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European Food Safety Authority

SCIENCE STRATEGY AND COORDINATION

COVER NOTE

DRAFT SCIENCE STRATEGY 2012-2016

The document that is hereby submitted to the Management Board is a revised version of the document that was discussed at the meeting of 20 October 2011. It includes substantial redrafting to integrate input received from the Management Board itself but it also takes on board further comments from the Scientific Committee and from the public consultation that was carried out.

The document includes additional analysis and explanations in relation to comments made by the Management Board. These concern the proposed increase in the reliance on EFSA staff for scientific work, the plans to enhance capacity on data collection and to optimise scientific cooperation, the attempt to balance out public health issues and the evaluation of regulated products, the structure and functioning of the Scientific Committee.

The Scientific Committee also provided useful input with a number of suggestions concerning most notably the crucial need to clarify and further strengthen the role of the Scientific Committee and of EFSA as a whole in the development of risk assessment guidance.

The public consultation closed on 21 November 2011. EFSA received more than 60 comments from 13 organisations and individuals. There was no fundamental criticism of the document and according to the comments received the changes made focus mainly on adding further details and explanations on the basic scientific risk assessment work performed in the Member States, on reviewing and balancing priorities, on interplay with stakeholders, on interaction between EFSA and risk managers. Furthermore, additional explicit reference has been made to EFSA's Policy on Independence, to data collection from European research projects, and to cooperation on data collection with international and EU agencies.

The document has been shaped to be fully compatible with the overall strategic framework within which EFSA operates.

The Management Board is asked to review and adopt the document.

European Food Safety Authority

SCIENCE STRATEGY AND COORDINATION

DRAFT SCIENCE STRATEGY 2012-2016

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Executive Summary

Since its inception in 2002, EFSA's scientific advice has been central to European decision making on the protection of the 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 increased 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 strategy has been guided by and will complement EFSA's corporate *Strategic Plan 2009-2013.* It has been built through a process of extensive consultation, internally with EFSA's Scientific Committee, Advisory Forum, Management Board and staff and its various stakeholders.

It begins by stating its vision, 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.

Next the document lays out 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.

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

(i) further develop excellence of EFSA's scientific advice;
(ii) optimise the use of risk assessment capacity in the EU;
(iii) develop and harmonise methodologies and approaches to assess risks associated with the food chain;
(iv) strengthen the scientific basis for risk assessment and risk monitoring.

This ambitious strategy will ensure that EFSA can continue to support the European food safety system in the coming years through the up-to-date science-based risk assessments. In so doing it contributes to improving the health and welfare of humans and animals as well as plant health. Through its contribution, EFSA fulfils not only its mission to protect consumers but also provides food operators a regulatory environment which is not only demanding but also predictable. This fosters technological innovation, thereby supporting sustainable growth.

To practically support the implementation of these objectives, a number of key initiatives are proposed one of which is to enhance the contribution of EFSA staff to support the scientific work of the EFSA Scientific Committee and Scientific Panels.

The strategy 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 Europe with the best scientific advice that enables timely decision-making to protect consumers from food-related risks and support healthy dietary choices

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. The present document concerns the core task of delivering scientific advice whereas the communication of this advice is addressed in EFSA's *Communications Strategy 2010-2013*[3].

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[4]. The issues raised in these discussions have been incorporated into the development of the strategy.

Where is EFSA Today?

Upon its creation, 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 the 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 internal scientific support, and in particular built data and information collection and analysis capabilities.

To ensure the high quality of its work, EFSA has developed guidance on methodologies for the risk assessment and the risk monitoring it undertakes. As laid down in its Founding Regulation, EFSA can initiate its own work (self-mandate). 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 and 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. nanotechnology). Other areas have been principally developed by its Scientific Panels e.g. efficacy evaluation, environmental modelling and safety assessment, statistical approaches, exposure assessment methods, microbiological safety assessment, antimicrobial resistance, etc.

EFSA has begun to put in place a quality assurance system. It has established procedures for handling requests for urgent advice, initiated training on these and successfully used them on a number of occasions (e.g. melamine,

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

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

dioxins, and the STEC (Shiga toxin-producing Escherichia coli) outbreaks) and has started developing processes to identify emerging risks, as foreseen in the Founding Regulation.

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.

