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European Food Safety Authority

DISCUSSION PAPER ON THE SCIENCE STRATEGY OF EFSA 2011-2016

Executive Summary

EFSA faces many challenges particularly in relation to the nature and volume of its scientific work. EFSA's workload continues to grow with over 950 questions in 2010 compared to 220 in 2007 with a growing proportion, approximately two thirds of these now concerning dossiers related to the evaluation of applications for the marketing of products which are subject to regulation. The nature and complexity of the questions has also changed as regulations increasingly call for advice on such issues as environmental risk, occupational health, risk benefit and efficacy requiring a diversity of expertise using a wider range of scientific evidence.

It is important that at this time when EFSA is facing competing challenges within a stabilising budget that it sets out its strategic objectives and key priorities for its scientific work in a transparent and open manner in consultation with its main partners: the European Commission and other Institutions, National Authorities, the scientific community and stakeholders. The Strategy will enable EFSA to clearly illustrate how it will meet evolving demands while being a trusted source of scientific advice, pursuing its work in keeping with its core values of independence, scientific excellence, responsiveness, openness and transparency.

EFSA has developed its work on the science strategy over the past year through holding surveys and workshops with its staff, and it has initiated discussions with the Scientific Committee and Advisory Forum. The issues raised in these discussions have been incorporated into the development of the strategy. In addition, EFSA commissioned an external study to identify with EFSA's stakeholders, including the Commission, scientific experts and national authorities, which aspects they would envisage EFSA addressing in developing its future strategic scientific direction.

The Science Strategy will be based on and complement the strategic direction given by the EFSA Strategic Plan 2009-2013[1], by laying down more specifically the foundations for its scientific work over the long term through a set of key strategic initiatives.

The Management Board is asked to consider this document and provide insight and guidance to the further elaboration of a Science Strategy. In particular the Board is asked to comment on the underlying vision and thinking in this document and to assess the direction and adequacy of the key strategic priorities identified on the basis of the evolving environment in which EFSA sits.

[1] http://www.efsa.europa.eu/en/corporate/pub/strategicplan.htm

Introduction

EFSA's Founding Regulation[2] established EFSA to provide scientific advice, scientific and technical support for the Community's legislation and policies in all fields which have a direct or indirect impact on food and feed safety[3] .

When it was established in 2002 EFSA's initial priorities were to put in place the necessary scientific infrastructure to enable it to deliver scientific opinions and advice to the requests it received. In this respect, the main focus was to establish the Scientific Committee and Panels comprising independent experts selected for their expertise and experience to deliver scientific opinions. Subsequently it put in place the necessary support, built data and information collection capabilities and laid the foundations for cooperation activities with the national authorities and more recently with those organisations with similar risk assessment mandates at the European level, in third countries and at international level.

Since 2002 a lot has been achieved. EFSA has published over 2500 scientific outputs including opinions, statements and reports. It has established guidance documents and methodologies to enhance the risk assessment process and the risk monitoring it undertakes and has put in place a quality assurance system for its scientific outputs. EFSA works annually with over 1500 scientific experts and has over 3000 on whom it may call through its Expert Database.

It has established cooperation activities with the national authorities within Europe setting up Focal Points in the Member States. EFSA has built 9 scientific networks for example on nanotechnology, animal health, GMOs with the objective of facilitating scientific cooperation by coordinating activities, exchanging information, developing and implementing joint projects and exchanging expertise and best practices. It has established an Information Exchange Platform with the national authorities with over 870 documents having been uploaded by the Focal Points including almost 740 risk assessments since 2009 with 2346 documents being downloaded. It has set up a list of 400 competent organisation in the Member States with whom it may cooperate under Article 36. The expenditure on grants and procurements for the outsourcing of preparatory and other support work has increased with 1 million Euros being allocated in 2007 rising to an expected 11 million in 2012.

EFSA has built dialogue with its stakeholders, consults on key scientific opinions, it has procedures for handling emergency issues and has started developing processes to identify emerging risks.

