European Food Safety Authority

EXECUTIVE OFFICE

Management Board
20 October 2011
Parma

| Subject : | EFSA's Science Strategy | |
|---|---|---|
| | | |
| Document number: | mb 20 10 11 - item 5 doc 4 | |
| | | |
| Submitted by : | Science Strategy & Coordination | |
| | | |
| Document for : | | Information |
| | X | Discussion |
| | | Possible adoption |

European Food Safety Authority

SCIENCE STRATEGY & COORDINATION

Since its inception in 2002, EFSA's scientific advice has been central to European decision making on the protection of the European Consumer against threats in the food chain. In the intervening years, the Authority's operating context has evolved considerably driven by, for example, scientific and technological advancement and the changing legislative framework and, as the organization has matured, its scientific capacity has developed considerably. These evolutions are reflected in EFSA's scientific work programme where in recent years the emphasis has shifted towards the evaluation of regulated products and where the assessment of environmental risk and risk- benefit and the post-market monitoring of authorised products are more prominent.

This Science strategy 2012-2016 lays out the vision of how EFSA will continue to support the European food safety system over the next five years and meet the demands that are placed upon it. The document explains why EFSA has selected certain strategic priorities and how it plans to make the best possible use of the resources at its disposal. It begins by taking stock of what has been achieved in its first ten years of existence and then explores the drivers for progress and change: the evolving European policy context; the nature and volume of EFSA's workload and, briefly, the economic context with the prospect of a stable budgetary situation for the duration of the strategy and the possibility of EFSA receiving fees for some of its work. In this manner, the strategy identifies the key challenges and future demands on the organization and how they will be met.

This strategy has been guided by and will complement EFSA's corporate Strategic Plan 2009-2013 and has been built through a process of extensive consultation, internally with EFSA staff and externally with stakeholders, partner European institutions, national authorities, and the Authority's Scientific Committee and Advisory Forum. All their inputs are reflected here. It will remain a "live document" that will be regularly reviewed to adjust the strategic direction in line with changes in the working environment. Progress in implementation will be assessed annually against EFSA's corporate key performance indicators and any remedial actions will be included in the multiannual work programme and annual management plans of the Authority.

The Management Board is asked to consider and comment the document before the public consultation is launched.

The revised draft science strategy will be thereafter submitted for possible adoption at the Management Board in December 2011.

European Food Safety Authority

SCIENCE STRATEGY AND COORDINATION

# DRAFT SCIENCE STRATEGY 2012-2016

Table of Contents

# Executive Summary

Since its inception in 2002, EFSA's scientific advice has been central to European decision making on the protection of the European consumer against threats in the food chain. In the intervening years, the Authority's operating context has evolved considerably driven by, for example, scientific and technological advancement and the changing legislative framework and, as the organisation has matured, its scientific capacity has developed considerably. These evolutions are reflected in EFSA's scientific work programme where in recent years the emphasis has shifted towards the evaluation of regulated products and where the assessment of environmental risk and risk-benefit and the post-market monitoring of authorised products are more prominent.

This *Science Strategy 2012-2016* lays out the vision of how EFSA will continue to support the European food safety system over the next five years and meet the demands that are placed upon it. The document explains why EFSA has selected certain strategic priorities and how it plans to make the best possible use of the resources at its disposal. It begins by taking stock of what has been achieved in its first ten years of existence and then explores the drivers for progress and change: the evolving European policy context; the nature and volume of EFSA's workload and, briefly, the economic context with the prospect of a stable budgetary situation for the duration of the strategy and the possibility of EFSA receiving fees for some of its work. In this manner, the strategy identifies the key challenges and future demands on the organisation and how they will be met.

In the coming five years, EFSA's scientific activities will focus on four key strategic objectives:

(i) further development of its scientific excellence and other core values – independence, openness, transparency and responsiveness;
(ii) optimal use of European risk assessment capacity;
(iii) development and harmonisation of risk assessment methodologies and approaches; and
(iv) strengthening of the scientific basis for risk assessment and risk monitoring.

To practically support the implementation of these objectives, a number of key initiatives are proposed which aim to enhance the skills of both internal staff and contributing experts, and further enhance the support provided to experts in areas such as dossier review, data collection and exposure assessment. In addition, EFSA's systems for identifying emerging issues and identifying new data that might require opinions to be reconsidered will be strengthened and the framework for collaboration with institutional partners will be re-evaluated to build on existing synergies.

This strategy has been guided by and will complement EFSA's corporate *Strategic Plan 2009-2013* and has been built through a process of extensive consultation, internally with EFSA staff and externally with stakeholders, partner European institutions, national authorities, and the Authority's Scientific Committee and Advisory Forum. All of their inputs are reflected here. It will remain a "live document" that will be regularly reviewed to adjust the strategic direction in line with changes in the working environment. Progress in implementation will be assessed annually against EFSA's corporate key performance indicators and any remedial actions will be included in the multiannual work programme and annual management plans of the Authority.

## Vision for EFSA's Scientific Work

> EFSA provides the best scientific advice that enables timely decision-making to protect European consumers from food-related risks and support healthy diets

The Founding Regulation[1] of the European Food Safety Authority's (EFSA) defines the principles of risk analysis, putting these in the European context and giving the responsibility for independent risk assessment at European level to EFSA[2]. The Authority's overall mission is two-fold: to deliver independent, high-quality and timely scientific advice on risks in the food chain from farm to fork in an integrated manner and to communicate on those risks in an open manner to all interested parties and the public at large. While EFSA aims to provide high-quality scientific advice, it is not a research organisation.

This document sets out how EFSA aims to further strengthen its scientific work in line with its mission through 2016. It does so by taking stock of what has been achieved thus far, identifying the key challenges, describing what the main goals are and how it aims to achieve these goals.

EFSA has developed this strategy over the past year through workshops with its staff, discussions with the Scientific Committee, Management Board and Advisory Forum, input from other stakeholders and through a public consultation. An external study was commissioned to identify with EFSA's stakeholders, including the Commission, scientific experts and national authorities, the key issues the Authority must address to develop its future scientific direction[3]. The issues raised in these discussions have been incorporated into the development of the strategy.