The strategic relationship of EFSA with the national food safety organisations is explicitly recognised in its Founding Regulation. Through the Advisory Forum, EFSA has established the foundation for its cooperation activities with the national food safety risk assessment and food research organisations throughout Europe. EFSA has set up Focal Points in the Member States and built nine European scientific networks (Annex 3) with its competent organisations thereby e.g. facilitating the exchange of risk assessment work. These have the objective of facilitating scientific cooperation. EFSA has established an Information Exchange Platform (IEP)[5] 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[6]. More recently, EFSA has developed cooperation with other European Union (EU) organisations, organisations in third countries and international organisations with mandates similar to EFSA's[7] EFSA has built dialogue with its stakeholders and holds public consultations on key scientific opinions.

Since 2002 much has been achieved. EFSA has published over 2,500 scientific outputs which have been used by the European Commission, Member States and the European Parliament to underpin measures taken to protect consumers. These have had a significant impact both for regulated products which are subject to pre-market authorisation and for general public health issues like zoonoses or contaminants.

Drivers for Progress and Change

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

EFSA's *Strategic Plan 2009 – 2013*[8] 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 climate change, and the changing demographics of the European population. Also, 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[9], leading to an increased number of requests for scientific advice to be delivered by EFSA.

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[10]. They have also highlighted the need to ensure food security both within Europe and internationally[11], the need for environmental, social and economic sustainability, and the specific needs of the aging population[12].

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

[6] 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.].

[7] EFSA's Strategic approach to international initiatives: http://www.efsa.europa.eu/en/keydocs/docs/intstrategy.pdf

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

[9] 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.

[10] 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.

[11] 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.

[12] 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.

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). 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. 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. This is because the nature of the work at hand may vary considerable depending e.g. on the extend to which new information needs to be gathered. It is reflective though of the growing importance of the evaluation of regulated products such as genetically modified organisms, pesticides, food and feed additives, food flavourings, colours and contact materials as well as for the evaluation of health claims.

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 (applications) has increased, the workload in the area of public health risks has also expanded due to major mandates such as the current one on meat inspection methods which covers microbiological and chemical food safety as well as animal health and welfare aspects for various 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. 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. The agri-food sector is increasingly innovative in the way it uses novel technologies, 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 is expected to remain around existing levels. However, as provided for in the Founding Regulation, the possible introduction of fees for the regulatory reviews EFSA carries out is currently under consideration by the European Commission. Even though it is therefore possible that EFSA would 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 excellence of EFSA's scientific advice
2. Optimise the use of risk assessment capacity in the EU
3. Develop and harmonise methodologies and approaches to assess risks associated with the food chain
4. Strengthen the scientific evidence for risk assessment and risk monitoring

1. Further develop excellence of EFSA's scientific advice

Scientific excellence and the other core values

It is of utmost importance that the European consumer and other stakeholders 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. EFSA aims to forge a reputation for the quality of its scientific advice which is recognised worldwide. Recognising that quality is inherent in our core values EFSA has decided to implement an integrated Quality Management system by 2016. This system will build on the foundations established in follow-up of the Scientific Committee recommendations[13,14] and will be fully compatible with the ISO 9001:2008 system.

Each of EFSA's core values is important in its own right and it is essential that the right balance be struck between these potentially "competing" core values.

Scientific excellence. While EFSA aims to provide high-quality scientific advice, it is however not a research organisation. Rather it draws on work carried out in such organisations and shares their standards for scientific excellence. The basis for the excellence of EFSA's scientific advice lies in the quality of its experts, the information and the methods available to address a given topic. These elements are further discussed in Objectives 2-4 below. Scientific excellence is not an absolute concept but rather excellence also 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.

For EFSA to be relevant it is essential that it be **responsive** and uses its resources judiciously. 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. To increase efficiency, it will therefore be important to continue to work with risk managers to ensure that questions and responses are framed in a manner that enables EFSA to optimise its risk assessment resources.

In relation to **independence**, 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. In new fields where expertise may be scarce and mostly in the hands of the organisations that have a commercial interest in developing the new technology and expertise which is viewed to be independent of these interests may not be readily available. At the same time in order not hinder technological innovation it is crucial that EFSA has appropriate access to the necessary expertise to avoid lagging behind in its scientific excellence. EFSA is currently updating its policy on independence[15] and will continue to update and communicate its systems and procedures for ensuring the independence of its work.

[13] 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.].

[14] 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.].