EFSA's Evolving Environment

Workload and Planning

Since 2002 the demands on EFSA have changed. In 2007 EFSA received 220 questions from the Commission; in 2009 that increased to 360 questions and in 2010 to 950. Although EFSA receives requests from the European Commission, Member States and the European Parliament, overall it is the Commission which is responsible for the majority of these at approximately 90%. Medium and longer term planning with the Commission services has been instigated but it will be essential for this to become even more comprehensive and efficient if EFSA is going to be able to predict fluctuations in workload and anticipate the specific expertise it needs to fulfil demands.

Regulatory developments since 2002 have demanded a significant increase in the resources allocated to the evaluation of regulated products such as pesticides, food and feed additives, and food contact materials – as well as health claims, which was not foreseen when the Founding Regulation was adopted. As a consequence, the resources committed to evaluations have doubled over the period 2008-2010 from 20% to 40% and about two-thirds of EFSA's annual scientific outputs now relate to applications. This trend is expected to continue into the foreseeable future.

[2] Regulation EC No 178/2002 of the European Parliament and of the Council on 28 January 2002, laying down the General Principles and requirements of food law, establishing a European Food Safety Authority and lying down procedures in matters of food safety.

[3] Within its mandate, EFSA carries out a wide range of risk assessments, safety assessments, risk-benefit assessments and evaluation of risk assessment documents dealing with human and animal nutrition, animal health and welfare, plant health and the environment.

Nature of the issues addressed - In addition, the complexity of the issues that have to be assessed is growing; for example, questions now include aspects on environmental impacts, occupational health, post-market monitoring, risk comparisons, health benefits and efficacy. The agro-food sector is innovative and uses advanced technologies in the products it seeks to market which require complex assessments. Multidisciplinary risk assessments which consider risks in an integrated manner are increasingly required in order to provide risk managers with comprehensive advice on which to base their decisions. In this respect, it is anticipated that a higher proportion of EFSA's future evaluations will be performed jointly by a number of panels.

Balancing priorities - At the same time as the workload on applications has increased, the workload in the area of public health risks has expanded due to major mandates such as that on meat inspection. EFSA will have to ensure that the generic public health orientated aspects of its work (for example risk assessment of biological and chemical hazards) are carried out, emerging risks are identified, and key issues are communicated. Above all there is a need to regularly balance and review prioritisation in a structured and transparent manner taking into consideration regulatory demand, health priorities and public expectations. EFSA can assist risk managers in developing their priorities and gain an accurate overview of the major health challenges in its area of competence by the provision of data and evidence with insights provided by risk monitoring and risk ranking.

Fit for purpose - In terms of the nature of the outputs, it is important that scientific opinions are "fit for purpose" and developed to the extent necessary to be useful to risk managers. Regular feedback from those using EFSA's opinions is needed to ensure that they are relevant, and fulfil the risk managers' and stakeholders' needs without being over comprehensive on the one hand or oversimplified on the other.

Emerging issues - Although a start has been made within EFSA to put in place an emerging risk capability with the Member States and other partners EFSA needs to be able to develop this further. This has to be done by further cooperation with the EU, national and international organisations to early identify those emerging issues which may have an impact on the safety of the European food supply.

Expertise

EFSA scientific expertise and capacity are made up of the members of the Scientific Panels and Committee and their Working Groups, the scientists who are on the Expert Database, the scientists working with EFSA in cooperation activities, in particular those in the National food safety agencies, in its networks, its outsourcing activities and EFSA's own internal scientific staff. Whereas the scientific expertise that is represented in the Panels and the Scientific Committee is core to EFSA, it is finite and in some areas overloaded with routine work. If EFSA is to increase its output while tackling the ever increasing complexity it has to consider how to maximise the use of all available resources.