## Where is EFSA Today?

EFSA's initial priority was to put in place the necessary scientific infrastructure to enable it to deliver scientific opinions and advice in response to the requests it received. In this respect, the main focus was to establish a Scientific Committee and Scientific Panels comprising independent experts selected for their expertise and experience to deliver scientific opinions. Initially, eight Scientific Panels were established but due to the evolution of the work, the number of Scientific Panels was increased to ten in 2008. Subsequently, EFSA has put in place the necessary support, built data and information collection capabilities and laid the foundations for cooperation activities with the national authorities. More recently, EFSA has developed cooperation with other European Union (EU) organisations with related risk assessment mandates and with organisations in third countries and international organisations with mandates similar to EFSA's.

Since 2002 much has been achieved. EFSA has published over 2,500 scientific outputs which have been used by risk managers (the European Commission, Member States and the European Parliament) to underpin measures taken to protect consumers. These have had a significant impact in many areas such as food additives, health claims, pesticides and zoonoses.

To ensure the high quality of its work, EFSA has developed guidance on methodologies for the *risk assessment* and the *risk monitoring* it undertakes and has put in place a quality assurance system for its scientific outputs.

---

[1] 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. Official Journal L 31, 1.2.2002, p.1-24

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

[3] Support and Assistance in the Development of the European Food Safety Authority´s Science Strategy 2010-2016. Author: Tony Hardy (*to be published*)

Since its inception, EFSA has also striven to work openly and transparently, relaying often complex scientific issues in a manner that is both accessible and useful to risk managers and other stakeholders. The Scientific Panels and the Scientific Committee have worked to ensure that scientific outputs clearly indicate what data or other information have been considered or disregarded and why; the nature and level of uncertainty; assumptions made; and any minority views that are held.

Through the Advisory Forum, EFSA has established cooperation activities with the national food safety authorities throughout Europe. EFSA has set up Focal Points in the Member States and built nine European scientific networks with its competent organisations. These have the objective of facilitating scientific cooperation. EFSA has established an Information Exchange Platform (IEP)[4] with the national authorities and set up a list of over 400 competent organisations in the Member States with whom it may cooperate under Article 36 of the Founding Regulation. The expenditure on grants and procurements for the outsourcing of preparatory and other support work has increased from 1 million Euros in 2007 to an expected 11 million Euros in 2012[5].

EFSA has built dialogue with its stakeholders and consults on key scientific opinions. It has established procedures for handling requests for emergency advice, initiated training on these and successfully used them on a number of occasions (e.g. melamine, dioxins, and the STEC (Shiga toxin-producing E. coli) outbreaks of 2011) and has started developing processes to identify emerging risks, as foreseen in the Founding Regulation.

## Drivers for Progress and Change

### EFSA's *Strategic Plan 2009 – 2013* within the evolving European food policy context

EFSA's *Strategic Plan 2009 – 2013*[6] identified the overall vision of EFSA over this period including an assessment of how EFSA could reach its strategic goals. It assessed the external and internal challenges presented by the changing expectations and requirements of EFSA's stakeholders, advances in science and technology, workload and the types of issues faced by EFSA particularly in relation to evolving European level policies. It also addressed emerging issues of relevance for EFSA such as those related to the international trade in food, climate change, and the changing demographics of the European population.

Since the adoption of the *Strategic Plan 2009-2013*, the EU's policy objectives have re-emphasised the importance of innovation as a means to increase the competiveness of Europe within the framework of the EU 2020 Agenda[7]. They have also highlighted the need to ensure food security both within Europe and internationally[8], the need for environmental, social and economic sustainability, and the specific needs of the aging population[9].

The overall trend in international trade has continued to rise with an increasing range and volume of imports from emerging markets of primary products, food products and ingredients[10], leading to an increased number of requests for scientific advice to be delivered by EFSA.

In addition, innovation in scientific knowledge has resulted not only in new food and feed products and production processes but also in new techniques and risk assessment methods which need to be developed or validated in order to be considered for use by EFSA in its risk assessment work.

[4] EFSA (European Food Safety Authority) 2011. Technical Report of EFSA. Information Exchange Platform-Evaluation Report. 2011:1 [59 pp.].

[5] EFSA (European Food Safety Authority) 2011. Technical Report of EFSA. Follow-up to the 2009 evaluation report of EFSA's grant and science procurement schemes. 2011:1 [16 pp.].

[6] EFSA's Strategic Plan 2009 – 2013: http://www.efsa.europa.eu/en/corporate/pub/strategicplan.htm

[7] European Commission: *Europe 2020 - a strategy for smart, sustainable and inclusive growth*: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2010:2020:FIN:EN:PDF.

[8] European Commission(2010) 672 final *The CAP towards 2020: Meeting the food, natural resources and territorial challenges of the future, Brussels, 18.11.2010:* http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:52010DC0672:EN:HTML.

[9] European Commission(2010) 546 final, *Europe 2020* Flagship Initiative Innovation Union, Brussels, 6.10.2010: http://ec.europa.eu/research/innovation-union/pdf/innovation-union-communication_en.pdf.

[10] Eurostat publication, *External and intra- European Union trade Data 2004-2009*, issued on 17 January 2011, page 20: http://epp.eurostat.ec.europa.eu/portal/page/portal/product_details/publication?p_product_code=KS-CV-10-001.

### Nature and volume of scientific work

The evolutions described above may affect the nature, fluctuation and volume of EFSA's scientific work. Since 2002, the demands on EFSA have changed and its output has substantially increased (Annex 1). It should be noted however that the workload associated with a question may vary considerably and therefore the number of questions alone is not sufficient to indicate the workload. It is reflective though of the growing importance of the evaluation of regulated products such as pesticides, food and feed additives, food contact materials as well as for the evaluation of health claims. The resources committed to the evaluation of regulated products 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 in the future.

Compared to other European agencies undertaking safety assessments, the Founding Regulation of EFSA does not provide an overall regulatory framework for the evaluation of regulated products. Rather, the regulatory processes that form the basis for EFSA's evaluation activities of regulated products are defined in a large number of sector-specific regulations with different requirements. Since 2002, these have been subject to significant changes. As a result, the volumes and content of application dossiers to be processed in a specific area have been subject to such changes that it has been challenging to plan and allocate the appropriate resources, both within EFSA and for Member State organisations that work with EFSA.

