fed back into decision making;

g. IT management systems do facilitate the networking with Member States and stakeholders;

h. Responsiveness of EFSA to a crisis.

[Organisational set-up and decision making]

Q8: **To what extend does the Agency's organisational set-up contribute to the effectiveness and efficiency of its operations?**

List of success criteria:

a. The size, composition and context of the Board strike a reasonable balance between the need to retain an effective decision-making body and the need to ensure the full range of necessary skills, backgrounds and geographical balance;

b. Board provides clear strategic direction and sets priorities. appropriate indicators of performance: Board meetings are focused on issues of strategic importance, delegation of tasks to the Executive Director;

c. The number, mandate, role and composition of EFSA’s scientific panels and Advisory Forum;

d. Development and reinforcement of the internal scientific expertise.

Q9**: To what extent do the Agency's procedures in the areas of financial and human resources management support or affect the efficiency of its operations?**

List of success criteria:

a. Flexibility of budget appropriations to unforeseen events;

b. Timely availability of reserve lists for scientific or administrative candidates.

Utility

Q10: **To what extent do the results and impacts (where applicable) of EFSA's activities fit with the requirements of its clients/beneficiaries/stakeholders and with the food safety issues it is meant to address?**

Indicative list of success criteria:

a. EFSA's activities have been instrumental to the delivery of Community policy in the area to which the Agency's activities pertain;

b. The clients, beneficiaries or stakeholders of EFSA are satisfied with the results of its activities.

Q11: **To what extent have the activities of EFSA resulted in any unintended or unplanned results and impacts (both desirable and undesirable)?**

5. Overall approach for data collection and analysis

5.1. Access to data and information will be broadly given to the contractor who will also gather opinions of interested parties (stakeholders and partners) through interviews. Key stakeholders and partners include risk management institutions (European Parliament, European Commission, Council), national competent authorities, relevant interest groups (consumers, manufacturers, retailers, farmers, NGOs..) and the press.

5.2. In order to facilitate their conduct, an interview guide will be elaborated.

6. Time Frame, management and budget

6.1. Time Frame

The evaluation will be conducted within the following time-frame:

- August - Internal discussions and meeting with Commission
- End August - Draft for Management Board consideration.
- September - December 2004 - finalisation of the Terms of Reference with Commission upon comments of the Board on the draft. Launch of a call for tender for the selection of independent consultant or use of the AMI list available. Commission to be associated to the selection of the contractor.
- November/December - Formal approval of the Board
- January 2005 - Appointment of contractor
- June 2005 - Interim report detailing the progress of the work
- October 2005 - Final report from the contractor, for consideration by the Board
- January 2006 - Recommendations from the Authority to the European Commission (report from the Management Board acting on a proposal from the Executive Director), to be made public. Report to be forwarded to European Parliament and Council.

6.2. Management of the project

The management of the project includes the following tasks:

- Drafting of the Terms of Reference and awards criteria for the evaluator,
- Responsibility of the evaluation project and what is the role of the stakeholders in this respect,
- Data collection and necessary arrangements within the service to carry it out,
- Decision-making process with regard to the evaluation process,
- Mechanisms for the approval of the quality of the submitted reports,
- Arrangements for the dissemination of evaluation results,
- Arrangements for the implementation of recommendations.

6.3. Budget

As far as the financial resources are concerned, the cost of an evaluation project can represent up to 0.5 % of the budget allocated to an expenditure programme. The relevance of this indication will depend on the nature and coverage of the evaluation sought. This expense will have to be assigned to a particular budget line in our PDB 2005.

7. External evaluator : clear selection criteria

7.1. Evaluators will have prime experience and track-records in evaluation processes. They will be able to analyse and describe the Authority's key inputs, outputs, results and impacts as well as the conceptual relations between these elements (i.e. the Authority's intervention logic).

7.2. The evaluators will validate the evaluation questions and related success criteria and to make proposals for further criteria as well as for indicators and target levels/baselines as they may see fit. These proposals will have to be approved by the manager of the evaluation during the inception phase.

7.3. The evaluators will have proven practice of specific techniques to be applied (e.g. cost-benefit analysis for the evaluation of EFSA's communication for instance, interviews techniques, etc …). The methodological guidance provided by the terms of reference to the evaluators will be kept to a strict minimum. They will be required to conduct interviews with stakeholders and will be invited to propose and structure the methodology they consider the most appropriate to evaluate the success criteria, measure the indicators and answer the evaluation questions.

8. Structure of the final report and progress reports

8.1. The evaluators will deliver different reports at various key stages of the evaluation process: inception report, intermediate report(s), draft final report and final report. Each report should be critically assessed as it provides a basis for tracking quality of the work done by the evaluator.

8.2. Inception report

This report closes the structuring phase of the evaluation. It will describe in detail how the method proposed by the evaluator is going to be implemented and in particular how the method will answer each evaluation question and provide a judgement. This document will provide the opportunity to make a final check of the feasibility of the method proposed and the extent to which it corresponds with the information needs outlined in the terms of reference.

8.3. Interim report

This report will provide information about initial analyses of data collected and the evaluator may already be in a position to provide preliminary answers to some of the evaluation questions. This report will provide the evaluation manager and the steering

group with the opportunity to check whether the evaluation is on schedule and whether the evaluation has actually focused on the specified information needs.

8.4. Draft final report

This document will provide the conclusions of the evaluator in respect to the evaluation questions in the terms of reference. These conclusions will be clearly based on evidence generated through the evaluation. Judgements provided should be clear and explicit. The draft final report may also contain some exploratory recommendations developed on the basis of the conclusions reached by the evaluator. The structure of the draft final report will respect the structure set up by common Evaluation Standards.

8.5. Final report

It will take into account the results of quality assessment and discussions with the steering group about the draft final report insofar as they do not interfere with the autonomy of the evaluators in respect to their conclusions.

9. The expected use, and users of the evaluation.

9.1. The Management Board of the Authority shall examine the conclusions of the evaluation and issue to the Commission such recommendations as may be necessary regarding changes in the Authority and its working practices.

9.2. The evaluation reports and the recommendations shall be forwarded to the Council and the European Parliament and shall be made public.