[15] http://www.efsa.europa.eu/en/consultationsclosed/call/110707b.htm

Transparency. Through open and transparent ways of working, EFSA will continue to ensure that its processes and the basis for its opinions are documented and understood. 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, the weight of evidence, data gaps, the underlying uncertainties and their potential impact on the decisions to be made.

Openness and dialogue. Further progress on the interaction between EFSA and risk managers will improve common understanding of risk assessment parameters (including benefits and limitations) and risk management goals, thereby contributing to more informed decision making.

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 risk perceptions and information needs and preferences, particularly related to new or complex scientific issues. For this, EFSA aims to strengthen the dialogue with all stakeholders on processes and adherence to core values. In doing so we will strengthen engagement and consultation between risk assessors and stakeholders. EFSA will also continue to perform public consultations on scientific opinions, particularly when preparing guidance documents, and by doing so collect views from various stakeholders, risk managers and risk assessors, including the global scientific community.

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 membership renewal, to ensure all areas of expertise that are normally needed are covered. For example, a new technology which is originally 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. This may also require inclusion of other European agencies e.g. the 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, 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.

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 as well as 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 additional scientific experts who do not belong to any Scientific Panel. This contrasts with the Scientific Panels which are composed of (up to) 21 scientific experts. Due to their particular responsibilities, the Chairs already have a high workload. Therefore, with the current number of non-Panel experts being limited to six only, 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 needs to allow it to fully execute its mandate to ensure the consistency of all the main aspects of EFSA's scientific 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. This

includes the systematic review for consistency of guidance developed by a particular Scientific Panel. To support the Scientific Committee and foster consistency across Scientific Panels in these areas, EFSA has already created task forces of EFSA staff and, most often, with Panel members. This has been the case for example with environmental risk assessment methods, antimicrobial resistance and statistical methods. Other means to reinforce the Scientific Committee may need to be explored.

Scientific outputs

EFSA scientific outputs are published in the EFSA Journal on a dedicated web area of the EFSA corporate website to disseminate them among the scientific community. The EFSA Journal is an open-access online scientific journal, which is free of charge. It has an editor-in-chief and is governed by an editorial board. The EFSA Journal is already indexed in various bibliographic databases relevant to EFSA's work such as Food Science and Technology Abstracts (FSTA), CAB Abstracts, SciFinder, ISI Web of Knowledge and library catalogues. It needs to be further developed to meet requirements of other key databases such as Web of Science (Thomson Reuters) and Medline. Over time this will provide tools to compare EFSA's scientific excellence through e.g. impact indicators.

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.

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. 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, 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*[16].

2. Optimise the use of risk assessment capacity in 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 scientific staff as well as the scientists in Member State institutions working with EFSA in cooperation activities through e.g. its networks as well as other forms of cooperation through grants and contracts. For EFSA to further increase its scientific output efficiently, while tackling the complexity of the scientific tasks at hand, it has to consider the planning and prioritisation of its work and, in light of these, how to optimise the input and engagement of these various sources of expertise.

Planning and priority setting

So that all areas of EFSA's remit are addressed adequately, reviewing and balancing priorities has to be done in a structured and transparent manner taking into consideration needs for review of regulated products, other health priorities and emerging issues by developing a prioritisation framework. Using risk monitoring and risk ranking studies[17], EFSA can assist risk managers, consumers and other stakeholders 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 emerging issues, including new technologies, which may have an impact on the safety of the European food supply. 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 further develop a proactive, integrated and focused capability to identify and evaluate emerging issues. Greater scientific

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

[17] 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).

cooperation with national, European, international agencies, and key third countries will be particularly useful in addressing the specific risks posed by increasing international trade and travel.

EFSA has striven to predict, prioritise and plan all its scientific activities efficiently over the short and medium terms in collaboration with its key risk assessment and risk management partners. 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 ever more vital to enable EFSA to identify whether it has appropriate resources and specific expertise available and plan priorities appropriately. While EFSA receives requests from the European Commission, Member States and the European Parliament, overall it is the European 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 these demands.

Scientific experts in Scientific Panels/Scientific Committee and internal scientific expertise

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. EFSA relies on them and their employers to engage in these activities at European level.

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. 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.

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. It is essential that EFSA is able to continue to attract the best external experts available, by using this key resource judiciously.

