European Food Safety Authority

Management Board
17 March 2011
Parma

Subject :	Draft Preliminary Management Plan 2012	
Document number:	mb 17 03 11 - item 5 doc 4	
Submitted by :	Office of the Executive Director and the Management Board	
Document for :		Information
		Discussion
	X	Possible adoption

European Food Safety Authority

DRAFT PRELIMINARY MANAGEMENT PLAN OF THE EUROPEAN FOOD SAFETY AUTHORITY FOR 2012

Document providing the predicted work of the Authority during 2012

Submitted for adoption in Parma, Italy
on March 17, 2011

Prof. Diána Bánáti
Chair

European Food Safety Authority - Largo N. Palli 5/a, I - 43121 Parma
Tel: (+39) 0521 036 200 • Fax: (+39) 0521 036 0200 • info@efsa.europa.eu • www.efsa.europa.eu

TABLE OF CONTENTS

1. EXECUTIVE SUMMARY

2012 will mark the tenth anniversary of EFSA's establishment and its activities will reflect the evolution of the organisation from a start-up situation focused on establishing the structures and systems to deliver its core mandate – risk assessment and risk communication – to a well-established organisation that aims to consolidate its achievements and implement best management practices. Efficiency will continue to be a major priority and the e^3 programme that started in 2010 will continue with the objective of optimising performance and preparing for future challenges. Those challenges may include changes in the Founding Regulation as a result of the external evaluation carried out in 2011, evolution of the working practices of the Scientific Panels, and the possible introduction of fees. Fees will be an important consideration in light of the ongoing preparation for the next Financial Framework for 2014-2020 for the Union. The outcomes of the external evaluation will be available before the end of 2011 and they will be instrumental in defining the added value of the organisation and aligning its objectives with the expectations of its stakeholders and partners. The recommendations of the evaluation will be adopted by EFSA's Management Board and implemented by the EFSA Executive in 2012. In addition, the results of the first phase of the impact assessment exercise completed in 2011 will be known and will also provide insight into the future priorities of the organisation.

From the perspective of the scientific work programme, evaluations of regulated products and claims will continue to be a prominent feature while the resources to deal with the more generic public health priorities (biological and chemical contaminants and nutrition) will be ring-fenced. The work programme associated with applications in the areas of food and feed additives, novel foods and botanicals will continue and will benefit from the resources allocated to increased dialogue with applicants. To this end, the series of technical meetings, workshops and consultations will continue to ensure that the opinions of EFSA embrace the full spectrum of scientific knowledge and schools of thought. The Science Strategy, adopted in 2011, will guide this process and its implementation will begin in 2012. Among the key issues which both the strategy and the external evaluation will address will be the role of the Scientific Panel system and in particular the distribution of tasks between external experts and internal staff. The use of tele-meetings will continue to be promoted and it is expected that 20% of all "expert days" will be achieved via this mechanism. Eight of EFSA's Scientific Panels and its Scientific Committee will be renewed in 2012; this represents a significant challenge to the organisation to ensure that it has the scientific expertise it needs to meet its future requirements while at the same time ensuring that the expertise is used optimally. The independence of its scientific advice will continue to be a key priority for the organisation and EFSA will begin to implement its Policy on Independence that was adopted in 2011.

Cooperation with Member States is a key tool in enabling EFSA to execute its work programme, share workloads and build a sense of joint ownership of EFSA's work. With the ongoing economic difficulties expected to continue to limit budgets at both the national and EU levels, synergistic working with the Member State authorities is vital in ensuring that resources are used efficiently and that pan-European risk assessment capacity is strengthened. The contracts and grants distributed to Member State organisations under EFSA's procurement and Article 36 programme are crucial in achieving these objectives and €11.3 million will be allocated to these activities in 2012. Improved medium-term planning has been recognised as a key tool in facilitating the involvement of national food safety agencies in EFSA's work programme and it will continue to be enhanced in cooperation with the Advisory Forum to ensure that Member States can identify opportunities for cooperation as early as possible. Execution of the contracts and grants programme has been identified as an area for improvement in 2011 and it will continue to be prioritised to ensure that its budget is fully utilised and to best effect. The EFSA networks have become an important mechanism for engaging Member State expertise and their activities will continue to be strengthened during the year.

Dialogue and consultation are central to the success of EFSA and the Authority will continue to build its programmes of engaging a wide range of stakeholders and partners in its work. The strengthening of the activities of the Stakeholder Consultative Platform – one of the mechanisms by which EFSA engages interested parties in its work – will continue in order to better anticipate and plan workloads. The structures put in place to enhance dialogue with applicants (applications desk, additional human resource etc) will be fully operational and IT governance and strategic planning will be strengthened. As EFSA adopts a more corporate risk-aware culture, the repositioned regulatory affairs unit will concentrate on the anticipation of risk in relation to any legal challenges to EFSA's science.

The tenth anniversary of the organisation presents a timely opportunity to communicate the role and real contribution that EFSA makes to the European food safety system. An international risk assessment/risk communication event is planned as one of the key events to mark the occasion. In relation to risk communication, focus will be on EFSA's core remit of

communicating EFSA's science to its target audiences clearly and consistently in cooperation with risk communicators in the Member States. In early 2012, EFSA will complete its move to its new Seat building and one of the key practical issues for 2012 is to ensure no loss of business continuity during the transition period.

2. VISION AND MISSION

2.1 Vision

EFSA's goal is to be globally recognised by 2013 as the European reference body for risk assessment on food and feed safety, animal health and welfare, nutrition, plant protection and plant health. Its ultimate objective is to protect public health and strengthen consumer confidence in the European food supply. It aims to be an independent, responsive and trusted partner for risk managers and proactive in contributing to the high level of consumer protection chosen by the European Union.

2.2 Mission

EFSA provides transparent and independent scientific advice to underpin the policies and decisions of risk managers in the European Commission, European Parliament and Member States. It also provides effective and timely communication on all risks associated with the food and feed chain to a wide audience, including the public and all interested parties, and promotes coherence in risk communication in cooperation with the Commission and Member States. The Authority is committed to the core values of scientific excellence, independence, openness, transparency and responsiveness.

3. ACTIVITY 1: PROVISION OF SCIENTIFIC OPINIONS AND ADVICE AND RISK ASSESSMENT APPROACHES

3.1 Overview

In 2012, the changes in organisational structure introduced in 2011 will be fully implemented and the reorganisation and repositioning of the Science Directorates will facilitate the efficient delivery of the work programme related to the core public health risk assessments. Renewal of the eight Scientific Panels and Scientific Committee in 2012 will represent a significant challenge and workload, and the outcome of the external evaluation will provide insight into the future of the panel system and the use of internal and external scientific expertise. EFSA will continue to deliver integrated scientific advice using the entirety of expertise available in its Scientific Committee Scientific Panels, and their working groups. Dialogue and consultation will be prominent features of the work programme as EFSA seeks to ensure that its advice is based on the broadest scientific base and is as relevant as possible to the needs of risk managers. In relation to the risk assessment programme, particular features will include the provision of animal welfare indicators. The European Commission has called for measurable animal welfare indicators to be developed to reinforce the scientific basis of EU regulation in this field. EFSA is developing a set of scientifically measurable animal welfare indicators to be included in its future conclusions and recommendations. The AHAW Panel is co-operating with scientific institutes in the Member States mandated to support EFSA on this major task. These welfare indicators will support decision-making on the acceptable conditions for farmed animals and will be used to underpin monitoring and control programmes, implemented at farm level, to guarantee standards of animal health and welfare and to help control diseases.

Meat inspection will also be an important feature of EFSA's risk assessment programme in 2012. In May 2010 the European Commission requested EFSA's assistance in providing the scientific basis for the modernisation of meat inspection in the EU. EFSA is charged, together with the European Centre for Disease Prevention and Control (ECDC), with helping to introduce a risk-based approach to meat inspection, at all relevant stages of the meat production chain. To fulfil this complex mandate, EFSA is drawing on its expertise in a wide range fields within its scientific remit: animal health and welfare, chemical contaminants in the food chain, biological health hazards including zoonoses (animal diseases transmissible to humans), risk assessment methodologies and data collection. Other highlights will include the delivery of opinions on dietary reference values for micronutrients by the NDA Panel – a key part of establishing food-based dietary guidelines in the Member States, risk assessments of mycotoxins by the CONTAM Panel, and the work on EU-wide plant risk assessments (PRAs) and the evaluation of PRAs by Members States and third countries by the PLH Panel. The appointment of a Science Strategy director will be important in horizon scanning in the area of food safety and preparing EFSA to meet future challenges. The Scientific Committee's work will focus on horizontal issues and risk assessment approaches in the following areas: statistical approaches, botanicals, risk assessment terminology, default values, nanotechnology, thresholds of toxicological concern, 90-day feeding trials, and establishing a compendium of botanicals.

3.2 Activity 1 at a glance[1]

Key deliverables in 2012	72 Scientific outputs Renewal of 8 Scientific Panels & Scientific Committee
Total budget allocation 2012 (€ m)	11.29
Number of staff 2012 (FTE)	99

3.3 Combined key performance indicators for EFSA scientific activities (Activities 1, 2, 3)

Objective	Indicator	Achieved 2010	Expected 2011	Minimum target 2012
Timeliness of scientific advice	Proportion of scientific outputs adopted within deadline	85%	85%	90%
Independence of experts	(i) Proportion of experts with approved annual DOI before invitation to first meeting of new working group	99%	100%	100%
	(ii) Proportion of experts with approved specific DOI prior to meeting	99%	100%	100%
Quality of scientific outputs	Proportion of outputs that receive critical comments (grade D) in the INEX (internal and external review programme) review process	N/A	5%	5%
Cooperation	(i) Value of new grants and contracts (€m)	7.7	8.3	11.3
	(ii) Utilisation of payment credits allocated to contracts and grants	87%	90%	95%
	(iii) Annual reports of networks published	50%	80%	85%
	(iv) No. of third party meetings (stakeholders, Member States etc)	332	350	375

3.4 Risks to delivery

Risks to delivery for EFSA scientific activities (Activities 1, 2 and 3) will be indentified during 2011 from a variety of sources including the annual High-Level Risk Assessment exercise planned for mid-2011.

4. ACTIVITY 2: EVALUATION OF REGULATED PRODUCTS

4.1 Overview

The work programme associated with the evaluation of regulated products and claims will remain considerable and many dossiers will include assessments of environmental impacts, occupational health, post-market monitoring and benefits or efficacy. This will require a wide range of expertise and a multidisciplinary approach and the number of joint evaluations between the Scientific Panels is expected to grow. With the increasing prominence of applications in EFSA's work

[1] For detailed information on EFSA deliverables in 2012, see Annex A.

programme, efficiency will be of paramount importance without compromising the scientific quality of the evaluations. One of the key objectives of the review of EFSA's organisational structure implemented in 2011 is to reflect the prominence of evaluations of regulated products and claims in the organisation's work programme. Similarly, the efficiency programme (e^3) has examined the working practices of the organisation including those associated with applications with a view to optimising their efficiency. Two key developments that will impact on the applications work programme in 2012 will be the establishment of an Applications Desk to enhance the quality of service and improve dialogue with applicants. Workshops, technical meetings and other forms of consultation will continue to be prioritised and EFSA will strive to achieve the optimal balance between dialogue on the one hand and timeliness on the other. EFSA will continue to harmonise its risk assessment procedures in relation to applications and to share best practices both internally between the Scientific Panels and externally with other risk assessment bodies.