To support the Panels and Committee it will be important that EFSA continues to increase its cooperation activities and other collaborative work and boost the capacity and role of EFSA's own internal scientific staff, leaving the Panels and Committee to focus on complex scientific issues, fundamental guidance and methodologies and the adoption of well prepared dossiers and opinions. This will help EFSA to maintain attractiveness for high level scientific experts while at the same time developing the important role for EFSA's in-house scientific staff enabling them to utilise to the full their breadth of scientific knowledge and expertise.

Coordination with the Member States, sharing of work programmes and joint initiatives to make the best use of available capacity and resources throughout Europe will have to be continually improved. Building capacity for the future will require such initiatives as training and developing expertise directly linked to the risk assessment process[4].

Evidence

EFSA has to have data and information at its disposal to provide robust risk assessments. In a number of its risk assessment areas EFSA receives comprehensive data and information from applicants or the questioner, but for many assessments, EFSA has to collect, collate and assimilate existing data, before conducting and finalising its work. EFSA's annual and ad hoc data collection activities provide much of the data for such assessments and these are increasingly planned over the mid to longer term something which will be vital for EFSA to have the right data to address key issues at the right time. In addition EFSA needs to build its capacity in literature review.

[4] The European Commission's training programme on Food Safety Risk Assessment – Better Training for Safer Food and other initiatives will be useful in this respect

EFSA's Information Exchange Platform and other cooperation networks permitting information sourcing and sharing should be further extended to other national agencies in Europe and beyond as well as to international agencies.

In areas where new risks emerge or where evaluations are needed in areas of innovation, or where there is a lack of data, EFSA must rely on other organisations to fill critical data gaps. EFSA with its Advisory Forum needs to contribute to the development of research activities at the European and international level. Detailed forward planning with public research organisations in Member States the European Commission's Directorate General (DG) on Research and Innovation and DG Joint Research Centre is important if information needs are to be filled. Cooperation with the national food agencies, utilising to the full studies and risk assessment work carried out by other organisations will also be required.

Methodologies

To be to be able to deliver high quality scientific advice, EFSA has to be consistent across its different work areas taking into consideration, and where appropriate, participate in the development of risk assessment methods at the international level. The Scientific Committee has developed documents to introduce general risk assessment approaches across the work of EFSA including, for example, on transparency, uncertainty, the benchmark dose approach, risk/benefit assessments and the margin of exposure approach for compounds which are both genotoxic and carcinogenic. On new areas, EFSA has used its Scientific Colloquia series to have an open scientific debate prior to developing or finalising guidance. Further development of methods will be required to ensure EFSA is able to ensure risk managers have the most robust risk assessments advice.

Although major progress has already been made during the last decade in the development of internationally harmonised risk assessment methodologies, there is a still a need for further harmonisation between various domains within EFSA as well as with the Member States and at the international level. EFSA's risk assessment methods represent internationally accepted state-of-the art approaches. In order to further build trust it is important that risk assessment methodologies as applied by other scientific organisations reflect those used within EFSA. International harmonisation of methodologies and approaches is therefore crucial.

The use of state-of-the-art methods also requires implementing suitable new concepts to improve these approaches. In the last decades, new ('omics') technologies and assessment methodologies (some of which developed to reduce animal testing) have become available which need to be carefully validated and, where considered to provide opportunities and benefits, implemented in EFSA's risk assessment practices. EFSA will need to work closely with the European Commission's scientific services, scientific organisations and experts to maintain its overview of scientific progress which may have an impact on EFSA's activities.

Ensuring EFSA's Scientific Advice is clear and relevant

It is of utmost importance that the European consumer and others can trust the science on which risk management measures are based and that the issues of concern are addressed.

While EFSA publishes all its findings on the web and strives for transparency in its processes it still faces challenges in ensuring that its findings are easily accessible and understandable to its stakeholders, target audiences and the general public. On such issues as transparently demonstrating how data provided to EFSA are used and managed and how an opinion is developed as well as how scientific consensus is reached, EFSA still needs to develop further.