As mentioned, the number of Scientific Panels has been increased from eight to ten. The number of Scientific Panels could conceivably be further increased where new areas of work emerge that are not already covered by a Scientific Panel. However, further increase in the number of Scientific Panels increases the need for coordination so as to maintain consistency in areas covered by several Scientific Panels.

A reduction of external experts' workload related to routine activities may be an effective way to increase EFSA's attractiveness to them. Hence, meeting the growing number of requests for advice will require EFSA to focus on further building as well as better utilising the internal scientific expertise among EFSA's scientific staff. This may be particularly true for work that is repetitive but can be standardised, such as well-established regulatory review processes which require substantial preparatory work. 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 will not only help EFSA to maintain its attractiveness to high-level external scientific experts but, at the same time, enable EFSA's in-house scientific staff to utilise to the full the breadth of their 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 internal support in dossier evaluations and in the preparation of draft outputs. Through the 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.

There will however be a need for enhanced developmental training on risk assessment for EFSA's staff, along with external experts, 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 and scientific staff by putting in place professional development initiatives and increasing scientific training. Specifically, EFSA will 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, is expected to have a leading role.

Cooperation with organisations in Member States

With the resource limitations that are anticipated, it is essential that duplication of work be avoided. Coordination 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.

Through the implementation of the EFSA *Strategy on Cooperation and Networking with Member States*[18], grants and contracts have been put in place with scientific organisations in the Member States since 2007. EFSA 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. This activity will need to rely heavily on medium- and longer-term planning to support the needs of EFSA's risk assessment work[19,20]. Increasing the involvement of MS' scientific organisations will contribute to maintain and build their capacity. However, building capacity for the future will require such initiatives as training and developing expertise directly linked to the risk assessment process. EFSA has already investigated how training programmes could be organised within the context of the EU[21,22].

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

Cooperation with EU agencies, international organisations and organisations in third countries

While maintaining its cooperation with national organisations through its EU networks, EFSA also needs to cooperate with other European scientific organisations, international organisations and agencies in non-EU countries on topics of common interest in order to share the workload, avoid unnecessary duplication of work and inconsistencies. This activity would benefit from a more structured medium-term approach through the development of cooperation with European agencies (ECDC, ECHA, EMA) and international liaison groups in the area of food chemical and food microbiological safety, with a view to optimising the utilisation of resources. EFSA will in particular work with key partners on initiatives for the harmonisation of existing and the development of new methodologies (see next section). It will take the lead, where appropriate, in the development, harmonisation or implementation of risk assessment approaches. In addition, EFSA may engage in joint projects carried out with partners in the area of chemical risk assessment (e.g. the Joint Research Centre (JRC), ECHA, World Health Organisation (WHO), US Environmental Protection Agency (USEPA), US Food and Drug Administration and the Organisation for Economic Cooperation and Development (OECD) – for example in developing a risk assessment framework for chemical mixtures and endocrine active substances and microbiological risk assessment (e.g. ECDC, US Center for Disease Control and Prevention (CDC), and US Department of Agriculture (USDA)).

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

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

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

[21] 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.].

[22] 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.

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

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.

EFSA will also strengthen the dissemination of cross-cutting guidance through training programmes for EFSA scientific experts and staff to ensure the uptake of guidance on cross-cutting risk assessment approaches.

Also the diversity and number of regulatory processes for the assessment of regulated products may need further consideration. While differences in legislation may be necessary, 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. In this regard, EFSA can contribute by identifying opportunities for harmonisation of methodologies across regulated areas within EFSA and possibly beyond (EMA, ECHA) and share its view at the occasion of legislation under preparation or revision regarding, its potential impact on efficiency and effectiveness of regulatory review processes.

New risk assessment methodologies

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.

This includes a broadening of the scientific discourse beyond safety and into areas such as health benefits and environmental risk assessment. In addition, there is a need to gradually move from an approach whereby a single chemical is assessed individually using a set of standard protocols (involving the use and sacrifice of numerous laboratory animals) for a particular use to a system which takes into account prior information, other routes of exposure, and the potential impact of other effectors. Taking, into account available information about related chemicals, may lead to tiered approaches for testing, targeted testing protocols thereby increasing the efficiency and effectiveness of safety evaluations. These concepts are further discussed in the Scientific Committee Scientific Opinion on the Threshold of Toxicological Concern[23]. As mentioned in this opinion, the use of pragmatic, science-based approaches in EFSA has already begun. In the area of risk assessment of micro-organisms, the Scientific Committee adopted an opinion on the use of the Qualified Presumption of Safety (QPS) approach for setting priorities within the risk assessment of microorganisms used in food/feed production referred to EFSA (EFSA, 2007)[24]. This practical risk assessment approach meets the need of EFSA to assess the safety of large numbers of micro-organisms deliberately added to food and feed within an acceptable time frame.