The workload associated with applications is expected to remain high in 2012 and will include food additives, feed additives, animal by-products, decontamination of carcasses, plastic food contact materials, active and intelligent packaging, processing aids and decontaminants, enzymes (under Regulation 1332/2008), GMOs, novel foods, health claims and pesticides. Assessments of flavourings will include: the re-evaluation of FGE.19 and footnote 10 substances under Regulation 1565/2000 Art 3; new flavourings under Regulation 1331/2008 Art 3 and smoke flavourings under Regulation 2065/2003 Art 8. Under Regulation 1831/2008, the FEEDAP Panel will adopt opinions on new additives, new uses of existing additives, re-evaluation of existing additives, modification of existing authorisations, as well as new guidance for applicants. As well as opinions on Article 14 and 13.5 claims, novel foods, and the re-evaluation of some Article 13 claims, the NDA Panel deliver further guidance on the scientific requirements for health claims and an update of the guidance document for novel food applications. PRAPeR will finalise the programme for the delivery of conclusions on substances of stage 4 of the review programme of existing active substances which have been included in Annex I to Directive 91/414/EEC without an EFSA conclusion (the so-called "green track" active substances), and for which EFSA has to deliver a conclusion by the end of 2012 (Regulation (EC) No 2229/2004). The second important workflow will be the peer review of new active substances for which a decision on compliance of the dossier has been taken before 14 June 2011 and which are therefore evaluated under Directive 91/414/EEC. By the end of 2012, the existing backlog of these substances should be eliminated. In 2012, PRAPeR expects to draft the first conclusions for new active substances evaluated under the new Regulation (EC) No 1107/2009, with application of the new criteria for approval of active substances introduced by this Regulation. PRAPeR may also be requested to deliver conclusions on basic substances (which after approval can be used without further national authorisation) and on rapporteur Member State evaluations of confirmatory data for substances already included in Annex I.

4.2 Activity 2 at a glance[2]

Key deliverables in 2012	350 Scientific outputs Renewal of Scientific Panels/Scientific Committee
Total budget allocation 2012 (€ m)	18.98
Number of staff 2012 (FTE)	173

5. ACTIVITY 3: DATA COLLECTION, SCIENTIFIC COOPERATION AND NETWORKING

5.1 Overview

EFSA will continue to build networks of scientific excellence and to develop electronic tools such as the Information Exchange Platform to facilitate collaboration with Member States, engage their experts, avoid any duplication of effort and prevent any unnecessary divergence of views. The EFSA Networks in fields such as animal health and welfare, GMOs, TSEs, microbiological risk assessment, and plant health will continue to be developed and several calls for data will be launched in relation to areas such as food additives, flavourings and GMOs. Dialogue with stakeholders will continue to be strengthened through the use of workshops, technical meetings and other forms of consultation.

[2] For detailed information on EFSA deliverables in 2012 see Annex A.

AMU will provide support to the Scientific Committee and the Panels on modelling and data analysis and will allocate a significant amount of resources to the statistical and methodological support for the evaluation of products. The further development of methodologies for detecting and predicting emerging risks in animal and plant health will be prioritised. Systematic literature searches will be provided to all units and methodological support will be given to systematic literature reviews including training for experts and staff. In order to further implement systematic and transparent approaches to support risk assessments, AMU will provide a scientific report on the development of a framework for expert knowledge elicitation.

DATEX will continue to collect and report on chemical contaminant occurrence and data on veterinary and pesticide residues from Member States. Reports will be issued on selected groups of contaminants and ad-hoc support to the Commission will be provided. DATEX will substantially contribute to the development and operability of the Data Warehouse for data sharing and data analysis. The Standard Sample Description and electronic data transmission will be further improved and promoted in the Member States to ensure the high quality of data collections. As a complement to food control data, collection of contaminant data through a total diet study framework will be promoted. This involves random testing for a range of contaminants in a market basket of foods reflecting normal consumption patterns. Specifically, data will be collected, analysed and summarised also for furan, acrylamide, perfluoroalkylated substances and veterinary drug residues, as in previous years. DATEX will further support the risk assessment work carried out by the Scientific Panels, in particular CONTAM and to support the evaluation of regulated products, by contributing to the collection and analysis of occurrence data and to the assessment of exposure. The use of the Comprehensive Food Consumption Database will increase the activities in this area. Probabilistic methodologies and tools for exposure assessment will be tested in 2012 in real cases, as an alternative to the traditional approaches. The Food Classification system developed in 2010-11 will be progressively implemented in EFSA activities and made available to the Member States. Its use will enable more accurate linkage of chemical occurrence and food consumption data for improved exposure assessment. Similarly, combination of food composition and food consumption data at high level of detail will make possible to calculate nutrient intake at a pan-European level and thus support public health policy development. The use of the Comprehensive Food Consumption Database will be fully implemented and the updating of the information from national dietary surveys will be maintained. Harmonisation of food consumption data collection will continue in 2012, with particular focus on dietary survey execution protocols. In the framework of the EU Menu pan-European food consumption survey project, the outcome of the pilot projects under execution will be summarised and the preparation activities in Member States will be supported.

The Zoonoses unit will continue to allocate major resources to the mandate from the Commission on public health hazards to be covered by inspection of meat. The unit has the specific task of proposing human health epidemiological indicators for biological hazards related to meat inspection and in 2012 the unit will be working on indicators for poultry, cattle, sheep and goats, horses and farmed game. This exercise is supported by in-depth analyses of the historical EU data on the hazards in question. The unit will also invest in providing stronger support to the scientific panels in data extractions and analyses of the data on zoonoses, food-borne pathogens and antimicrobial resistance. During 2012, analyses of results from the EU-wide baseline survey on *Listeria monocytogenes* in ready-to-eat foods will be commenced. These analyses will include an estimation of the growth potential of the bacterium in foods and a shared comparative analysis with the European Centre for Disease Prevention and Control (ECDC) of the subtyped *Listeria* isolates from human cases and food to investigate the sources of human infections. Once again, two annual EU summary reports on zoonoses and food-borne outbreaks and on antimicrobial resistance will be produced, in close collaboration with ECDC. Special attention will be paid to enhanced analyses of antimicrobial resistance and food-borne outbreak data. In data reporting the use of automatic data transfer tools and the reporting of sample based data will be further expanded and Member States will be supported by EFSA's grants in their migration to the XML data transfer. In the harmonisation of annual data reporting, the focus will be on vector-borne zoonoses, where specifications for sentinel animal species to be monitored are to be issued.

EFSA's activities in the identification of emerging risks will be based on the strategy outlined in the 2010 *Emerging Risks Report* and in EFSA's forthcoming *Science Strategy*. The EMRISK unit, in collaboration with the Scientific Committee and the Advisory Forum, will continue to develop the capability to proactively identify and assess emerging issues. Further work will be carried out through working groups and outsourcing to develop methodologies for evaluating and prioritising signals of emerging risks. Consolidation and harmonisation of EFSA's chemical hazard characterisation databases will facilitate better exploitation and sharing of data with other agencies. International cooperation is central to the identification of emerging risks and EFSA will continue to build a Member State Network and a Stakeholder consultative group on emerging risks for gathering and sharing data and signals, with a particular focus on unknown non-regulated hazards. EMRISK will be responsible for coordinating EFSA's preparation for answering urgent requests. In 2012, a crisis training and simulation

exercise with MS will be organised. The procedures for responding to urgent requests will be tested and, if necessary, revised building on experience gained through the training exercises and following real cases.

The priority objectives for 2012 for PRAPeR's pesticide residue work will be the timely delivery of reasoned opinions on proposals for new or the amendment of existing maximum residue levels (MRLs; application under Article 9 of Regulation (EC) No 396/2005). In addition, EFSA will prioritise the MRL review process as defined in the Article 12 of the above mentioned regulation. Another priority in 2012 will be the completion of the *Annual Report on Pesticide Residues*. As requested by the European Commission, PRAPeR will continue to provide scientific advice on high-priority issues such as urgent requests or support for the preparatory work for the Codex Committee Meeting on Pesticide Residues (CCPR meeting).

The SCO unit will continue to foster scientific cooperation with Member States with the support of the network of Focal Points by ensuring the exchange of scientific information, access to the best expertise in Europe and access to competent organisations in Member States. In this context, the medium-term planning process will help to identify capacities and core competences in Member States. The SCO Unit will continue to organise scientific colloquia on subjects of interest in Member States and EFSA, support the pre-accession programme and build awareness of EFSA's scientific outputs by seeking indexation of the *EFSA Journal* in more bibliographic databases.

The Scientific Committee will publish reports on quantitative structure-activity relationships (QSARs) and other types of computational toxicology and the development of quantitative methods for expressing uncertainty. Meetings of the nanotechnology network and the network for the harmonisation of risk assessment will be organised and the Working Group on Endocrine Active Substances will publish a technical report.

5.2 Activity 3 at a glance[3]

Key deliverables in 2012	283 Scientific outputs Crisis preparedness programme IT tools for Expert Database, Information Exchange Platform and Art 36 Updated list of Art 36 organisations Data collection/analysis tools Data monitoring reports
Total budget allocation 2012 (€ m)	28.64
Number of staff 2012 (FTE)	75

[3] For detailed information on EFSA deliverables in 2012 see Annex A.

Table 1: Predicted scientific outputs and supporting publications 2012

	AHAW	AMU	ANS	BIOHAZ	CEF	CONTAM	DATEX	Em Risk	FEEDAP	GMO	NDA	PLH	PPR	PRAPeR	SC and AF	SCO	Zoonoses	Total
Activity 1. Provision of scientific opinions and advice & risk assessment approaches																		
Guidance of the Scientific Committee/Scientific Panel												1						**1**
Opinion of the Scientific Committee/Scientific Panel	16		2	16	2	10			4		7	9			4			**70**
Statement of EFSA						1												**1**
Total scientific outputs Act. 1	**16**		**2**	**16**	**2**	**11**			**4**		**7**	**10**			**4**			**72**
Activity 2. Evaluation of products, substances and claims subject to authorisation																		
Conclusion on Pesticides Peer Review														77				**77**
Guidance of the Scientific Committee/Scientific Panel					1				2	2	4							**9**
Opinion of the Scientific Committee/Scientific Panel			23	6	85				71	20	59							**264**
Total scientific outputs Act. 2			**23**	**6**	**86**				**73**	**22**	**63**			**77**				**350**

	AHAW	AMU	ANS	BIOHAZ	CEF	CONTAM	DATEX	Em Risk	FEEDAP	GMO	NDA	PLH	PPR	PRAPeR	SC and AF	SCO	Zoonoses	Total
Activity 3. Data Collection, scientific cooperation and networking																		
Guidance of the Scientific Committee/Scientific Panel													4					**4**
Reasoned Opinion														260				**260**
Scientific Report of EFSA		9					4	1						1			4	**19**
Total scientific outputs Act. 3		**9**					**4**	**1**					**4**	**261**			**4**	**283**
Supporting publications																		
Event report	4			1						2			1			2		**10**
External Scientific Report	5	3		2			10	2		7		3	5		1		2	**40**
Technical report	1	1		2				3		11		1				5	4	**28**
Total supporting publications	**10**	**4**		**5**			**10**	**5**		**20**		**4**	**6**		**1**	**7**	**6**	**78**
Total outputs	**26**	**13**	**25**	**27**	**88**	**11**	**14**	**6**	**77**	**42**	**70**	**14**	**10**	**338**	**5**	**7**	**10**	**783**