At the same time as the workload on regulated products has increased, the workload in the area of public health risks has also expanded due to major mandates such as the one on meat inspection methods which covers microbiological and chemical food safety as well as animal health and welfare aspects for most relevant terrestrial food animal species. EFSA will thus have to ensure that, not only the work on applications, but also the generic public health orientated aspects of its work as well as its work on emerging issues are carried out effectively.

Concomitant with the increasing workload, there is a shift in the nature and complexity of the scientific advice requested. The agri-food sector is increasingly innovative in the way it uses novel technologies (e.g. nanotechnology) and the assessment of the risk they may carry is potentially more complex. Further to this, there is an increasing trend for risk assessments to include assessment of issues that require a marked broadening of the scientific discourse, such as environmental impacts, occupational health, post-market monitoring, risk comparisons and health benefits.

### Resources

The budget allocated to EFSA's work is expected to remain around existing levels. Although it is possible that EFSA may receive fees for work associated with the evaluation of regulated products, the timing and overall implications of this on EFSA's budget is not known at present.

## Meeting the Challenges: Four Strategic Objectives

Taking into consideration the challenges raised above, EFSA has identified four key strategic objectives which will provide the focus for its scientific activities over the coming five years. These strategic objectives for 2012-2016 are:

1. Further develop EFSA's scientific excellence and its other core values
2. Optimise the use of risk assessment capacity across the EU
3. Develop and harmonise methodologies and approaches to assess risks associated with the food chain
4. Strengthen the scientific basis for risk assessment and risk monitoring

### 1. Further develop EFSA's scientific excellence and its other core values

It is of utmost importance that the European consumer and others can trust the quality of the science on which risk management measures are based. This quality reflects the degree to which EFSA has successfully implemented its core values of independence, scientific excellence, responsiveness, openness and transparency. The trust that European consumers and stakeholders have in the quality of EFSA's scientific work – and thus the scientific basis

for European risk management measures – reflects the degree to which EFSA has successfully implemented these core values.

Each of EFSA's core values is important in its own right and it is essential that the right balance is struck between these potentially competing core values. As an example, scientific excellence is not an absolute concept but rather excellence has to meet the expectations of those who will use the opinion i.e. be "fit for purpose" and developed to the extent necessary to meet this aim. Similarly, scientific excellence may compete with responsiveness e.g. in the case where urgent advice is needed. Rapid developments in workload in new areas may challenge the core values e.g. requiring guidance documents to be developed quickly; this is particularly important in new fields where expertise may be scarce and mostly in the hands of the organisations that have an interest in developing the new technology.

Scientific excellence

EFSA aims to forge a reputation for the quality of its scientific advice which is recognised worldwide. This is essential for the confidence in the European food safety system. As we continue to develop, it is essential that we maintain and build on both the reputation and the systems that have been put in place to assure that reputation (Annex 3).

Recognising that quality is inherent in our core values of Independence, Excellence, Responsiveness, Openness and Transparency, it has been decided to implement a fully integrated Quality Management system by 2016. This system will build on the foundations established in follow-up of the Scientific Committee recommendations[11,12] and will be fully compatible with the ISO 9001:2008 system.

EFSA will also need to integrate into its working practices the systematic collection of feedback from those mandating EFSA's opinion in order to ensure that the delivered advice is relevant and fulfils the needs of risk managers and other stakeholders without being over-comprehensive on the one hand or over-simplified on the other. EFSA will also continue to perform public consultations on scientific opinions, where relevant, and by doing so collect views from stakeholders, risk managers and risk assessors, including the global scientific community.

EFSA will strive to build awareness in the scientific community of EFSA's scientific work by continuing to promote the active participation of EFSA's scientific experts and staff at scientific conferences within the remit of EFSA and events and by continuing to develop the *EFSA Journal* and ensuring it is recognized as a scientific publication in citation databases.

Integrated advice. Collectively, the scope of the Scientific Panels and Scientific Committee encompasses the entire food chain (Annex 2). The assessments carried out by an individual Scientific Panel vary in scope, depending on which of the following areas of risk and/or benefit assessment they do or do not routinely cover: human, animal, plant, or environmental health. The expertise present in each panel represents what is normally needed for that panel to carry out its work in assessing risks and/or benefits. Where new developments can be anticipated, EFSA will ensure and enhance multidisciplinary membership of concerned Scientific Panels, as well as the Scientific Committee, with each triennial renewal, to ensure all areas of expertise that are normally needed are fully covered. For example, a new technology which is originally used or considered to be in the remit of only the Scientific Committee or a single Panel may later be applied by other Panels.

As identified in EFSA's *Strategic Plan 2009-2013*, it is increasingly expected that risk assessments which consider risks in a wider integrated manner will be required in order to provide risk managers with comprehensive advice on which to base their decisions. When risk assessments have required a broader range of skills than may currently exist in one single Panel, EFSA has established joint work between Scientific Panels to ensure the full range of disciplines is available to build the risk assessment. It is anticipated that a higher proportion of future evaluations will be performed jointly in this manner and in some cases this may include other European agencies e.g. the

[11] EFSA (European Food Safety Authority) 2006.Transparency in risk assessment carried out by EFSA: Guidance Document on procedural aspects. EFSA Journal 2006; 353 [16 pp.].

[12] EFSA (European Food Safety Authority) 2009. Scientific Opinion of EFSA. Transparency in Risk Assessments-Scientific Aspects. Guidance of the Scientific Committee on Transparency in the Scientific Aspects of Risk Assessments carried out by EFSA. Part 2: General Principles. EFSA Journal 2009; 1051 [22 pp.].

European Medicines Agency (EMA), the European Centre for Disease Prevention and Control (ECDC), or the European Chemicals Agency (ECHA). In this respect, the Scientific Committee is assigned a crucial role through the Founding Regulation, both in assessing the consistency of the guidance document and in being formally responsible for the Scientific Opinions on what is termed in the Founding Regulation as multi-sectoral issues. EFSA may need to adapt its operating procedures in order to be better able to accommodate a growing demand on the Scientific Committee in these areas.

Reviewing and balancing priorities has to be done in a structured and transparent manner taking into consideration regulatory requirements, health priorities and emerging issues so that all areas of EFSA's remit are addressed adequately. Using risk monitoring and risk ranking studies[13], EFSA can assist risk managers, consumers and other stakeholders in the EU food supply intends to develop prioritisation tools and criteria to help support the medium- and long-term planning of the Authority's work. EFSA needs to be able to identify and evaluate in cooperation with European, national and international organisations emerging issues, such as new technologies, which may have an impact on the safety of the European food supply.