The potential simultaneous exposure to a multitude of hazards (chemicals, micro-organisms and other effectors) possibly through different routes also highlight the necessity to move beyond the single hazard approach and consider e.g. exposure to chemical mixtures. The EFSA Scientific Panel on Plant Protection Products and their Residues (PPR) has already elaborated a framework for the human risk assessment of mixtures of pesticides and applied it to triazole pesticides. Other Scientific Panels have also dealt with the risk assessment of chemical mixtures, but in these situations specific approaches were developed rather than a general framework. Other bodies, such as the US-EPA and WHO, have also developed frameworks for mixture toxicity assessment. EFSA is currently carrying out a critical review of such frameworks[25]. It will serve to support the further development of a harmonised and consistent approach for the human health risk assessment of chemical mixtures in food and feed.

[23] http://www.efsa.europa.eu/en/consultationsclosed/call/110712a.htm

[24] http://www.efsa.europa.eu/en/efsajournal/pub/587.htm

[25] Internal Mandate proposed by EFSA to the EMRISK Unit for a Scientific report on international frameworks dealing with the human risk assessment of chemical mixtures

In addition, the emergence of new technologies (nanotechnologies, new breeding techniques) may require existing risk assessment methods to be revised. In these new areas of work, EFSA will need to work closely with the European Commission's scientific services (DG-RTD and the JRC) and other scientific organisations and experts to maintain its overview of scientific progress which may have an impact on EFSA's risk assessment methods. 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 light of the above and following consultation with key partners, EFSA will establish a multi-annual work plan on guideline review and development which takes into consideration work carried out elsewhere. In developing new methodologies, EFSA will continue to closely liaise with and provide assistance and advice to risk managers so that these new methodologies and approaches are adequately reflected in legislation.

Harmonisation of approaches on regulated substances

To improve the clarity and efficiency of the evaluation of regulated substances, current processes may need to be streamlined where appropriate. For example, existing mechanisms for dialogue with applicants concerning issues related to the application assessment process will need to be reviewed. To implement this EFSA has now created and is gradually building of an applications help desk function for applicant companies (as well as any other stakeholders) regarding the assessment of regulated products.

4. Strengthen the scientific evidence 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 issues.

Regulatory reviews

For risk assessments concerning authorisations, EFSA most often receives comprehensive data and information from applicants (individually or as a consortium) or the mandatory. . The information to be provided by applicants is described in guidance documents and test protocols, including quality standards that need to be adhered to. This is not to say that other available scientific information will not be considered. For example, EFSA's new guidance document for applicants seeking approval of active substances in pesticides explicitly requires that studies found in peer-reviewed open scientific literature should be considered. The fact that particular standards such as for Good Laboratory Practices need to be adhered for industry-sponsored studies should therefore not be equated to a refusal to consider evidence that would have come from non-GLP studies.

Data collection

For the other assessments all the information has to generally be collected by EFSA itself, prior to being able to conduct the risk assessment. EFSA does not generate these data itself but rather relies on other organisations that generate this information.

It is vital for EFSA to possess 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[26]. 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 activities at MS level. The exposure assessment work uses on the one hand microbiological or chemical occurrence data and on the other hand food consumption information. EFSA has launched a key project on harmonised food consumption data collection (EUMENU)[27,28] which aims to support harmonised food consumption data collection across the EU. EFSA's current annual and ad hoc occurrence data collection activities have begun to provide much of the data for its microbiological and chemical risk assessment and risk monitoring activities. As is already the case for pesticide

[26] 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.].

[27] http://www.efsa.europa.eu/en/press/news/datex100212.htm

[28] http://www.efsa.europa.eu/en/efsajournal/pub/1435.htm?wtrl=01

residues, it is envisaged that annual risk monitoring reporting will not only concern occurrence but also include exposure assessments.