6. ACTIVITY 4: COMMUNICATION AND DIALOGUE

6.1 Overview

The key objective for 2012 will be the further implementation of EFSA's *Communications Strategy 2010-2013* which emphasises the core communications remit and the adoption of a more proactive, thematic and impactful approach in areas such as the independence of EFSA's risk assessment advice, zoonoses, GMOs and the safety of chemicals used in the food chain such as pesticides. The reorganisation of communications activities in 2011 in order to streamline editorial structures, content development and dissemination will be instrumental in enhancing efficiency and impact. Some of the key priorities will be to adapt the structure of EFSA's website to reflect the more thematic approach and to broaden the user base of the website to include a wider range of stakeholders and interested parties. The Authority will continue to work synergistically with the Member States to increase the relevance and understanding of its communications amongst its key target audiences and informed lay audience. As part of this work, EFSA will continue to build on risk communication guidelines developed in collaboration with the Member States and will initiate work on the development of a lexicon of risk assessment terms, again in collaboration with national risk communicators. 2012 will mark the 10th anniversary of EFSA's inception and this will be marked by activities throughout the year and, in particular, the organisation of a joint risk assessment/risk communication conference in Parma, taking into account the inauguration of the new EFSA Seat building. In cooperation with the Advisory Forum and Focal Points and working closely with the Advisory Forum Working Group on Communications, EFSA will seek to increase its outreach in the Member States. The Authority will continue to use the full communications mix available and reinforce in particular its online communications including the use of multimedia. Furthermore, EFSA will promote coherence through strengthened cooperation with relevant authorities at national, European and international levels and continue to enhance dialogue with stakeholders and increase audience interactivity. EFSA will develop the terms of reference and launch a call for quantitative research amongst its key target audiences in all 27 Member States to better assess the impact of its communications work, building on the results of the qualitative research in 2010. Crisis communication will continue to be a central part of EFSA's crisis preparedness programme and further training and simulation exercises will be conducted in 2012. EFSA will continue to engage a wide range of stakeholders and interested parties in its work via the Stakeholder Consultative Platform, workshops, technical meetings and other means.

6.2 Communications and dialogue at a glance[4]

Key deliverables in 2012	Ongoing implementation of *Communications Strategy 2010-2013* Thematic approach to communications and reflection in EFSA website Further develop risk communication guidelines with Member States International risk assessment/risk communication conference (EFSA 10th anniversary) Risk assessment lexicon
Total budget allocation 2012 (€ m)	7.4
Number of staff 2012 (FTE)	46

[4] For detailed information on EFSA deliverables in 2012 see Annex A.

6.3 Key performance indicators for communication

Objective	Performance Indicator	Achieved 2010	Expected 2011	Minimum target 2012
Visibility	Web visits	3 m	3.2 m	3.4 m
	Bibliographic databases indexing the *EFSA Journal*	3	4	5
Coherence	Message penetration and tracking:			
	1. One key message taken up by media	93%	95%	95%
	2. Two key massages taken up by media	70%	75%	75%
Outreach	Newsletter subscribers	27,000	28,000	29,000
	Number of public consultations	91	95	100

**Excludes outputs released in batches.*

6.4 Potential risks to delivery

Risks to delivery will be indentified during 2011 from a variety of sources including the annual High-Level Risk Assessment exercise planned for mid-2011.

7. SUPPORT ACTIVITIES

7.1 Overview

In 2012, the efficiency programme (e^3) will continue to guide improvements in organisational efficiency. Based on the analyses carried out in 2010/2011 six programmes were identified for action: update of EFSA strategy, optimisation of processes, restructuring of the organisation, measuring and monitoring performance, optimisation of human capital and knowledge management; and the optimisation of IT management. These programmes have started in 2011 but will enter the technical implementation phase in 2012. Further priorities in 2012 will be the fine-tuning of the finance and IT strategy, the implementation of knowledge management, and the optimisation of the processes concerning strategic management support, IT and communications. Enhanced efficiency in the fields of meeting organisation will be promoted with the full integration of the Meeting Management System and the resulting review of workflows. With the migration to the new ABAC financial system in September 2011, the second phase will aim at linking the local systems to ABAC in order to automatically upload payment data in the financial system. In relation to grants and contracts, the deployment of the grant and procurement management tool will allow closer control over the whole sequence of procurement and contract management. Streamlining of ex-ante verifications and controls and enhanced corporate reporting possibilities will be made possible by the further automation of workflows and tasks. EFSA will continue to ensure sound financial management and to make resources available in accordance with its policy objectives. As regards accounting and treasury management, the Authority will closely adhere to Commission accounting rules and will provide financial statements as required. In addition, EFSA will provide timely information to EFSA Management, Court of Auditors, the Internal Audit Service (IAS) of the Commission and other EU institutions. It will ensure efficient implementation of payment transactions, collection of revenue and recovery of amounts. In 2012, EFSA will be using the ABAC (accrual-based accounting) financial system. The key objective for IT and Operations will be the completion of the move to the new EFSA seat building, adopting responsibility for the new systems and premises, the handover to the owners of the previously rented premises, and the set-up of the new services in the EFSA seat (such as canteen and bar services). The further development of customised core systems such as the risk assessment workflow, and the DOI tool will continue. Support for the annual community reports annual and grants and procurements will continue. The development of a new human resources system should reach its first implementation this year and further evolutions of other support systems will take place as planned. The Human Resources Unit, as one of the contributing actors to the effective restructuring of the organisation and within an overall strategy of human capital and knowledge management optimisation, will continue to provide its direct support in 2012 to the required implementation processes. It will continue to oversee the adopted implementing rules related to the EC Staff Regulations. Moreover, work focused on the implementation of an integrated IT human resources management system initiated

in 2011, will continue throughout 2012. The IT management project, part of the e[3] programme, will be implemented and will lay the foundations for efficiency improvements in the IT area. In addition to EFSA's founding regulation (178/2002) and the horizontal governance legislations applicable to any Union agency, EFSA is subject to a large variety of specific EU legislative acts and workflows that form the basis of EFSA's work. To date, 34 sectoral legislative and implementing acts and 39 different regulatory workflows are applicable to EFSA. In addition, pertinent internal governance rules (such as EFSA Policy on Declaration of Interest) are applicable to EFSA. Particularly in the area of regulated substances, all EFSA's scientific outputs are subject to a variety of different legal and regulatory requirements at different stages of the process. As EFSA is obliged to produce scientific outputs in line with the legal and regulatory requirements, the development of a compliance assurance system will be explored.

7.2 Corporate and support activities at a glance[5]

Key deliverables in 2012	e[3] efficiency programme (Phase 2) Finalisation of EFSA Seat project Implementation of outcome off second statutory evaluation of EFSA Integration of ABAC financial system Human resource management system Integration of meeting management system
Total budget allocation 2012 (€ m)	13.01
Number of staff 2012 (FTE)	101

7.3 Key performance indicators for corporate and support activities

Objective	Indicator	Achieved 2010	Expected 2011	Minimum target 2012
Effective use of financial resources	Budget execution:			
	• Committed	99%	100%	100%
	• Paid	84%	90%	95%
Human resource management	Average length of time to fill vacancies (months)	7	8	7
Efficient use of IT resources	Projects delivered within budget and deadline	85%	90%	95%

7.4 Risks to delivery

Risks to delivery will be indentified during 2011 from a variety of sources including the annual High-Level Risk Assessment exercise planned for mid-2011.

[5] For detailed information on EFSA deliverables in 2012 see Annex A.

ANNEXES

Annex A: Detailed deliverables per activity in 2012

Activity 1: Provision of scientific advice and risk assessment approaches

Subject	Expected outcome	Number		FTE in 2012	Direct operational costs (€ k)
		Finalised	Ongoing		
AHAW					
Welfare risks associated with transport of fish (species specific)	Opinion of the Scientific Committee/Scientific Panel	3	4	1.85	138
Animal-based welfare indicators: beef and calves, laying hens and broilers	Opinion of the Scientific Committee/Scientific Panel	4	4	1.7	74
Vector borne diseases: leishmaniasis, Crimean-Congo haemorrhagic fever (CCHF), African horse sickness and equine encephalosis	Opinion of the Scientific Committee/Scientific Panel	3	3	1.8	171
Risk assessment in animal health in support of the new animal health law: swine vesicular fever, vesicular stomatitis, *Histomonas meleagridis*, bee diseases, bovine tuberculosis in wildlife	Opinion of the Scientific Committee/Scientific Panel	3	3	2.15	145
Meat inspection revision, implications for animal health and welfare	Opinion of the Scientific Committee/Scientific Panel	2	2	4.75	88
Aquatic animals health: Comparative risk of viral haemorrhagic septicaemia and infectious salmon anaemia strains	Opinion of the Scientific Committee/Scientific Panel	1	1	1.25	24
Total		**16**	**17**	**13.5**	**640**
ANS					
Anticipated need for urgent generic requests related to food additives and nutrient sources	Opinion of the Scientific Committee/Scientific Panel	2	2	1	50
Total		**2**	**2**	**1**	**50**
BIOHAZ					
Food-borne zoonoses including food-borne viruses and salmonella in turkeys	Opinion of the Scientific Committee/Scientific Panel	6	6	4	319
Food hygiene including meat inspection	Opinion of the Scientific Committee/Scientific Panel	5	7	4	228
TSE opinions, e.g. mandates related to the TSE road map	Opinion of the Scientific Committee/Scientific Panel	4	5	1.5	83
Qualified presumption of safety (QPS)	Opinion of the Scientific Committee/Scientific Panel	1	1	1	40
Total		**16**	**19**	**10.5**	**669**
CEF					
Anticipated need for urgent generic requests (Art. 29)	Opinion of the Scientific Committee/Scientific Panel	2	2	1.5	70
Total		**2**	**2**	**1.5**	**70**
CONTAM					
Contaminants in food and feed (mycotoxins and natural plant toxicants)	Opinion of the Scientific Committee/Scientific Panel	7	7	6.75	405
Contaminants in food (meat inspection and previous cargoes)	Opinion of the Scientific Committee/Scientific Panel	3	3	3.5	161

Subject	Expected outcome	Number		FTE in 2012	Direct operational costs (€ k)
		Finalised	Ongoing		
Contaminants in feed	Opinion of the Scientific Committee/Scientific Panel	0	1	0.5	11
Pharmacologically active substances covered by Reg (EC) 470/2009 Art. 19 (1)	Opinion of the Scientific Committee/Scientific Panel	0	1	0.25	11
Anticipated need for urgent requests on contaminants in food	Statement of EFSA	1	1	0.25	0
Total		**11**	**13**	**11.25**	**588**
FEEDAP					
Feed additives: nutritional, sensory	Opinion of the Scientific Committee/Scientific Panel	4	6	1	13
Total		**4**	**6**	**1**	**13**
NDA					
Dietary reference values for micronutrients	Opinion of the Scientific Committee/Scientific Panel	5	5	2	113
Anticipated need for advice on general aspects related to nutrition, dietetic foods and health claims (energy conversion factors, labelling reference intake values, generic conditions of use)	Opinion of the Scientific Committee/Scientific Panel	2	2	1	38
Total		**7**	**7**	**3**	**151**
PLH					
Evaluation of pest risk assessments (PRAs) and other justification documents prepared by EU Member States or Third Countries (e.g. *Phytophthora ramorum, Anoplophora chinensis, Rhynchophorus ferrugineus, Agrilus planipennis*, citrus canker)	Opinion of the Scientific Committee/Scientific Panel	4	5	4	198
Extension or adaptation to the whole EU territory of PRAs prepared by Member States or EPPO (pine wood nematode, *Tuta absoluta*)	Opinion of the Scientific Committee/Scientific Panel	1	2	2	100
Preparation of PRAs for the EU territory (*Monilinia fructicola*, solanaceous pospiviroids, plum pox virus)	Opinion of the Scientific Committee/Scientific Panel	2	3	3	100
Evaluation of options to reduce pest risk	Guidance of the Scientific Committee/Scientific Panel	1	1	0.75	52
Anticipated need for short term delivery of advice	Opinion of the Scientific Committee/Scientific Panel	2	2	0.25	51
Total		**10**	**13**	**10**	**501**