Other core values: Independence, Openness, Transparency and Responsiveness

For EFSA to be relevant it is essential that it be responsive and uses its resources judiciously. In this regard, scientific excellence in risk assessment is not an absolute concept but rather is concerned with meeting the expectations of those who will use the opinion i.e. be "fit for purpose" and developed to the extent necessary to meet this aim. To increase efficiency, it will therefore be important to continue to work with risk managers to ensure that questions are framed in a manner that enables EFSA to optimise its risk assessment resources. Similarly, a key objective is also to streamline the processing of dossiers for evaluation and to simplify the process for submission and review through initiatives such as electronic submission and other IT- supported initiatives.

In relation to independence, members of EFSA's Scientific Panels are selected on the basis of an open call for expression of interests, with the best scientists who apply being chosen while providing a balance of expertise across a given scientific sphere of activity. The opinions adopted by the Scientific Panel are the outcome of collective deliberations and decisions, each member having an equal opportunity to express his or her views. All members of a Panel have a shared responsibility for the scientific output and EFSA has put in place a comprehensive system to record and evaluate the declared interests of scientific experts and to manage any conflicts of interest. EFSA also records, where appropriate, minority views in the opinions, as well as any specific interests that have been declared in the minutes of the meetings.

EFSA's scientific independence is nevertheless occasionally challenged and EFSA will therefore need to continue to communicate its systems and procedures for ensuring the independence of its work.

Openness and transparency. On such issues as transparently demonstrating how data provided to EFSA are used and managed, as well as the mechanisms by which an opinion is developed and scientific consensus is reached, EFSA still needs to develop further, including for example, the documentation of its preparatory work. As the nature and complexity of EFSA's work is expected to continue to increase, this will be an ongoing challenge for the years ahead.

As food and feed safety continues to be of interest to a range of differing audiences, including such stakeholders as consumers, industry, non-governmental organisations (NGOs), etc., the outputs of EFSA not only have to be appropriate for risk management needs but also convey sufficient information presented in a relevant and accessible manner for other audiences.

Through open and transparent ways of working, EFSA will continue to ensure that its processes and the basis for its opinions are understood and communicated relevantly and clearly.
While EFSA publishes all its findings on its website and strives for transparency in its processes, it still faces challenges in ensuring that its findings are understandable to its stakeholders, target audiences and the general public. The clarity and usability of EFSA's scientific outputs will be kept under continuous review. In particular,

[13] Such as the studies conducted by the Dutch National Institute of Public Health and the Environment (RIVM, 2006; *cf.* http://www.rivm.nl/bibliotheek/rapporten/270555009.pdf ) and in the framework of the EUGLOREH project in 2007 (*cf.* www.eugloreh.it).

EFSA will strive to enhance the clarity, consistency and framing of EFSA's outputs, tailoring better communications with a focus on thematic communication tools defined in the *Communications Strategy 2010-2013*[14].

### 2. Optimise the use of risk assessment capacity across the EU

EFSA's scientific expertise and capacity consists of the members of the Scientific Panels and SC, the Working Groups, the Authority's own internal scientific staff as well as the scientists working with EFSA in cooperation activities through e.g. its networks. For EFSA to further increase its output, while tackling the complexity of the scientific tasks at hand, it has to consider how to maximise the use of all available resources. This will entail a process were EFSA seeks to optimise the input and engagement of the three core sources of expertise available to EFSA

#### Scientific experts in Scientific Panels and the Scientific Committee

The Scientific Panels and the Scientific Committee are composed of independent scientific experts who are not employed by EFSA but volunteer part of their time to this task. While the scientific expertise that is represented in the ten Scientific Panels and the Scientific Committee is core to EFSA's activities, it is finite and in some areas overburdened. This may be particularly true for work that can be standardised, such as well-established regulatory review processes. As mentioned, the number of Scientific Panels has been increased from eight to ten. Every further increase in the number of Scientific Panels increases the need to maintain consistency in areas covered by several Scientific Panels. The number of Scientific Panels could however be further increased where new areas of work emerge that are not already covered by a Scientific Panel.

#### Internal scientific expertise

Meeting the growing number of requests for advice will require EFSA to focus on building and utilising better the internal scientific expertise among EFSA's scientific staff. Through streamlining of its administrative and scientific processes (e.g. efficiency of meetings), EFSA aims to increase its proportion of scientific staff from 60% to 70%. This will increase the level of support for the work of the Scientific Committee and Scientific Panels, in particular through the development of preparatory work and in carrying out support tasks in areas of high standardisation, such as regulatory review which is already well established. It will enable the Scientific Panels and Scientific Committee to focus more on novel and critical scientific issues, including guidance development, while assuring that the same levels of scientific excellence and independence are maintained. This in turn will help EFSA to maintain its attractiveness to high-level external scientific experts while, at the same time, enabling EFSA's in-house scientific staff to utilise to the full their breadth of scientific knowledge and expertise.

EFSA has already built capacity among its own staff and established dedicated units to provide scientific support at the various stages of the scientific work: collection and analysis of data and information including literature review and exposure assessment and modelling. There is also substantial support from the units in dossier evaluations and in the preparation of draft outputs. There will however be a need for enhanced developmental training on risk assessment for EFSA's staff, including a need for greater engagement with the wider scientific community.

EFSA will launch a knowledge management project to enhance working practices among EFSA's external experts by putting in place development initiatives (2012) and increasing scientific training (2012-2016). EFSA will also implement a tri-annual programme for sharing of best risk assessment practices between scientific staff and external experts of EFSA (2013-2015). In this the Scientific Committee, with support from its working groups, can have a key role.

#### Cooperation with other scientific organisations

With the resource limitations that are anticipated, it is essential that duplication of work be avoided with national organisations, other European agencies and international agencies.

Through the implementation of the EFSA *Strategy on Cooperation and Networking with Member States*[15], grants and contracts have been put in place with scientific organisations in the Member States since 2007. Coordination

[14] EFSA Communications Strategy 2010–2013: http://www.efsa.europa.eu/en/keydocs/docs/commstrategyperspective2013.pdf.

with organisations in the Member States, the sharing of work programmes and the use of joint initiatives will have to be continually improved in order to make the best use of available capacity and resources throughout Europe.