Whereas the focus in the occurrence monitoring has been initially on microbiological and chemical contaminants, it is broadening into monitoring of chemicals which are subject to a marketing authorisation, such as plant protection products or food additives. This permits to assess whether the exposure envisaged at the time of marketing authorisation matches with the true exposure, when marketed (Annex 4).

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. broadening of the investigation and reporting of food-borne adverse effects beyond microbiological hazards and into chemicals – including e.g. allergies, 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 bio-monitoring tools, and targeting subpopulations potentially more highly exposed - such as children[29] or groups that are more susceptible. Others concern the monitoring of any impact (including potential environmental effects) of compounds subject to pre-marketing authorisation.

It is also important to identify where new areas 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 key partners and key organisations[30].

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 may need to further expand and develop data collections itself or support other organisations, including international organisations such as e.g. European and Mediterranean Plant Protection Organization (EPPO) or World Organisation for Animal Health (OIE), 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.

As 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 agencies (e.g. ECDC, EFSA, EMA) and international organizations (e.g. FAO, WHO, OECD).

Scientific literature and reports

EFSA will ensure efficient access to and processing of information from scientific literature and unpublished scientific studies. For this EFSA needs to further boost its capacity and efficiency to support EFSA's Scientific Committee and Scientific Panels to monitor and screen new scientific information and provide systematic literature review.

One element that needs further development concerns the establishment of a system to regularly identify and take stock of new information and identify new data which could require re-consideration of existing opinions. To be efficient and effective, the stock-taking of new evidence is a process which EFSA, in close liaison with the risk managers, plans to carry out in a structured, rather than ad hoc, manner.

To take into account the full breadth of risk assessments EFSA has taken the initiative to develop a database for hazard characterization, to be built in liaison with other agencies.

Access to studies and risk assessment work carried out by other organisations carrying out work in EFSA's remit, is also needed. This also requires that the IEP and cooperation networks permitting information sourcing and sharing be further expanded e.g. international organisations such as WHO.

[29] 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.].

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

Research

Completed research projects are obviously an important source of data and information to which EFSA needs access.

Future data needs may also necessitate the conduct of new research. EFSA, with its Scientific Committee and Advisory Forum, already contributes to the development of research priorities at the European 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 indeed important if information needs are to be filled. For this, EFSA will continue to 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 as well as international agencies and partners in third countries for the identification of joint research needs.

Conclusion

The trust that European consumers and stakeholders have in the quality of its scientific work – and thus the scientific basis for European risk management measures – is key for EFSA's authority. It reflects the degree to which EFSA will have managed to successfully implement its core values.

This ambitious strategy will ensure that EFSA can continue to support the European food safety system in the coming years through the up-to-date science-based risk assessments. In so doing it contributes to improving the health and welfare of humans and animals as well as plant health. Through its contribution, EFSA fulfils not only its mission to protect consumers but also provides food operators a regulatory environment which is both demanding and predictable. This fosters technological innovation, thereby supporting sustainable growth and development.

The various initiatives proposed in this document will need prioritisation. 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, a key objective is also to streamline and simplify the process for regulatory submission and review through initiatives such as electronic submission and other IT- supported initiatives. The development of such an electronic dossier submission platform as well as the further building of for risk monitoring programmes are resource-intensive. As these activities are in large part related to regulatory review and post-authorisation monitoring of regulated products, the use of potentially available fees to fund these activities may impact the feasibility of these projects. Training of external and internal scientific experts is also a necessity. These investments will reap dividends as they will ultimately result in greater efficiency and enable EFSA to continue to uphold its core values.

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.

Submitted for adoption in Warsaw, Poland
on 15 December 2011

For the EFSA Management Board

Prof. Diána Bánáti
Chair of the Management Board

568 # 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**

569 **Output targets 2011-11-28*
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	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**			X	X	X	X	X	X	X	
	Exposure Assessment			X	X	X	X	X	X	X	
	Risk Characterisation			X	X	X	X	X	X	X	
Microbiological risk assessment and animal welfare assessment	**Hazard identification & characterisation**	X	X		X		X				X
	Exposure assessment	X	X		X		X				X
	Risk characterisation	X	X		X		X				X
Environmental risk assessment	**Environmental fate and behaviour**	X			X		X			X	
	Eco-biodiversity	X			X		X				X
Import risk assessment		X									x
Benefit /efficacy assessment	**Human**		X					X		X	
	Animal				X						

572 * The Scientific Committee is not listed explicitly as its role is overarching