Scientific Committee					
Preparation of scientific advice on horizontal subjects and risk assessment approaches (statistical approaches, botanicals, risk assessment terminology, default values, nanotechnology, thresholds of toxicological concern, 90day feeding trials, compendium of botanicals, etc.)	Opinion of the Scientific Committee/Scientific Panel	4	6	5.5	596
Workshops/meetings on horizontal issues	Workshop/meeting reports	0	2	1.5	63
Total		**4**	**8**	**7**	**660**
Administration					
IT and Operations					
Develop IT tools to support to provision of reporting and monitoring for risk assessment (risk assessment workflows, declaration of Interest tool)	Application development of IT tools to support to provision of reporting and monitoring for risk assessment (Risk Assessment Workflows, Declaration of Interest tool)	0	0	0.5	1000
Total		**0**	**0**	**0.5**	**1000**

Activity 2: Evaluation of regulated products

Subject	**Expected outcome**	**Number**		**FTE in 2012**	**Direct operational costs (€ k)**
		Finalised	**Ongoing**		
ANS					
Additives: new applications	Opinion of the Scientific Committee / Scientific Panel	10	10	2	126
Additives: re-evaluation of food colours	Opinion of the Scientific Committee / Scientific Panel	5	16	4	125
Additives: re-evaluation of preservatives	Opinion of the Scientific Committee / Scientific Panel	3	26	5.5	145
Evaluation of nutrient sources and other substances	Opinion of the Scientific Committee / Scientific Panel	5	10	2	127
Total		**23**	**62**	**13.5**	**523**
BIOHAZ					
Animal by-product (ABP) applications	Opinion of the Scientific Committee / Scientific Panel	4	6	3	132
Decontamination dossiers	Opinion of the Scientific Committee / Scientific Panel	2	3	1	55
Total		**6**	**9**	**4**	**188**

CEF					
Plastic food contact materials substances (Regulation 1935/2004)	Opinion of the Scientific Committee / Scientific Panel	13	13	2	127
Plastic food contact materials substances: revision of guidance	Guidance of the Scientific Committee / Scientific Panel	1	1	1	25
Recycling of FCM: existing and new processes (Regulation 282/2008 Art 5)	Opinion of the Scientific Committee / Scientific Panel	21	21	3.5	85
Active and intelligent packaging materials (Regulation 450/2009 Art 8)	Opinion of the Scientific Committee / Scientific Panel	2	2	0.75	13
Processing aids/Decontaminants	Opinion of the Scientific Committee / Scientific Panel	2	2	0.75	14
Flavourings: Re-evaluation of FGE.19 and footnote 10 substances (Regulation 1565/2000 Art 3), New flavourings (Regulation 1331/2008 Art 3) & Smoke flavourings (Regulation 2065/2003 Art 8)	Opinion of the Scientific Committee / Scientific Panel	35	35	5	276
Enzymes: Scientific opinions for applications in the preparation and presentation of applications (Regulation 1332/2008)	Opinion of the Scientific Committee / Scientific Panel	12	12	1	59
Total		**86**	**86**	**14**	**598**
FEEDAP					
New additives or new uses for a feed additive (Article 4 of Regulation (EC) 1831/2003)	Opinion of the Scientific Committee / Scientific Panel	10	12	2.7	64
New additives or new uses for a feed additive and re-evaluation of existing feed additives (Article 4 and Art 10 of Regulation (EC) 1831/2003)	Opinion of the Scientific Committee / Scientific Panel	11	11	2.5	71
Re-evaluation of existing feed additives (Article 4 and Art 10 of Regulation (EC) 1831/2003)(priority 1)	Opinion of the Scientific Committee / Scientific Panel	40	60	10.25	603
Modification of existing authorisations (Article 13 of Regulation(EC) 1831/2003)	Opinion of the Scientific Committee / Scientific Panel	6	7	1.75	56
Requests associated with negative/inconclusive opinions under Regulation(EC) 1831/2003	Opinion of the Scientific Committee / Scientific Panel	4	7	1.75	55
New Guidance on support for applicants in the preparation and presentation of applications (covering additional issues not included in previous guidances) and one administrative guidance document	Guidance of the Scientific Committee / Scientific Panel	2	5	1.75	27
Total		**73**	**102**	**20.7**	**877**
GMO					
Applications received under Directive 2001/18/EC, Regulation 1829/2003, 1831/2003 and 1831/2008	Opinion of the Scientific Committee / Scientific Panel	15	320	20	645
EC requests related to new techniques and PMEM reports	Opinion of the Scientific Committee / Scientific Panel	5	5	1.5	82

Guidance on applications (GM animals FF safety, Environmental RA of GM animals	Guidance of the Scientific Committee / Scientific Panel	2	2	2.25	319
EFSA overall opinions on applications (Regulation 1829/2003)	Technical report	9	9	0.75	0
Public consultation on guidance document (GD) for GM animals FF safety, Environmental RA of GM animals	Technical report	2	2	1.25	26
Total		**33**	**338**	**25.75**	**1,072**
NDA					
Novel Foods (EC 258/97)	Opinion of the Scientific Committee / Scientific Panel	7	7	1.5	81
Novel foods (EC 258/97): Update of guidance document for preparation of novel foods application, including guidance on data requirement to document tradition of safe use(draft guidance not expected to be published in 2011)	Guidance of the Scientific Committee / Scientific Panel	2	2	2	50
Article 14 and 13.5 claims (Health Claims Regulation, EC 1924/2006)	Opinion of the Scientific Committee / Scientific Panel	20	20	5	154
Re- evaluation Article 13 (EC 1924/2006)	Opinion of the Scientific Committee / Scientific Panel	30	50	5	90
Guidance on scientific requirements for health claims	Guidance of the Scientific Committee / Scientific Panel	2	3	2	50
Other applications (allergies, infant formulae) (Directive 2000/13/EC; Directive 2006/141/EC)	Opinion of the Scientific Committee / Scientific Panel	2	2	1	63
Total		**63**	**84**	**16.5**	**489**
PRAPeR					
Dir. 91/414/EEC, Art 6	Conclusion on Pesticides Peer Review	37	39	18	237
Reg. 2229/2004, Art. 25a	Conclusion on Pesticides Peer Review	30	30	7.5	162
Reg. 1107/2009, Art. 23(4)	Conclusion on Pesticides Peer Review	3	4	1	0
Inclusion directives	Conclusion on Pesticides Peer Review	3	4	0.5	0
Reg. 1107/2009, Art. 12	Conclusion on Pesticides Peer Review	4	6	1.5	27
Total		**77**	**83**	**28.5**	**425**
Risk Assessment					
Support Service for applicants	Enhancement of the services provided by EFSA to the applicants	0	0	5	NA
Total		**0**	**0**	**5**	**0**
SCA					
Support Service for applicants	Enhancement of the support and service provided to the applicants	0	0	4	NA
Total		**0**	**0**	**4**	**0**

Activity 3: Data collection, scientific cooperation and networking

Subject	Expected outcome	Number		FTE	Direct operational costs (€ k)
		Finalised	Ongoing		
AHAW					
Systematic reviews as preparatory work for AHAW mandates	External Scientific Report	2	2	0.5	60
Proofreading of opinions		0	0	0	60
Update and upgrade of AHAW database on vector borne diseases	External Scientific Report	2	2	0.5	100
Methodological aspects of validation of indicators for animal welfare	External Scientific Report	1	1	0.5	150
Member State collaboration with AHAW network	Technical report	1	1	0.5	89
Stakeholder consultation and technical meetings (GM-animals, animal based indicators, RA guidelines		0	0	0	0
Workshop on methodological approach of Risk Assessment for emerging issues in animal and plant health	Event report	1	1	0.75	16
Stakeholder consultation and technical meetings (fish welfare during transport)	Event report	1	1	1	34
Animal-based welfare indicators (technical hearing)	Event report	2	2	0.75	33
Total		**10**	**10**	**4.5**	**543**
ANS					
Calls for data on food additives in accordance with regulation EU 257/2010	Data collection on specific food additives in form of calls for data to support the re-evaluation of food additives	0	5	1.5	0
Preparatory documents received from outsourcing activities: re-evaluation of food additives	Preparatory documents, which will serve as the basis for the work on the pre-evaluation of food additives	0	20	2	0
Editing and proofreading of draft opinions	proof-read draft opinions	15	15	0.5	15
Preparatory work to support the ANS Panel	preparatory documents to serve as basis for opinions	0	8	1.5	300
Total		**15**	**48**	**5.5**	**315**
Assessment Methodology					
Assistance to the Assessment Methodology Unit for statistical analyses and ad hoc consultation upon request (statistics), ongoing from previous years	External Scientific Report	1	2	1	86
Assistance to the EFSA scientific units on toxicology and eco-toxicology and ad hoc consultation upon request	External Scientific Report	1	2	1	86
Further implementation of systematic approaches to support risk assessment	External Scientific Report	0	1	0	229

Subject	Expected outcome	Number		FTE	Direct operational costs (€ k)
		Finalised	Ongoing		
	Internal Report	5	5	3	1
Special project: environmental post marketing monitoring	Scientific Report of EFSA	1	1	0	350
Further method development for the assessment of emerging risks on animal and plant health	External Scientific Report	1	3	2	258
Support for generic opinions	Internal Report	7	7	2	0
	Scientific Report of EFSA	3	4	2	42
Support for the evaluation of products, substances and claims	Internal Report	10	10	1.5	0
	Scientific Report of EFSA	2	3	1.5	42
Harmonisation of Risk Assessment Methods	Scientific Report of EFSA	3	4	1	75
	Technical report	1	1	1	0
Purchase - Access to databases/documents	Science items: subscriptions to e-journals, e-databases and other science reviews	0	0	0	175
Total		**35**	**43**	**16**	**1,344**
BIOHAZ					
Preparatory work to support the BIOHAZ panel	External Scientific Report	2	3	1	394
Proofreading and scientific editing of adopted opinions		0	0	0	15
Member State collaboration with microbiological risk assessment (MRA) and TSE networks	Technical report	2	2	0.4	39
Workshops with stakeholders on food hygiene issues	Event report	1	1	0.1	15
Total		**5**	**6**	**1.5**	**462**
CEF					
Outsourcing: Bibliography reports on BPA	Preparatory work	0	0	0.5	20
Outsourcing: Collection of data on flavourings and preparation of summaries (draft FGEs)	Preparatory work	0	0	1.5	250
Outsourcing: Food contact materials (FCM): preparation of non-toxicological summary data sheets (SDS)	Preparatory work	0	0	1.25	125
Outsourcing: FCM: preparation of toxicological datasheets	Preparatory work	0	0	1.25	140
Total		**0**	**0**	**4.5**	**535**
CONTAM					
Influence on processing on nitrate levels in vegetables - data needs identified in order to refine risk assessment	External Scientific Report	0	1	0.25	60
Alternaria toxins - data needs identified in order to refine risk assessment (genotoxicity test)	External Scientific Report	0	1	0.25	250