EFSA also aims to further develop outsourcing for various preparatory tasks, including in the area of review of regulated products by bringing investment in scientific cooperation with Member States in the areas of GMOs, nutrition and feeds to the same level as other scientific areas by the end of the period. This activity will need to rely heavily on medium- and longer-term planning to support the needs of EFSA's risk assessment work[16,17].

Increasing the involvement of MS' scientific organisations will allow them to maintain and build capacity. However, building capacity for the future will require such initiatives as training and developing expertise directly linked to the risk assessment process. EFSA will investigate how trainings programmes could be organised within the context of the EU[18,19].

While maintaining its cooperation with national organisations through its EU networks, EFSA also cooperates with other European scientific organisations, international organisations and agencies in non-EU countries on topics of common interest. This latter activity would benefit from a more structured medium-term approach through further development of international liaison groups in the area of food chemical and food microbiological safety, with a view to optimising the utilisation of resources.

### Dialogue with stakeholders and risk managers

As the overall volume of requests for risk assessments continues to rise, open dialogue with risk managers on the quantity (total number and its variation over time), nature and complexity of the workload is vital to enable EFSA to identify whether it has appropriate resources and specific expertise available and plan priorities and deployment appropriately. EFSA has striven to prioritise, predict and plan all its scientific activities efficiently over the short and medium terms in collaboration with its key risk assessment and risk management partners. While EFSA receives requests from the European Commission, Member States and the European Parliament, overall it is the Commission which is the source of the majority of these at approximately 90%. As the bulk of EFSA's work is in response to requests from the Commission, it has been – and continues to be – imperative that EFSA develops and agrees principles and criteria for the prioritisation of its activities in conjunction with the Commission while ensuring that the needs and demands for its advice of its other key partners (the European Parliament, Member States and stakeholders) are met. Such medium- and longer-term planning with the Commission services has already been instigated. It will be essential for medium- and longer-term planning to become even more comprehensive and efficient if EFSA is going to be able to accommodate fluctuations in workload and anticipate the specific expertise it needs to fulfil demands.

To maintain and build trust further, EFSA will need to continue to seek ways to build meaningful dialogue with consumers and other stakeholders in order to understand and address their concerns particularly when addressing new or complex scientific issues. For this, EFSA aims to strengthen the dialogue with stakeholders on processes and adherence to core values. In doing so we will strengthen engagement and consultation between risk assessors, stakeholders and other interested parties, including when preparing guidance documents.

To improve the procedures for the evaluation of regulated substances, existing mechanisms for dialogue with applicants concerning issues related to the application assessment process will need to be reviewed to ensure that relevant expectations are met. In line with this, EFSA will complement existing channels with the creation and

[15] EFSA Strategy on Cooperation and Networking with Member States (2006), http://www.efsa.europa.eu/en/keydocs/docs/msstrategyreview.pdf.

[16] Scientific Cooperation between EFSA and Member States: taking stock and looking ahead (brochure) (http://www.efsa.europa.eu/it/corporate/doc/mediumtermplanning.pdf).

[17] EFSA (European Food Safety Authority) 2011. Technical Report of EFSA. Scientific Cooperation between EFSA and Member States: taking stock and looking ahead [57pp.].

[18] EFSA (European Food Safety Authority) 2011. Technical Report of EFSA. Technical specifications on training regarding principles and methods of food safety risk assessment. [22 pp.].

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

building of an applications help desk function for applicant companies as well as any other stakeholders who have queries regarding the assessment of regulated products.

Reviewing and balancing priorities has to be done in a structured and transparent manner taking into consideration regulatory requirements, health priorities and emerging issues so that all areas of EFSA's remit are addressed adequately. Using risk monitoring and risk ranking studies[20], EFSA can assist risk managers, consumers and other stakeholders in the EU food supply intends to develop prioritisation tools and criteria to help support the medium- and long-term planning of the Authority's work.

### 3. Develop and harmonise methodologies and approaches to assess risks associated with the food chain

EFSA's current risk assessment methods represent internationally accepted state-of-the art approaches. EFSA can initiate its own work (self-mandate), as laid down in its Founding Regulation. To date, EFSA has self-mandated on close to 100 occasions and this has in particular enabled it to develop fundamental approaches, methodologies and guidance documents. In particular, the Scientific Committee has developed documents to introduce general risk assessment approaches across the work of EFSA (e.g. guidance on transparency, uncertainty), on aspects of mammalian toxicology (the benchmark dose approach, the margin of exposure approach) for compounds which are both genotoxic and carcinogenic and on new or emerging areas (e.g. nanomaterials or botanicals). On the other hand, other areas have been principally developed by the Scientific Panel e.g. efficacy evaluation, environmental modelling and safety assessment, statistical approaches, exposure assessment methods, microbiological safety assessment, antimicrobial resistance, etc. To foster consistency across Scientific Panels in the latter areas, EFSA has created task forces, often with external experts; this has been the case for example with environmental risk assessment methods, antimicrobial resistance and statistical methods.

#### Harmonisation

Although major progress has already been made during the last decade in the development of internationally harmonised risk assessment methodologies, there is still a need for further harmonisation between various domains within EFSA, with the Member States, with other EU agencies as well as at the international level. For example, the work towards improvement and harmonization of risk assessment terminology, such as for addressing uncertainties (expressing these with transparency and relevance), needs to be reinforced.

In particular, the diversity and number of regulatory processes for the assessment of regulated products needs harmonisation. The current situation is challenging the efficiency of EFSA's scientific processes and the diversity makes it difficult to standardise the handling of dossiers and invest IT resources.

EFSA can also assist the Commission with legislative initiatives. In particular, EFSA can contribute to the harmonisation of methodologies across regulated areas within EFSA and beyond (EMA, ECHA) and will strive to share its view on legislation under preparation or revision regarding its potential impact on scientific processes.

The Founding Regulation gives the Scientific Committee the task of general coordination to ensure the consistency of scientific procedures, in particular with regard to the adoption of working procedures, the harmonisation of working methods and the responsibility to provide opinions on multi-sectoral issues falling within the competence of more than one Scientific Panel and on issues which do not fall within the competence of any Scientific Panel. The Scientific Committee is composed of the Chairs of the Scientific Panels and six independent scientific experts who do not belong to any Scientific Panel. This contrasts with the Scientific Panels which are composed of (up to) 21 independent experts. Due to their particular responsibilities, the Chairs already have a high workload. Therefore, it is important to find new mechanisms for enhancing the capacity of the Scientific Committee to meet the responsibilities assigned to it in the Founding Regulation.