EFSA's scientific outputs often aim to address questions of a difficult scientific nature which by their nature use data and approaches which are complex and which can be difficult to explain. Nevertheless it is incumbent on EFSA to ensure that its findings are both communicated accurately, in a relevant manner and understandably. This will not only assist risk managers to use to the full the advice produced by EFSA it will also assist other stakeholders to understand the issues underpinning EFSA's advice.

Further engagement with stakeholders and the scientific community will be undertaken to build better insights into and understanding of EFSA's scientific work and procedures.

Proposed Strategic objectives

Taking into consideration the issues raised above, EFSA has identified four key strategic objectives which will provide the focus for its scientific activities over the coming 5 years. The Board is asked to comment on their direction and appropriateness.

The proposed key strategic objectives for 2011-2016 are:

1. Extending and improving the evidence base for risk assessment and risk monitoring
2. Ensuring risk assessment capacity in the EU is adequate to meet needs
3. Taking the lead in the harmonisation of methodologies and approaches to assess risks associated with the food chain
4. Enhancing scientific support to decision makers and stakeholders through clear and relevant scientific outputs

Objective 1: Extending and improving the evidence base for risk assessment and risk monitoring

Key initiatives :

- Identify and develop further with partners formalised data generation, collection and collation methods and protocols.
- Strengthen data sharing and data access agreements with other key organisations.
- Identify where new frameworks for the harmonised collection of scientific data are needed and implement.
- Establish a database for hazard characterisation in cooperation with other agencies and continue building harmonised food consumption data from across the EU.
- Strengthen comprehensive literature reviews and bibliography library services in collaboration with Member States.
- Develop a pro-active, integrated and focused capability to identify and evaluate emerging issues.

Objective 2: Ensuring risk assessment capacity in the EU is adequate to meet needs

Key initiatives :

- Develop in cooperation with the Commission and EFSA's key partners transparent and consistent prioritisation tools to assist with the planning of EFSA's work over the medium and long term
- Increase and strengthen planning and prioritisation in conjunction with the European Commission services, Member States and stakeholders.
- Increase the use of internal and external expertise to support the Committee and Panel system.
- Increase cooperation with EU agencies, national agencies, research institutes and international partners to share work.
- Put in place career development initiatives, increase activities for training and sharing of best practices between staff and external experts and make best use, enhance and broaden staff's and experts knowledge base.
- Identify research priorities in EFSA's risk assessment areas and work with key research partners to develop initiatives.
- Further develop quality and Impact assessment activities to assess fitness for purpose and utility of EFSA's opinions.

Objective 3: Taking the lead in the harmonisation of methodologies and approaches to assess risks associated with the food chain

Key initiatives

- Increase cross-discipline sharing of ideas, cross-fertilization and the building of concepts both within EFSA and with other organisations.
- Identify and work with national, EU and international organisation on key initiatives for the harmonisation of existing and new methodologies and approaches.
- Take the lead, where appropriate, in the development, implementation and harmonisation of approaches in existing and new scientific areas.
- Work with international, national and EU partners to identify and develop risk assessment methods for innovative technologies,
- Develop and implement guidance to harmonise the use of risk assessment terminology across EFSA's scientific experts.
- Further develop internal and external quality procedures including peer review and scientific audits.

Objective 4: Enhancing scientific support to decision makers and stakeholders through clear and relevant scientific outputs

Key initiatives

- Strengthen engagement and consultation between risk assessors, stakeholders and other interested parties in particular when preparing guidance documents.
- Enhance the clarity, consistency and framing of EFSA's outputs, and processes by implementing further cross disciplinary advice and guidance.
- Enhance the visibility and excellence of EFSA's scientific work in the scientific community.
- Tailor better communications with particular focus on thematic communication tools as defined in the Communication Strategy[5]
- Ensure that EFSA's scientific outputs meet the needs of risk managers, provide a basis for the protection of health.
- Strive to increase the impact and visibility of its evidence base in the scientific community by contributing to or preparing scientific peer reviewed publications involving EFSA's scientific experts and scientific staff.

[5] EFSA Communications Strategy 2010 – 2013