Subject	Expected outcome	Number		FTE	Direct operational costs (€ k)
		Finalised	Ongoing		
Proofreading and scientific editing of adopted opinions		0	1	0	15
Mineral hydrocarbons toxins - data needs identified in order to refine risk assessment	External Scientific Report	0	1	0.25	230
Total		**0**	**4**	**0.75**	**555**
Data Collection Exposure					
Access to high performance probabilistic calculation computer service	Internal Report	5	5	0.5	50
Food market intelligence services	Internal Report	4	4	0.25	70
EU Menu IARC support phase 3	External Scientific Report	1	1	0.5	114
Development of detailed survey methodology and tools for the collection of Food Consumption Data	External Scientific Report	0	1	0.5	368
Data evaluation and reporting	Internal Report	8	8	2	0
Responding to calls for topical scientific reports	Scientific Report of EFSA	2	2	1	0
Support to MSs to facilitate chemical occurrence data entry in conformity with the Standard Sample description, with particular focus on food description according to the EFSA harmonised system	External Scientific Report	0	3	0.25	220
Updating and completing the SSD catalogues, including methods of analysis	External Scientific Report	1	1	0.25	50
Continuing data collection for contaminants and other chemical substances, including a data evaluation and response service for stored data	Internal Report	3	3	4	0
Special project: post marketing monitoring chemicals	Scientific Report of EFSA	1	1	0	350
Nutritional intake calculations using an updated food composition database and comprehensive food consumption information	External Scientific Report	1	1	0.5	100
Preparation for the EUMenu project food consumption data collection methods, including capacity building	External Scientific Report	1	3	1	350
Assistance to Member States to map database structures to EFSA requirements and to submit data using the xml protocol.	External Scientific Report	3	5	0.75	300
Updating the comprehensive food consumption database by incorporating recently collected data in adults and children	External Scientific Report	3	3	0.75	128
Support for specific opinions	Internal Report	8	8	2	0
Harmonisation of exposure assessment methodology	Scientific Report of EFSA	1	1	2.25	234
Support for the evaluation of products, substances and claims	Internal Report	3	3	0.5	0
Total		**45**	**53**	**17**	**2,334**

Emerging Risks					
Data sources and hazard databases	External Scientific Report	0	1	0.5	65
Crisis assistance	Simulation exercise and support in situations of urgent requests and update of emergency manual	0	0	0.5	60
	Technical report	1	1	0.5	43
Emerging risk Identification	External Scientific Report	0	1	0.5	225
Monthly monitoring and operation of internal collaboration group (ERIC)	Technical report	1	1	3.7	0
Development of the Emerging Risks identification process	Technical report	1	2	3	58
Emerging risks exchange with MS	External Scientific Report	1	2	0.5	31
Annual report emerging risks	Scientific Report of EFSA	1	1	0.3	0
Emerging Risks exchange with Stakeholders	External Scientific Report	1	1	0.5	5
Total		**6**	**10**	**10**	**487**
FEEDAP					
Preparation of background documents for the re-evaluation of feed additives	Preparatory work	0	0	1.7	420
Proofreading of opinions		0	0	0.3	15
Outsourcing literature review and data collection on aspects related to the evaluation of particular categories of feed additives	External Scientific Report	0	1	0.3	200
Total		**0**	**1**	**2.3**	**635**
GMO					
Procurement for initial RA of renewal applications to be received under regulations 1331/2008 & 1332/2008 Food additives as well as regulation 1831/2003 art 10, Framework contract 300 K euro 2012-2015	External Scientific Report	3	3	0.5	40
Data collection and methodology support in GMO risk Assessment	External Scientific Report	1	1	0.5	280
Statistical support for evaluation of risk assessment of GMO dossiers	External Scientific Report	3	3	0.5	200
Proofreading of opinions		9	9	0.25	15
EFSA-Member State GMO scientific risk assessment network	Event report	1	1	0.25	34
Meetings with MS and stakeholders e.g. on guidance document (GD) for GM animals FF safety and Environmental RA of GM animals as part of public consultation	Event report	1	1	2.25	23
Total		**18**	**18**	**4.25**	**591**
NDA					
Scientific Cooperation related to data collection on Novel foods	External Scientific Report	0	1	0.5	325
Proofreading of opinions		0	0	0	15
Meetings with stakeholders health claims	Event report	0	1	2	34

Meeting with stakeholders on health claims guidance document	Event report	0	1	2	49
Total		**0**	**3**	**4.5**	**423**
PLH					
Support for Plant Health activities	External Scientific Report	1	2	0.25	171
Proofreading and scientific editing of adopted opinions		0	0	0	15
Support for Plant Health risk assessment activities	External Scientific Report	2	2	1.5	456
Member State collaboration with PLH network	Technical report	1	1	0.25	59
Total		**4**	**5**	**2**	**701**
PPR					
Scientific support, literature and data collection for RA on microbial organisms used as Plant Protection Products	External Scientific Report	1	1	0.5	100
Preparatory work for the revision on the GD on birds and mammals/follow up of open questions identified by RMs on GD on Birds and Mammals	External Scientific Report	1	1	0.5	100
Work supporting the revision of the GDs on Aquatic and Terrestrial Ecotox, e.g. follow up of IUCLID database compilation, population modelling	External Scientific Report	1	1	0.5	100
Preparatory work for a new Guidance Document for evaluation of absorption, distribution, metabolism and excretion (ADME) properties of pesticides	External Scientific Report	0.5	0.5	0.5	100
Support for data collection and preparation work for the PPR opinions	External Scientific Report	0.5	0.5	0.2	200
Proofreading of opinions		0	0	0	15
Outsourcing: toxicology and environmental guidance documents	External Scientific Report	1	1	1	229
Workshop in toxicology	Event report	1	1	0.8	51
Developing and updating EU GDs on toxicology, ecotoxicology, environmental fate and pesticide residues.	Guidance of the Scientific Committee / Scientific Panel	4	4	2.5	171
	Opinion of the Scientific Committee / Scientific Panel	5	7	5.5	403
Total		**15**	**17**	**12**	**1,469**
PRAPeR					
Reg. 396/2005, Art. 32	Scientific Report of EFSA	1	2	2	127
Reg. 396/2005, Art. 10	Reasoned Opinion	100	125	3	0
Reg. 396/2005, Art. 12	Reasoned Opinion	150	225	4	481
Reg. 396/2005, Art. 43	Reasoned Opinion	10	12	0.5	0
Total		**261**	**364**	**9.5**	**608**
Scientific cooperation					
Focal Point network (comprising 29 contracts with EU/EEA/EFTA Member States)	Management of Focal Point network	0	0	1.5	74
	Technical report	1	1	1.5	760

Expert database	Internal Report	4	4	0.5	0
	Management of Expert database IT tool	0	0	1	0
	Technical report	1	1	0.5	0
Information Exchange Platform (IEP)	Improved IT tool	0	0	0.5	182
	Internal Report	12	12	0.5	0
	Technical report	1	1	0.5	26
Recognition and visibility of EFSA's scientific work (better indexed EFSA Journal)	EFSA Journal indexed in more databases	0	0	1	0
	Management of Steering Group, Coordination Group and Editorial Board	0	0	0.5	0
Article 36 network	Management of List of Art. 36 competent organisations (updated)	0	0	1	0
	Management of two IT tools: (1) Art 36-NET on ScienceNet and (2) Art 36-DATABASE	0	0	1	0
	Technical report	1	1	1	0
Scientific Cooperation projects with Member States/horizontal projects	Technical report	1	1	1.5	8
Organisation of scientific events	Event report	2	2	0.5	0
Total		**23**	**23**	**13**	**1,050**
Zoonoses					
Community Summary Reports on zoonoses, and food-borne outbreaks	Scientific Report of EFSA	1	2	2.5	320
	Technical report	2	2	0.5	1
Community Summary Reports on antimicrobial resistance	Scientific Report of EFSA	1	2	2.25	129
Database and reporting applications	Internal Report	2	2	0.75	150
	IT assistance to Member States	0	0	0.5	300
	Technical report	2	2	1	24
	Web reporting application, data warehouse, XML schemas	0	0	1	20
Baseline survey preparation and analyses	Scientific Report of EFSA	0	3	1.75	173
Other data analyses reports	External Scientific Report	1	1	0	0
Assistance to EFSA panels	Internal Report	6	8	1.5	0

Meat inspection mandate - defining epidemiological indicators	External Scientific Report	1	4	0.25	100
	Scientific Report of EFSA	1	5	4	101
Harmonisation of monitoring and reporting	Scientific Report of EFSA	1	1	0.5	25
Development of analytical methods for the annual data	Scientific Report of EFSA	0	1	0.5	0
Total		**18**	**33**	**17**	**1,344**

Activity 4: Communication and dialogue

Subject	**Expected outcome in 2012**	**Number/indicator**	**FTE**	**Direct operational costs (€ k)**
Communications				
Support for development of EFSA's communications strategy	Advisory Group on Risk Communication (AGRC) meetings	3	2	28
Enhanced understanding of EFSA's target audiences and consumer risk perception	Quantitative and qualitative target audience research; research on communication outputs	3	3	150
Platform for risk communication	Develop a Platform for risk communication with international and third countries food agencies	0	0	0
Total		**6**	**5**	**178**
Press Office				
Ensure coherent risk communications through close liaison with EU institutions, national food safety authorities and international partners	AFWGC meetings	4	1.2	92
	Exchanges with relevant international partners on pre-notification of opinions	5	0.2	0
Communicate EFSA scientific advice to the media	Media responses to questions/ interviews	800	2.2	0
	Press briefings	2	1	31
	Press releases/statements/ web news stories	70	3.5	0
Build media relationships to achieve better understanding/ coverage of EFSA	Face-to-face meetings with the media	6	0.6	12
	Media training for scientists	3	0.3	0
	Press contacts database	1	0.2	0
Evaluation of EFSA-related media coverage	Media monitoring and analysis reports (monthly and annual)	18	1.8	278
Total		**909**	**11**	**413**

Public Info and Events				
Improve overall understanding of EFSA work within context of EU food safety system	Corporate events (including inauguration new building/10 year anniversary, promotional material, photo-shooting)	26	2.3	283
	Corporate multimedia products	2	0.75	125
	Corporate publications (including all EU languages versions)	54	2	150
	Joint events with Member States	1	0.25	8
		0	0	0
Visibility and recognition of EFSA's work	Newsletters (all EFSA working languages)	56	1.7	109
	Scientific events (EFSA supported, EFSA led)	3	0.7	148
	Scientific publications (reports, colloquia reports, posters etc.)	26	1.3	149
Total		**168**	**9**	**973**
Web				
Enhance simplicity and usability of EFSA website and online services	Create web content	50	2	0
	EFSA Journal support	24	1	0
	Implement usability improvements	30	2.5	56
	Manage online subscription services	100	0.2	0
	Manage public enquiries via Ask EFSA	1200	0.5	0
	Monitor and analyse online communications	40	0.3	0
Enhance transparency and understanding of EFSA's operations and outputs through online media	Publish content to the website in EFSA's 4 working languages	7500	2.8	0
	Webcasting of Management Board and other key meetings	8	0.7	300
Total		**8952**	**10**	**356**