573 Annex 3: Scientific process workflow
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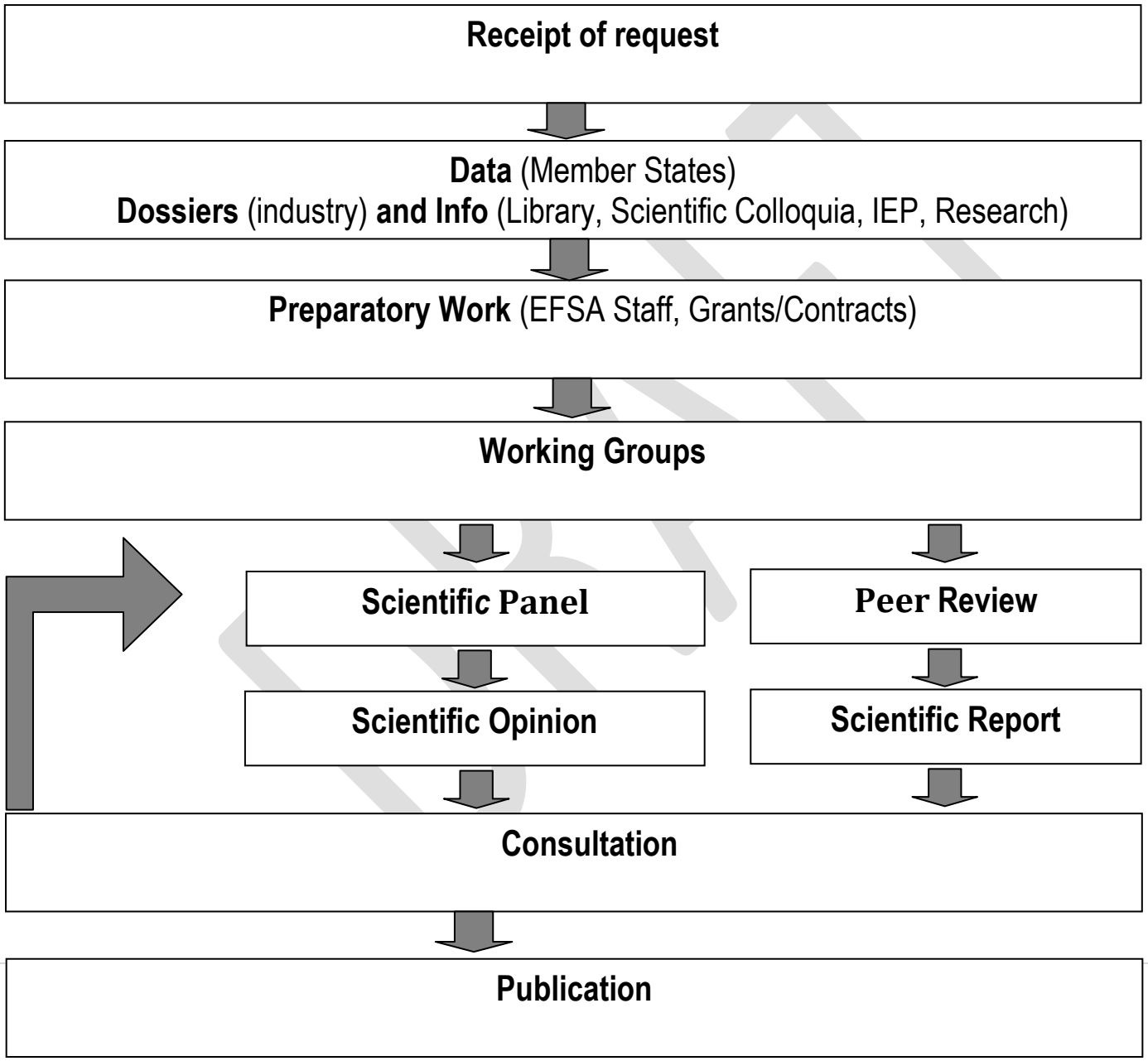