Strengthening the support to and the effectiveness of the Scientific Committee can be achieved by developing a set of (ad hoc or standing) working groups which the Scientific Committee can rely on to cover the main aspects of EFSA's activities i.e. general risk assessment processes, mammalian toxicology, environmental health, microbial

safety assessment methods, antimicrobial resistance, efficacy, novel and emerging issues, and data collection and exposure assessment. EFSA will also strengthen the dissemination of cross-cutting guidance to Scientific Panels through

- annual training plans from the Scientific Committee to ensure the uptake of its GD on general risk assessment approaches by the Scientific Panel; and
- increased cross-discipline sharing of ideas, cross-fertilization and the building of concepts within EFSA on cross-cutting subjects, including the review of guidance developed by a particular Scientific Panel (e.g. environmental risk assessment, efficacy assessment) through the relevant working group of the Scientific Committee.

As further discussed in the next section, EFSA will also identify and work with national, EU and international organisations on key initiatives for the harmonisation of existing, and the development of new, methodologies and approaches.

### New methodologies and approaches

EFSA's *Strategic Plan 2009–2013* identifies the need for EFSA to be at the forefront of the development and implementation of risk and benefit assessment methodologies and practices in Europe and internationally. For example, in the last decades, new '-omics' technologies and assessment methodologies, some of which were developed to reduce animal testing, have become available. It is crucial that EFSA is also actively involved in international projects on development of methodologies and approaches. To ensure that EFSA provides the most robust scientific advice to the risk manager and to further build trust it is indeed important that new risk assessment methodologies applied by other scientific organisations are reflected upon by EFSA.

The use of state-of-the-art methods also requires new technologies to be carefully validated and, where considered to provide opportunities and benefits, implemented in EFSA's risk assessment practices. In these new areas of work, EFSA will need to work closely with the European Commission's scientific services (DG-RTD and the JRC), scientific organisations and experts to maintain its overview of scientific progress which may have an impact on EFSA's risk assessment. In addition, through its series of Scientific Colloquia EFSA will continue to have an open scientific debate prior to developing or finalising new methods and guidance.

In developing fundamental new methodologies, EFSA will continue to provide assistance and advice to risk managers so that these new methodologies and approaches are adequately reflected in legislation.

EFSA will work with key partners on initiatives for the harmonisation of existing and the development of new methodologies and approaches and will establish a multi-annual work plan on guideline review and development which takes into consideration work carried out elsewhere. It will take the lead, where appropriate, in the development, harmonisation or implementation of risk assessment approaches in new or existing scientific areas. In addition, EFSA will report on joint projects carried out with partners in the area of chemical risk assessment (e.g. the JRC, ECHA, WHO, US Environmental Protection Agency and OECD) – for example in developing a risk assessment framework for chemical mixtures and endocrine active substances during the period 2013-2016 – and microbiological risk assessment (e.g. ECDC, US Centers for Disease Control and Prevention, and US Department of Agriculture).

## 4. Strengthen the scientific basis for risk assessment and risk monitoring

EFSA's *Strategic Plan 2009–2013* identified the long-term need for EFSA to have access to high-quality scientific data to ensure that it is able to deliver scientifically robust assessments of risk and to identify emerging risks. For risk assessments concerning authorisations, EFSA most often receives comprehensive data and information from applicants or the mandator, but for many other assessments all the information has to be collected by EFSA. In the latter cases, EFSA collects, collates and assimilates existing data and scientific reports, before being able to conduct its risk assessment work or provide scientific assistance.

### Data collection

It is vital for EFSA to have or have access to the right data to address key issues at the right time. In order to obtain data of adequate quality it is essential that data collection is planned over the medium to longer term[21]. For this it is necessary to develop multi-annual work programmes focused on filling data gaps and setting priorities for data collections.

EFSA's data collection for human exposure assessment generally relies on monitoring and collection activities at MS level. Currently, EFSA's annual and ad hoc data collection activities have begun to provide much of the data for microbiological risk assessment and the exposure part of risk assessments. Regular review of these activities in terms of representativeness, accuracy and compatibility is required to sustain the quality of the data. Also, further optimisation and priority setting of the collection of these data will be required e.g. investigation and reporting of food-borne outbreaks and continued building of the harmonised food consumption database based on harmonised food consumption surveys conducted across the EU and consideration to initiatives such as food composition data, total diet studies, data linked to the health status of the European citizen over time, use of biomonitoring tools, and targeting vulnerable groups - such as children[22].

It is also important to identify where new frameworks for the harmonised collection of scientific data are needed. EFSA will aim to set priorities for the extension of the evidence base for risk assessment and risk monitoring in collaboration with internal and external experts, key partners and key organisations[23]. One example are databases for hazard characterization, to be built in cooperation with other agencies. Others concern post-marketing monitoring, including potential environmental effects.

EFSA needs to able to assess risks resulting from the increasing worldwide trade of foods and related commodities, travel, migration, climate change. For this it needs to further expand and develop data collections itself or by supporting other organisations through international scientific data collection networks as well as those at the European level. EFSA already cooperates with third country and international food safety bodies and this activity will continue to be important for EFSA to be able to develop clear insights in human, animal and plant health risks related to international trade in food of plant and animal origin as well as feed.

It will also develop further with partners formalised data generation, collection and collation methods and protocols, there is a need to strengthen data sharing and data access agreements with other key national, European and international organisations.

### Scientific literature

EFSA will ensure efficient access to and processing of information including those from literature and unpublished scientific studies. EFSA needs to boost its capacity and efficiency to support EFSA's Scientific Committee and Scientific Panels with comprehensive literature retrieval and systematic literature review. One element that needs further development concerns ensuring the establishment of a system to identify new data which could require re-consideration of existing opinions.

To enable EFSA's experts full to access relevant but not scientific information, Cooperation with the European and national food agencies, utilising to the full studies and risk assessment work carried out by other organisations will also be required. This requires that the IEP and other cooperation networks permitting information sourcing and sharing should be further extended to other national agencies. Eventually this concept needs to be expanded beyond Europe.