Scientific Committee/Advisory Forum				
Advisory Forum plenary meetings	Minutes of the meetings	4	2	240
Interfacing between Member States and EFSA, including bilateral visits and participation in other EFSA meetings	Ongoing interfacing between Member States and EFSA	0	0.8	0
Other Advisory Forum related meetings	Minutes of the meetings	4	0.7	60
Total		**8**	**3.5**	**300**
IT and Operations				
Develop IT tools to support Communication and Outreach activities (Web tool, EFSA Journal)	Application maintenance of existing IT tools to support Communication and Outreach activities (Web tool, EFSA Journal)	Adherence to IT planning assumptions and status (IT Dashboard) with 90% respect of time and costs.	0.5	370
Total			**0.5**	**370**
Legal and Policy Affairs				
Stakeholder Consultative Platform (Brussels)	Strengthen stakeholder consultation processes	Organise at least 2 meetings	0.4	27
Stakeholder Consultative Platform (Parma)	Strengthen stakeholder consultation processes	Organise at least 1 meeting of the Stakeholder Platform	0.4	13
Stakeholder WG	Strengthen stakeholder consultation processes	Organise at least 2 meetings	0.2	6
International activities	Legal and administrative support for bilateral agreements Coordination of the implementation of the EFSA's international strategy Support of international visits to EFSA	Foster network of contacts in international organisations	1	25

Management and coordination of relations with EU Institutions	Direct, support and coordinate EFSA's relations with the European Parliament, the European Commission, and the Council	EFSA attendance at all relevant EP meetings (in particular ENVI Committee) Participation in Council Working Groups as required and coordination with EU Presidency as appropriate Coordinate EFSA attendance at the DG-SANCO Advisory Group Organise at least 3 EFSA/DG-SANCO bilaterals Coordinate and ensure the in-house dissemination of information on EFSA attendance at the DG-SANCO Standing Committees	2	9
Coordination of EFSA's Pre-Accession and Neighbourhood activities	Support competent authorities in Candidate and Potential Candidate countries through the organisation of events such as training seminars, study tours and participation in EFSA meetings as observers. In addition organise European Neighbourhood Programme events.	Coordination and management of seminars, training	2	0
Total			**6**	**80**

Support activities

Subject	**Expected outcome**	**FTE**	**Performance Indicator**	**Direct operational costs (€ k)**
Finance				
Budget Management and ABB (activity-based budgeting)	Make budget resources available to conduct the planned activities Monitor and report on the relationship between the financial resources employed and the results achieved (efficiency) Monitor the budget, its financial execution & forecast and report to Management	1.5	Budget execution rate over 99% Transfers to/from chapters below 5% of budget Carry-forward below 20% of budget	50

Efficiency Initiative	Critically review EFSA workflows and working processes, review organisational structure, implement improvements	0	Reports on efficiency discussed in the Steering Committee and recommendations implemented	200
Finance Management	Ensure compliance with the Financial Regulation and related guides or procedures and train the staff Verify the adequacy of the financial resources used to conduct an activity within the principles of economy Monitor and report on invoice payments in compliance with the Financial Regulation and best practises	5.5	Regular financial training Financial verifications implemented within the Internal rules Payments processed before the Regulation deadlines	NA
Procurement & Grant Management	Provide support and guidelines to the organisation with regards to regulation and financial aspects of procurement and grants Set up, monitor and launch the procurement and grants programme Disseminate knowledge and best practice through training and streamlining of procedures	6.5	Timely launch of tenders and calls, according to programme schedule Critical audit findings below 5 Establish improved reporting and management tools	NA
Workflow Management	Develop further the automation tools to streamline the financial, mission, meeting, shuttle, translation and order workflows Improve the management of the centralised budget lines in order to enhance support to the organisation and generate efficiency gains Ensure full integration of ABAC financial system and provide ongoing training on the financial tools	7.5	Integration of meeting workflow with the other workflows (ABB, RAW and ABAC) Automatic upload of mission payments into financial system Implementation of centralised meeting organisation and processing Development of the cost of question system	NA
Total		**21**		**250**
Human Resources				
Staff welfare	Analyse the current services with respect to staff welfare and well-being, and explore the introduction of additional services for staff, in line with those offered in other EU Agencies of a comparable size.	2	Carry-out benchmarking of welfare services with other EU Agencies of similar size and the EC with the aim of introducing complementary welfare services via appropriate procurement procedures, in line with available budget	403

	Conduct a staff feedback survey	0	Analysis and assessment of staff survey results in view of organising specific workshops for the definition and implementation of concrete action plans	35
Staffing	Ensure full occupancy of EFSA posts, anticipating competences needs and reducing vacancy period.	5	All posts occupied at all time. Vacancy resulting from departure not longer than 3 months.	155
Learning & Training	Develop training programmes to enhance the managerial, scientific, linguistic, professional and interpersonal skills and competences of staff and explore complementary and innovative learning and training methodologies.	4	Analysis and report on current learning and training offer; Exploration and introduction of specific training for scientific staff, via appropriate procurement procedures, in line with the available budget; Introduction of e-learning and multimedia language learning packages as part of the overall learning and training offer, in line with the available budget.	716
Human Capital management	Ensure HR unit management, process optimisation, strategic staffing planning, delivery of effective services and the monitoring and reporting thereof. Empowerment of managers to optimise in an autonomous way the deployment and monitoring of their human capital. Analyse, monitor and report on Human Resources budget allocation in line with EFSA's objectives and priorities. Ensure its financial execution and forecast.	3.7	Ensure strategic alignment with EFSA Management objectives and evolutions in core business, monitored through the 2011 HR-work plan Automation of processes through introduction of an modern HR-database, first modules implemented in 2011. Staff budget execution over 97%	NA
Personnel Services	Ensure timely and accurate payment of all salaries, entitlements and other allowances for all staff, as well as, providing staff with clear and comprehensive information, and advise staff on their statutory rights. Provide insight on resources usage of activity based budget. Record and report on absence and manage all types of leave requests.	5	No delays in monthly salary payments Changes in entitlements and other allowances processed for next months payroll as a rule. All relevant information uploaded and/or updated on the Intranet Portal. Through time-tracking activity codes, monthly reporting of average number of working hours per Directorate and Unit. Report on average number of leave and /or absence days taken per Directorate and Unit.	NA

Performance management and career development	Consolidate the performance management (CDAC) processes and assess the current reclassification/ promotion policy in view of the alignment to the Agencies model decision on promotion/ reclassification	2	Introduction into the staff performance assessment of points of reference/ standards to be used for the elaboration of specific/individual job descriptions, annual objectives, KPIs and training by job category Impact assessment on the current promotion/ reclassification policy	NA
Internal Communication	Enhance internal communication within the organisation, through the use of appropriate tools, such as the intranet portal, decentralised taskforces and other appropriate internal communication actions Continuous, transparent and structured content management of the intranet portal monitored by the EFSA representative Editorial Committee chaired by HR	1.3	Usage and satisfaction rate of intranet portal measured through focused yearly users survey Decrease of number of queries addressed by staff through phone and mail to the various support functions (HR, Finance, IT, facilities, …)	NA
Total		**23**		**1,309**
IT and Operations				
Adaptation works to be completed before leaving previously rented premises to accommodate alternate emergency premises for business continuity.	Alternate emergency premises in previously rented building.	0.7	Availability of alternate premises in previously rented buildings.	50
Develop IT tools to support streamlining and cost reduction of EFSA Administrative Processes (financial workflows, human resources workflows, intranet portal, expert management tool, meeting organisation system)	Application development of existing custom IT tools (financial workflows, human resources workflows, intranet portal, expert management tool, meeting organisation system)	0.2	Adherence to IT planning assumptions and status (IT Dashboard) with 90% respect of time and costs.	50
Total		**0.9**		**100**
Legal and Policy Affairs				
Identify legal risk	Prevent litigation and if necessary provide appropriate defence	3.5	Positive outcome of court cases for EFSA	100
Legal and regulatory advice	Maintain current knowledge and awareness of all legislation relevant to EFSA Maintain uniform application and interpretation of relevant legislation Provide input for the Legislator when relevant Development of internal rules	2.5	Avoid inconsistencies in EFSA's application of the regulatory framework Feedback from Units on responsiveness Increased awareness and compliance with internal rules	NA
Total		**6**		**100**

Accounts				
Execution of payments and collection of revenue	Efficient execution of payments	2.7	Payment delays less than 3.0 days	NA
Accounting Management	Monitor and report to Management			
Establishment of EFSA accounts	EFSA annual financial accounts report	0.5	Publication of EFSA final accounts in the Official Journal	NA
Liaison with Court of Auditors (CoA)	Accounts prepared in accordance with the Financial Regulation and Commission accounting rules	0.3	CoA findings free of material misstatement Positive statement of assurance on EFSA annual accounts	NA
ABAC implementation	ABAC implementation	0.5	Successful implementation	NA
Total		**4**		**0**
Administration				
Business Continuity Plan	Test and update the EFSA Business Continuity Plan. Implement further actions to improve the resilience of the supporting systems in support to EFSA business	1	Perform one walk-through and one simulation of the Business Continuity plan and crisis management procedure in 2011	NA
Security policy implementation	Complete second level policies for the implementation of the Security Policy	0.2	Draft identified second level policies by the end of 2011	NA
Information management and document management	Full implementation of the information and document management and archiving policy Identification of IT tools to implement the policy electronically	0	Policy enforced in all units by end of 2011 Plan for implementation of IT tools to automate enforcement of policy by end of 2011	NA
Data Protection	Notifications to DPO by data controllers on processing operations under their supervision involving personal data Register of personal data processing operations at EFSA Advice and awareness raising on data protection with data controllers Maintain contacts with the EDPS – European Data Protection Supervisor	0.5	All 'ex post' notifications on existing processing operations in EFSA completed Maintenance of online register for in-house consultation Timely responses provided to data controllers Enhanced collaboration with the EDPS	NA
Total		**1.7**		**0**

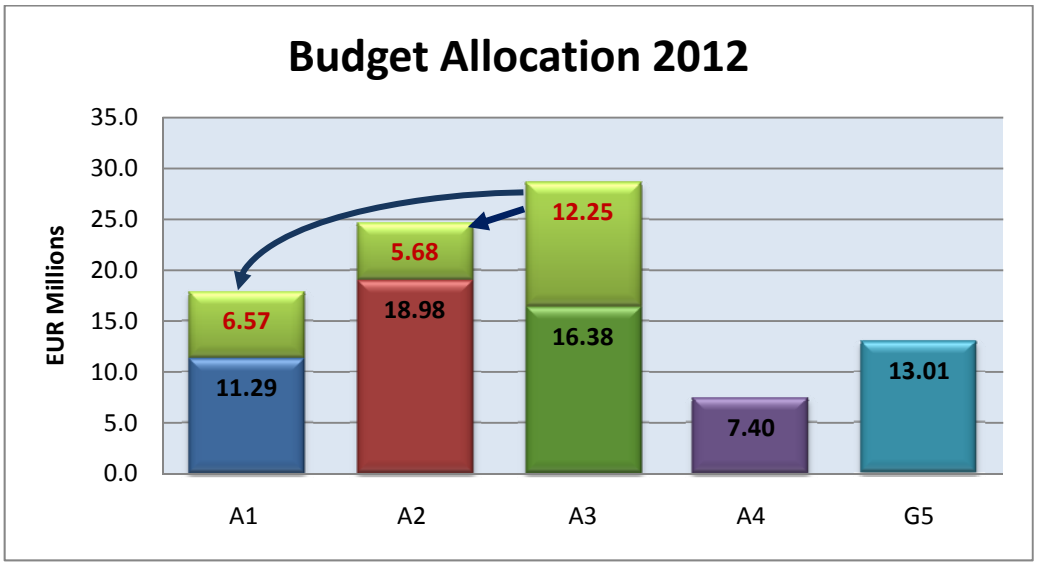
Library				
Library stocks, purchase and preservation of non-science items	Non-science items	0	Fully equipped library with access provided to all the relevant information sources within the budget limits	12
Miscellaneous library items, documentation and reproduction equipment	Generic equipment (e.g. shelves and other miscellaneous library items)	0		18
Subscriptions, purchase of information media NEWSPAPERS	Information media, newspapers, subscriptions to institutional information services	0		30
Total		**0**		**60**
Internal Audit				
Programming and planning	Update the Internal Audit Strategic Plan based on the annual audit risk assessment and translated into an annual audit plan	0.5	Adoption of the audit plans by the Audit Committee.	NA
Perform internal audit engagements	Advise EFSA on managing risks in order to improve the implementation of operations and promote sound financial management Provide independent opinions and recommendations on the quality of management and control systems	0.5	Percentage of audit reports reviewed by the Audit Committee	NA
Follow-up of audits	Follow up and report at each Audit Committee meeting on the level of completion of accepted audit recommendations	0.5	Percentage of recommendations implemented/closed for the IAS, ECA and the EFSA Internal Audit Capabilities	NA
Liaison function	Coordinate audit activities with external auditors and audit bodies including the Internal Audit Services of the European Commission (IAS), the European Court of Auditors (ECA) Provide the contact point between EFSA and OLAF (European Anti-Fraud Office).	0.5	Feedback from auditees and auditing bodies obtained through a satisfaction survey	NA
Total		2		**0**
Office of Executive Director				
2 MB meetings in Parma	Organisation of Four Management Board meetings	0	Effective organisation, on-time delivery of the MB documents, meeting minutes and on-site publication	33
3 MB meetings outside Parma		0		50
MB members attending non-MB meetings		0.5		14
Chair/Vice Chair/ED meetings		0		11