575 **Annex 4: Monitoring of risks and Exposure Compliance**

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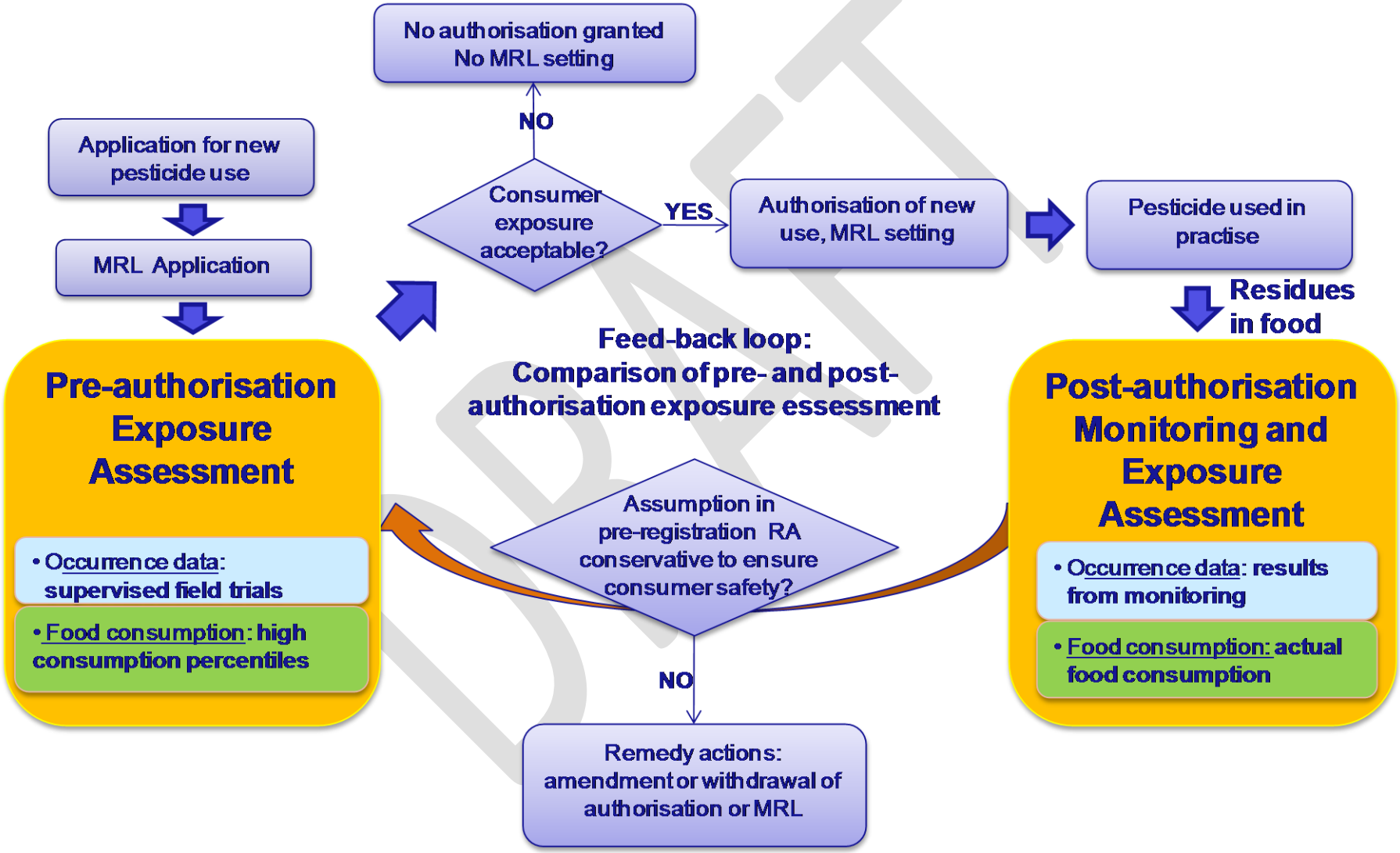

Glossary of Terms

CDC – US Center for Disease Control and Prevention
EBA – European Budgetary Authority
ECDC – European Centre for Disease Prevention and Control
ECHA – European Chemical Agency
EMA – European Medicines Agency
EPPO – European and Mediterranean Plant Protection Organization
EU – European Union
IEP – Information Exchange Platform
JRC – Joint Research Centre of the European Commission
MS – EU Member States
NGO – Non-Governmental Organisation
OECD – Organisation for Economic Cooperation and Development
OIE – World Organisation for Animal Health
Risk monitoring – surveys conducted to measure, for example, the occurrence and concentrations of chemicals and micro-organisms in food
USDA – United States Department of Agriculture
USEPA – United States Environmental Protection Agency
WHO – World Health Organisation