[21] EFSA (European Food Safety Authority) 2010. Technical Report of EFSA. EFSA Report on Data Collection: Future Directions. EFSA Journal 2010; 8(5):1533. [35 pp.].

[22] EFSA (European Food Safety Authority) 2011. Technical Report of EFSA. Activities, Processes and Quality Assurance Elements on Data Collection Programmes with Member States. Supporting Publications 2011:127. [57 pp.].

[23] EFSA (European Food Safety Authority) 2011. Technical Report of EFSA. Advisory Forum Discussion Group on Data Collection (to be published).

### Emerging issues

Although various activities have already taken place within EFSA to build its capability to identify and evaluate emerging risks, EFSA needs to strengthen this further. To this end, EFSA will develop a proactive, integrated and focused capability to identify and evaluate emerging issues. The priority activities of the Emerging Risk Unit (EMRISK) will be established following consultation with the Scientific Committee and Advisory Forum and in this manner its work programme in 2012-2016 will be developed. Greater scientific cooperation with European and international agencies and other organisations will be particularly useful in addressing the specific risks posed by increasing international trade and travel.

EFSA, with its Scientific Committee and Advisory Forum, also contributes to the development of research priorities at the European and international level. Detailed forward planning with public research organisations in Member States and with European Agencies, the European Commission's Directorate General on Research and Innovation (DG-RTD) and the Joint Research Centre of the European Commission (JRC) is important if information needs are to be filled. For this, EFSA will identify research priorities in EFSA's risk assessment areas in order to fill data gaps and work with key research partners to develop initiatives. This will be communicated through the submission of EFSA's annual and multi-annual research priorities to DG RTD and the JRC and the sharing of research priorities with other EU and Member State agencies for the identification of joint research needs.

## Conclusion

This ambitious strategy will ensure that EFSA can continue to support the European food safety system in the coming years. Even with the extensive streamlining of its activities, efficiency gains and redeployment of staff and resources that is already underway at EFSA, investments will be required in order to successfully implement the strategy. For example, investment will be required for the development of an electronic dossier submission platform, and for the building of databases. Training of external and internal scientific experts is also a necessity. The investment will reap dividends as these initiatives will ultimately result in greater efficiency and enable EFSA to continue to uphold its core values.

The initiatives proposed in this document will need prioritisation. Hence, progress in implementing the strategy will be assessed annually against EFSA's corporate key performance indicators and any remedial actions will be included in the multiannual work programme and annual management plans of the Authority. The strategy itself will also be reviewed at regular intervals to adjust the strategic direction in line with changes in the operating environment.

511 Annex 1: Overview of EFSA's scientific outputs

| | 2005 | 2006 | 2007 | 2008 | 2009 | 2010 | 2011* | Total |
|---|---|---|---|---|---|---|---|---|
| Activity 1. Provision of scientific opinions and advice & risk assessment approaches | | | | | | | | |
| Opinion of the Scientific Committee/Scientific Panel | 35 | 27 | 61 | 70 | 54 | 44 | 57 | 348 |
| Statement of the Scientific Committee/Scientific Panel | 5 | 6 | 2 | 3 | 9 | 8 | 1 | 34 |
| Guidance of the Scientific Committee/Scientific Panel | 0 | 1 | 2 | 1 | 5 | 2 | 5 | 16 |
| Statement of EFSA | 0 | 0 | 1 | 4 | 3 | 5 | 4 | 17 |
| Guidance of EFSA | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Scientific Report of EFSA | 11 | 1 | 0 | 2 | 4 | 4 | 6 | 28 |
| Total scientific outputs Act. 1 | 51 | 34 | 66 | 80 | 75 | 63 | 73 | 442 |
| Activity 2. Evaluation of products, substances and claims subject to authorisation | | | | | | | | |
| Opinion of the Scientific Committee/Scientific Panel | 121 | 97 | 137 | 180 | 354 | 241 | 328 | 1458 |
| Statement of the Scientific Committee/Scientific Panel | 0 | 3 | 2 | 4 | 37 | 6 | 4 | 56 |
| Guidance of the Scientific Committee/Scientific Panel | 0 | 3 | 1 | 15 | 3 | 3 | 15 | 40 |
| Statement of EFSA | 0 | 0 | 1 | 0 | 0 | 0 | 2 | 3 |
| Guidance of EFSA | 0 | 0 | 0 | 0 | 2 | 1 | 2 | 5 |
| Scientific Report of EFSA | 3 | 1 | 2 | 0 | 0 | 2 | 4 | 12 |
| Conclusion on Pesticides Peer Review | 20 | 30 | 20 | 62 | 30 | 69 | 70 | 301 |
| Total scientific outputs Act. 2 | 144 | 134 | 163 | 261 | 426 | 322 | 425 | 1875 |
| Activity 3. Data collection, scientific cooperation and networking | | | | | | | | |
| Guidance of EFSA | 0 | 0 | 0 | 0 | 1 | 2 | 4 | 7 |
| Reasoned Opinion | 0 | 0 | 3 | 20 | 75 | 68 | 175 | 341 |
| Statement of EFSA | 0 | 0 | 0 | 0 | 1 | 1 | | 2 |
| Scientific Report of EFSA | 0 | 1 | 6 | 10 | 16 | 15 | 18 | 66 |
| Total scientific outputs Act. 3 | 0 | 1 | 9 | 30 | 93 | 86 | 197 | 416 |
| TOTAL SCIENTIFIC OUTPUTS (Activities 1, 2 and 3) | 195 | 169 | 238 | 371 | 594 | 471 | 695 | 2733 |
| Supporting Publications | | | | | | | | |
| Event report | 1 | 2 | 3 | 4 | 4 | 5 | 9 | 28 |
| External Scientific Report | 0 | 0 | 1 | 2 | 39 | 37 | 42 | 121 |
| Technical report | 0 | 0 | 1 | 3 | 15 | 32 | 50 | 101 |
| Total supporting publications | 1 | 2 | 5 | 9 | 58 | 74 | 101 | 250 |