Cost of meeting organised in Parma- (average)			0		50
Cost of meeting organised outside Parma (average)			0		147
Total			**0.5**		**306**
Quality Management					
Possible research in the area of QM/ISO 9000/EFQM	Development and implementation of an IQMS in EFSA		0	Number of implemented standard operating procedures (SOPs) and work instructions (WINs)	15
Total			0		15
Strategy and Prospective					
Foresight and Associated Studies	Ensure that EFSA is aware of its changing environment and is able to prepare accordingly Identify issues of relevance to EFSA's future planning	2	Five in-depth reports Associated studies Planning exercise successfully carried out	30	
Strategy	Provide regular overviews of strategic activities at the international, European and national level which may impact on EFSA Monitor and report and review the implementation of Strategic Plan 2009–2013 and other strategies Develop further the impact assessment methods and tools Associated work linked to mission	1	18 "What's Next" reports delivered Impact assessment tools reviewed and progress delivered to Management Board in 2012	40	
Total		3		70	

Annex B: Resources

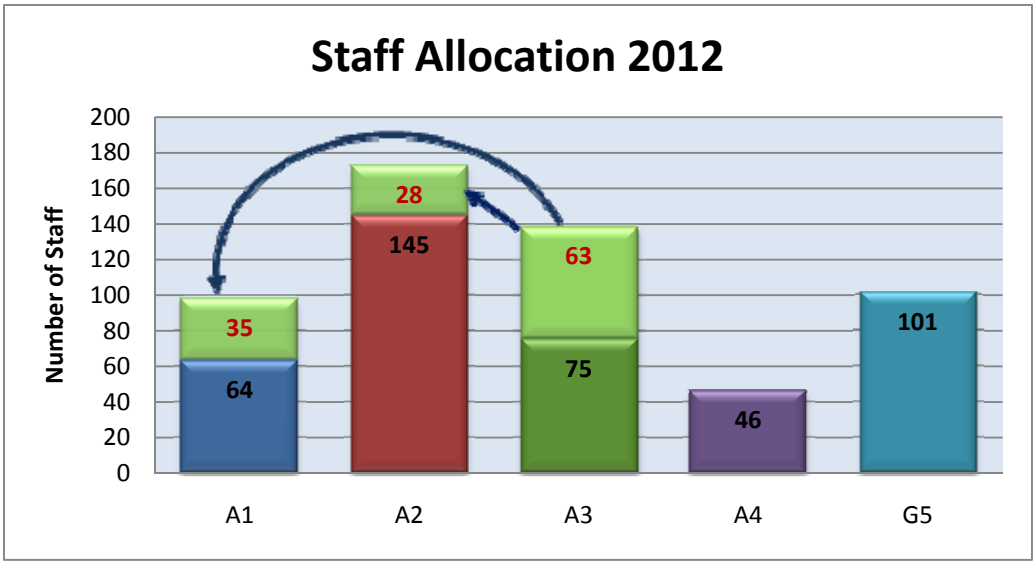
Financial resources 2012

Activity (in M€)	Executed 2010	B2011	PDB 2012 (A3 global)	PDB 2012 (A3 allocated)	%
A1 Scientific opinions & advices	13.05	11.60	11.29	17.87	23%
A2 Evaluation of products	18.55	21.60	18.98	24.66	31%
A3 Data collection & scientific cooperation	23.06	23.21	28.64	16.38	21%
A4 Communication & dialogue	7.85	8.30	7.40	7.40	9%
G5 Governance & Administration	11.30	12.60	13.01	13.01	16%
TOTAL	**73.81**	**77.31**	**79.32**	**79.32**	**100%**



Human resources 2012

Activity (in FTE)	RA	SCA	COM	EXEC	ADMIN	TOTAL 2012	%	B 2011
A1 Scientific opinions & advices	66	17		11	5	99	20.0%	71
A2 Evaluation of products	124	47		2	0	173	35.0%	156
A3 Data collection & scientific cooperation	13	57		3	2	75	15.2%	110
A4 Communication & dialogue			35	4	7	46	9.3%	54
G5 Governance & Administration		0	0	8	93	101	20.5%	103
TOTAL	**203**	**121**	**35**	**28**	**107**	**494**	**100%**	**494**



Annex C: Legislation in force relevant to EFSA and legislation in preparation likely to have an impact on EFSA[6]

I. Legislation in force relevant to EFSA

1. Legislation of a horizontal nature

EFSA Founding Regulation ("The General Food law")
Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1) *[last amended by Regulation (EC) No 596/2009]*

Implementing measures of Regulation (EC) No 178/2002
Commission Regulation (EC) No 1304/2003 of 11 July 2003 on the procedure applied by the European Food Safety Authority to requests for scientific opinions referred to it (OJ L 185, 24.7.2003, p. 6)

Commission Regulation (EC) No 2230/2004 of 23 December 2004 laying down detailed rules for the implementation of European Parliament and Council Regulation (EC) No 178/2002 with regard to the network of organisations operating in the fields within the European Food Safety Authority's mission (OJ L 379, 24.12.2004, p. 64)

Commission Regulation (EU) No 16/2011 of 10 January 2011 laying down implementing measures for the Rapid alert system for food and feed (OJ L 6, 11.1.2011, p. 7)

Other relevant horizontal legislation
Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43)

Regulation (EC) No 1367/2006 of the European Parliament and of the Council of 6 September 2006 on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community institutions and bodies (OJ L 264, 25.9.2006, p. 13)

Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.1.2001, p. 1)

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1; corrected version in OJ L 136, 29.5.2007, p. 3) *[last amended by Commission Regulation (EU) No 143/2011]*

Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004 establishing a European Centre for disease prevention and control (OJ L 142, 30.4.2004, p. 1)

Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1) *[last amended by Regulation (EU) No 1235/2010 of the European Parliament and of the Council]*

Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23) *[amended by Council Decision 2006/512/EC]*

[6] List is not exhaustive.

Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13)

Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009 adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny — Adaptation to the regulatory procedure with scrutiny — Part Four (OJ L 188, 18.7.2009, p. 14)

2. Sectoral legislation

Animal health and animal welfare

Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene (OJ L 35, 8.2.2005, p. 1) *[last amended by Regulation (EC) No 219/2009 of the European Parliament and of the Council]*

Directive 2003/65/EC of the European Parliament and of the Council of 22 July 2003 amending Council Directive 86/609/EEC on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes (OJ L 230, 16.9.2003, p. 32)

Council Directive 2003/85/EC of 29 September 2003 on Community measures for the control of foot-and-mouth disease repealing Directive 85/511/EEC and Decisions 89/531/EEC and 91/665/EEC and amending Directive 92/46/EEC (OJ L 306, 22.11.2003, p. 1) *[last amended by Commission Decision 2011/7/EU]*

Council Directive 2008/119/EC of 18 December 2008 laying down minimum standards for the protection of calves (OJ L 10, 15.1.2009, p. 7)

Directive 2008/97/EC of the European Parliament and of the Council of 19 November 2008 amending Council Directive 96/22/EC concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists (OJ L 318, 28.11.2008, p. 9)

Animal nutrition

Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (OJ L 268, 18.10.2003, p. 29) *[last amended by Regulation (EC) No 767/2009 of the European Parliament and of the Council]*

Commission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives (OJ L 133, 22.5.2008, p. 1)

Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed (OJ L 140, 30.5.2002, p. 10) *[last amended by Commission Directive 2010/6/EU]*

Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption (OJ L 273, 10.10.2002, p. 1) *[last amended by Commission Regulation (EU) No 790/2010]*

Regulation (EC) No 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed, amending European Parliament and Council Regulation (EC) No 1831/2003 and repealing Council Directive 79/373/EEC, Commission Directive 80/511/EEC, Council Directives 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EC and 96/25/EC and Commission Decision 2004/217/EC (OJ L 229, 1.9.2009, p. 1) *[last amended by Commission Regulation (EU) No 939/2010]*

Biological hazards

Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption (OJ L 273, 10.10.2002, p. 1) *[last amended by Commission Regulation (EU) No 790/2010]*

Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (OJ L 147, 31.5.2001, p. 1) *[last amended by Commission Regulation (EC) No 220/2009]*

Contaminants

Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food (OJ L 37, 13.2.1993, p. 1) *[last amended by Commission Regulation (EC) No 596/2009]*

Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs (OJ L 364, 20.12.2006, p. 5) *[last amended by Commission Regulation (EU) No 165/2010]*

Flavourings

Regulation (EC) No 2065/2003 of the European Parliament and of the Council of 10 November 2003 on smoke flavourings used or intended for use in or on foods (OJ L 309, 26.11.2003, p. 1) *[amended by Regulation (EC) No 596/2009 of the European Parliament and of the Council]*

Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC (OJ L 354, 31.12.2008, p. 34)

Food additives

Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorized for use in foodstuffs intended for human consumption (OJ L 40, 11.2.1989, p. 27) *[last amended by Regulation (EC) No 1333/2008 of the European Parliament and of the Council]*

European Parliament and Council Directive 94/36/EC of 30 June 1994 on colours for use in foodstuffs (OJ L 237, 10.9.1994, p. 13) *[last amended by Regulation (EC) No 1333/2008 of the European Parliament and of the Council]*

European Parliament and Council Directive 94/35/EC of 30 June 1994 on sweeteners for use in foodstuffs (OJ L 237, 10.9.1994, p. 3) *[last amended by Commission Directive 2009/163/EU]*
European Parliament and Council Directive No 95/2/EC of 20 February 1995 on food additives other than colours and sweeteners (OJ L 61, 18.3.1995, p. 1) *[last amended by Commission Directive 2010/69/EU]*

Directive 2006/52/EC of the European Parliament and of the Council of 5 July 2006 amending Directive 95/2/EC on food additives other than colours and sweeteners and Directive 94/35/EC on sweeteners for use in foodstuffs (OJ L 204, 26.7.2006, p. 10)

Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 354, 31.12.2008, p. 1)

Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97 (OJ L 354, 31.12.2008, p. 7)

Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16) *[amended by Commission Regulation (EC) No 238/2010]*

Food contact materials

Commission Directive 2002/72/EC of 6 August 2002 relating to plastic materials and articles intended to come into contact with foodstuffs (OJ L 220, 15.8.2002, p. 18) *[last amended by Commission Directive 2011/08/EU]*

Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4) *[amended by Commission Regulation (EC) No 596/2009]*

Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food (OJ L 12, 15.1.2011, p. 1)

Food labelling
Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs (OJ L 109, 6.5.2000, p. 29) *[last amended by Commission Regulation (EC) No 596/2009]*

Commission Directive 96/8/EC of 26 February 1996 on foods intended for use in energy-restricted diets for weight reduction (OJ L 55, 6.3.1996, p. 22)

Council Directive 90/496/EEC of 24 September 1990 on nutrition labelling for foodstuffs (OJ L 276, 6.10.1990, p. 40) *[last amended by Regulation (EC) No 1137/2008 of the European Parliament and of the Council]*

Directive 2009/39/EC of the European Parliament and of the Council of 6 May 2009 on foodstuffs intended for particular nutritional uses (OJ L 124, 20.5.2009, p. 21)

Food supplements
Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51) *[last amended by Commission Regulation (EC) No 1170/2009]*

Genetically modified organisms (GMO)
Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ L 268, 18.10.2003, p. 1) *[last amended by Regulation (EC) No 298/2008 of the European Parliament and of the Council]*

Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (OJ L 268, 18.10.2003, p. 24) *[amended by Regulation (EC) No 1137/2008 of the European Parliament and of the Council]*

Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1) *[last amended by Directive 2008/27/EC of the European Parliament and of the Council]*

Commission Regulation (EC) No 641/2004 of 6 April 2004 on detailed rules for the implementation of Regulation (EC) No 1829/2003 of the European Parliament and of the Council as regards the application for the authorisation of new genetically modified food and feed, the notification of existing products and adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation (OJ L 102, 7.4.2004, p. 14)

Commission Regulation (EC) No 1852/2001 of 20 September 2001 laying down detailed rules for making certain information available to the public and for the protection of information submitted pursuant to European Parliament and Council Regulation (EC) No 258/97 (OJ L 253, 21.9.2001, p. 17)

Human nutrition
Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods (OJ L 404, 30.12.2006, p. 9; corrected version in OJ L 12, 18.1.2007, p. 3) *[last amended by Commission Regulation (EU) No 116/2010]*

Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods (OJ L 404, 30.12.2006, p. 26) *[last amended by Commission Regulation (EC) No 1170/2009]*

Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC (OJ L 401, 30.12.2006, p. 1) *[amended by Commission Regulation (EC) No 1243/2008]*

Directive 2009/39/EC of the European Parliament and of the Council of 6 May 2009 on foodstuffs intended for particular nutritional uses (OJ L 124, 20.5.2009, p. 21)

Novel foods
Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (OJ L 43, 14.2.1997, p. 1) *[last amended by Regulation (EC) No 596/2009]*

Plant health
Council Directive 2000/29/EC of 8 May 2000 on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community (OJ L 169, 10.7.2000, p. 1) *[last amended by Commission Regulation (EU) No 1/2010]*

Plant protection products
Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1) *[last amended by Commission Directive 2011/9/EU]*

Commission Regulation (EC) No 451/2000 of 28 February 2000 laying down the detailed rules for the implementation of the second and third stages of the work programme referred to in Article 8(2) of Council Directive 91/414/EEC (OJ L 55, 29.2.2000, p. 25) *[amended by Commission Regulation (EC) No 1044/2003]*

Commission Regulation (EC) No 1490/2002 of 14 August 2002 laying down further detailed rules for the implementation of the third stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC and amending Regulation (EC) No 451/2000 (OJ L 224, 21.8.2002, p. 23) *[last amended by Commission Regulation (EU) No 741/2010]*

Commission Regulation (EC) No 2229/2004 of 3 December 2004 laying down further detailed rules for the implementation of the fourth stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC (OJ L 379, 24.12.2004, p. 13) *[last amended by Commission Regulation (EU) No 741/2010]*

Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1) *[last amended by Commission Regulation (EU) No 893/2010]*

Commission Regulation (EC) No 647/2007 of 12 June 2007 amending Regulation (EC) No 2229/2004 laying down further detailed rules for the implementation of the fourth stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC (OJ L 151, 13.6.2007, p. 26)

Commission Regulation (EC) No 1095/2007 of 20 September 2007 amending Regulation (EC) No 1490/2002 laying down further detailed rules for the implementation of the third stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC and Regulation (EC) No 2229/2004 laying down further detailed rules for the implementation of the fourth stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC (OJ L 246, 21.9.2007, p. 19)

Commission Regulation (EC) No 33/2008 of 17 January 2008 laying down detailed rules for the application of Council Directive 91/414/EEC as regards a regular and an accelerated procedure for the assessment of active substances which were part of the programme of work referred to in Article 8(2) of that Directive but have not been included into its Annex I (OJ L 15, 18.1.2008, p. 5) *[amended by Commission Regulation (EU) No 78/2010]*

Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1)

Residues of pharmacologically active substances in foodstuffs of animal origin
Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11)

Zoonoses
Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC (OJ L 325, 12.12.2003, p. 31) *[last amended by Commission Regulation (EC) No 219/2009]*
Regulation (EC) No 2160/2003 of the European Parliament and of the Council of 17 November 2003 on the control of salmonella and other specified food-borne zoonotic agents (OJ L 325, 12.12.2003, p. 1) *[last amended by Regulation (EC) No 596/2009]*

II. Legislation in preparation with (expected) relevance for EFSA

1. Legislation of horizontal nature

Proposal for a Regulation of the European Parliament and of the Council regarding public access to European Parliament, Council and Commission documents, COM(2008) 229 final

2. Sectoral legislation

Food labelling
Proposal for a Regulation of the European Parliament and of the Council on the provision of food information to consumers, COM(2008) 40 final

Genetically modified organisms (GMO)
Proposal for a Regulation of the European Parliament and of the Council amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory, COM(2010) 375 final

Novel foods
Proposal for a Regulation of the European Parliament and of the Council on novel foods and amending Regulation (EC) No XXX/XXXX, COM(2007) 872 final (*inter alia* aiming at repealing Regulation (EC) No 258/97)

Annex D: Strategic Objectives and Targets (from *Strategic Plan 2009-2013*)

Activity 1: Provision of Scientific Opinions and Advice and Risk Assessment Approaches

Strategic Objectives 2009-2013

- Focus on providing an integrated approach to delivering scientific advice associated with the food chain from field to plate.
- Position EFSA at the forefront of risk assessment methodologies and practices in Europe and internationally
- Assure the responsiveness, efficiency and effectiveness of EFSA

Targets

- Develop further the multidisciplinary approach to the provision of scientific advice
- Ensure EFSA has access to the full range of expertise and information required to fulfil its mandate
- Harmonise and advance risk assessment methodologies in Europe
- Ensure that EFSA is fully engaged in international forums to keep abreast of innovation in risk assessment and actively contribute to the development of risk assessment methodologies
- Ensure the responsiveness of EFSA

Activity 2: Evaluation of Regulated Products

Strategic Objectives 2009-2013

- Provide timely, high-quality evaluation of products, substances and claims subject to the regulatory authorisation process
- Position EFSA at the forefront of risk assessment methodologies and practices in Europe and internationally
- Assure the responsiveness, efficiency and effectiveness of EFSA

Targets

- Ensure that workflows associated with authorisations are efficient and streamlined
- Assure the quality of EFSA evaluations
- Harmonise and advance risk assessment methodologies in Europe
- Ensure that EFSA is fully engaged in international forums to keep abreast of innovation in risk assessment and actively contribute to the development of risk assessment methodologies

Activity 3: Data Collection, Scientific Cooperation and Networking

Strategic Objectives

- Coordinate the collation, dissemination and analysis of data in the fields within EFSA's remit
- Position EFSA at the forefront of risk assessment methodologies and practices in Europe and internationally

Targets

- Develop and provide access to pan-European databases in the fields within EFSA's remit
- Enhance EFSA's capacity to identify emerging risks
- Harmonise and advance risk assessment methodologies in Europe
- Ensure that EFSA is fully engaged in international fora to keep abreast of innovation in risk assessment and actively contribute to the development of risk assessment methodologies

Activity 4: Communication and Dialogue

Strategic Objectives 2009-2013

- Reinforce confidence in EFSA and contribute to building trust in the EU food safety system through effective risk communication and dialogue with partners and stakeholders.

Targets

- Increase confidence in EFSA and the EU food safety system in general
- Increase coherence and relevance of risk communications messages across the EU
- Enhance dialogue with stakeholders

Glossary

AF – Advisory Forum
AFWGC – Advisory Forum Working Group on Communications
AGRC – Advisory Group on Risk Communication
AHAW Panel – Panel on Animal Health and Welfare
AMU – Assessment Methodology Unit
ANS – Panel on Food Additives and Nutrient Sources Added to Food
BIOHAZ Panel – Panel on Biological Hazards
BSE – Bovine Spongiform Encephalopathy
CEF – Panel on Contact Materials, Enzymes, Flavourings and Processing Aids
CoA – Court of Auditors
CONTAM Panel – Panel on Contaminants in the Food Chain
CRL – Community Reference Laboratory
CVO – Chief Veterinary Officer
DATEX – Data Collection and Exposure Unit
DG ENV – Directorate General Environment
DG RDT – Directorate General Research and Technical Development
DG SANCO – Directorate General for Health and Consumers
DOI – Declaration of Interest
ECDC – European Centre for Disease Prevention and Control
ECB – European Chemicals Bureau
ECHA – European Chemical Agency
EDPS – European Data Protection Supervisor
EEA – European Environment Agency
EMEA – European Medicines Agency
EMRISK – Emerging Risks Unit
END – Seconded National Expert
ENP – European Neighbourhood Policy
ENVI – The European Parliament Committee for Environment, Public Health and Food Safety
EP – European Parliament
ESCO – EFSA Scientific Cooperation projects
FAO – Food and Agriculture Organization
FDA – Food and Drug Administration (US)
FEEDAP Panel – Panel on Additives and Products or Substances Used in Animal Feed
GD – Guidance Document
GMO Panel – Panel on Genetically Modified Organisms
IAS – Internal Audit Service of the European Commission
INEX – Self, Internal and External Quality Review programme
JECFA – Joint FAO/WHO Expert Committee on Food Additives
JEMRA – Joint FAO/WHO Meetings on Microbiological Risk Assessment
JMPR – Joint FAO/WHO Meetings on Pesticide Residues
JRC – Joint Research Centre of the European Commission
MRL – Maximum residue Levels
MS – EU Member States
NDA Panel – Panel on Dietetic Products, Nutrition and Allergies
NGO – Non-Governmental Organisation
OIE – Office International des Epizooties
OECD – Organisation for Economic Cooperation and Development
OJ – Official Journal
PLH Panel – Panel on Plant Health
PPR Panel – Panel on Plant Protection Products and Their Residues
PRA – Pest risk assessment
PRAPeR – Pesticides Risk Assessment Peer Review Unit
QMRA – Quantitative Microbiological Risk Assessment
QPS – Qualified Presumption of Safety
SC – Scientific Committee
SCENIHR – Standing Committee on Emerging and Newly Identified Health Risks
SCO – EFSA Scientific Cooperation Unit
SOP – Standard Operating Procedure
TSE – Transmissible Spongiform Encephalopathy
WHO – World Health Organisation
ZOONOSES – Zoonoses Unit