512
513 **Output targets 2011*
514

| Annex 2: Summary of the main fields of expertise and scientific activities carried out by EFSA | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | **EFSA's main areas of work** | | | | | | | | | | | |
| | | Animal health | Biological hazards/ zoonoses | Food/feed contaminants | Feed additives | Flavourings | Food additives | Food contact materials | Genetically modified organisms | Nutrition | Novel foods | Pesticides | Plant health |
| **Chemical risk assessment (including residues)** | **Hazard Identification & Characterisation**<br><br>Analytical chemistry<br><br>Chemistry<br><br>Mammalian toxicology<br><br>Toxicokinetics, ADME[a] | | | X | X | X | X | X | X | | X | X | |
| | **Exposure Assessment**<br><br>Food consumption and occurrence data<br><br>Statistics and mathematical modelling | | | X | X | X | X | X | X | | X | X | |
| | **Risk Characterisation** | | | X | X | X | X | X | X | | X | X | |

| | | EFSA's main areas of work | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Animal health and welfare | Biological hazards/ zoonoses | Food/feed contaminants | Feed additives | Flavourings | Food additives | Food contact materials | Genetically modified organisms | Nutrition | Novel foods | Pesticides | Plant health |
| **Microbiological risk assessment and animal welfare assessment** | **Hazard identification & characterisation** | X | X | | | | | | | | | | |
| | **Exposure assessment** | X | X | | | | | | | | | | |
| | **Risk characterisation** | X | X | | | | | | | | | | |
| **Environmental risk assessment** | **Environmental fate and behaviour** | X | | | X | | | | X | | | X | |
| | **Eco-biodiversity** | X[b] | | | X | | | | X | | | X | |
| **Import risk assessment** | | X | | | | | | | | | | x | |
| **Benefit /efficacy assessment** | **Human** | | X | | | | | | | X | | | |
| | **Animal** | | | | X | | | | | | | | |

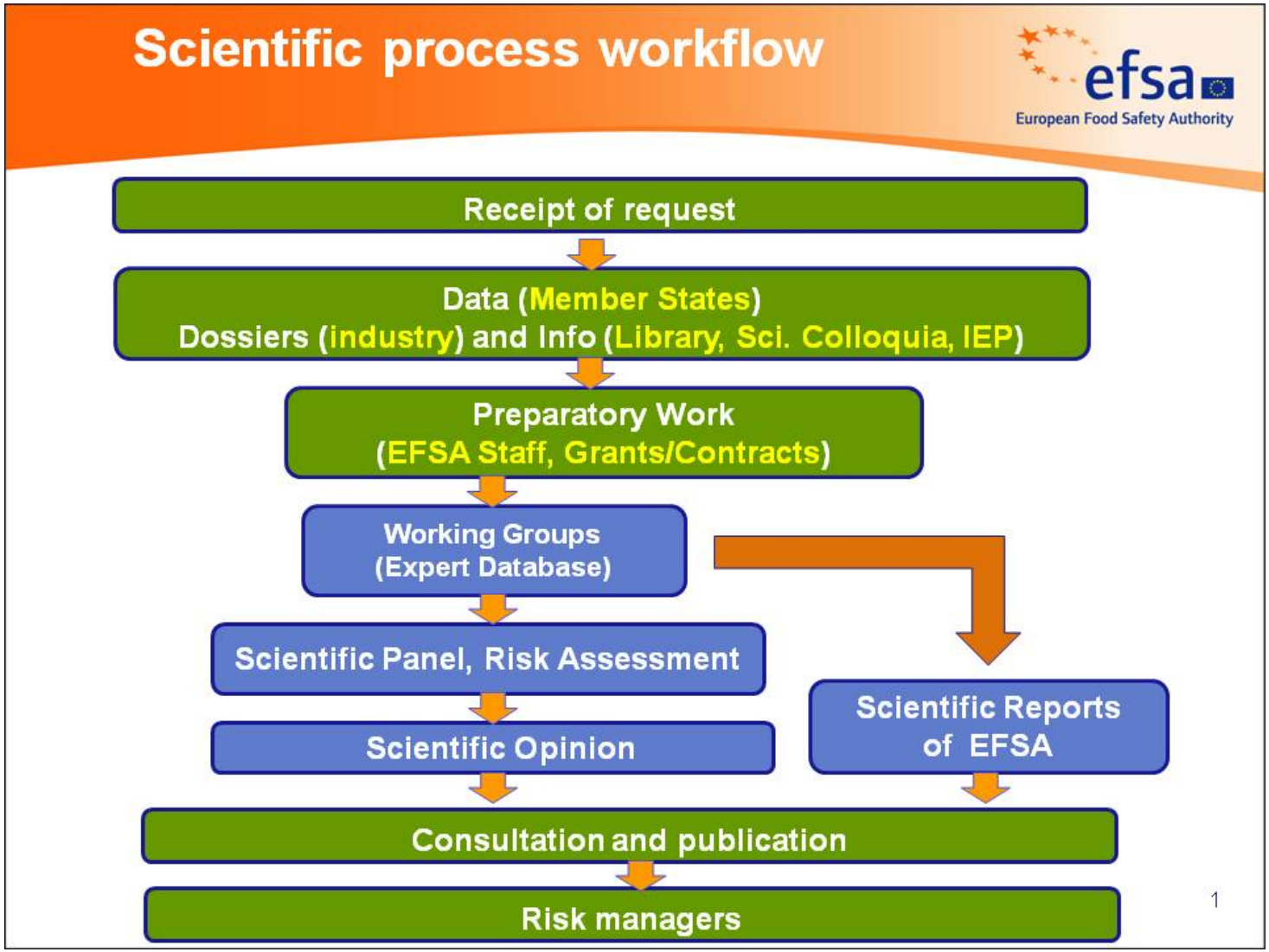
515

516 [a] ADME: administration, distribution, metabolism, excretion

517

518 [b] Wildlife component

519 Annex 3: Scientific process workflow
520




521

## Glossary of Terms

AF – Advisory Forum
CDC – US Centers for Disease Control and Prevention
EBA – European Budgetary Authority
ECDC – European Centre for Disease Prevention and Control
ECHA – European Chemical Agency
EC – European Commission
EMA – European Medicines Agency
EMRISK – Emerging Risks Unit
EP – European Parliament
EU – European Union
GD – Guidance Document
JRC – Joint Research Centre of the European Commission
MS – EU Member States
NGO – Non-Governmental Organisation
OECD – Organisation for Economic Cooperation and Development
USDA – United States Department of Agriculture
USEPA – United States Environmental Protection Agency
WHO – World Health Organisation