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European Food Safety Authority

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

Document providing the predicted work of the Authority during 2012

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1. EXECUTIVE SUMMARY

The work programme described herein for 2012, the tenth anniversary of the establishment of the European Food Safety Authority, reflects both the remit given to the Authority in its Founding Regulation[1] as well as the evolving demands on the organisation due to changes in the legislative framework and the operating environment. EFSA's core public health remit in 2012 will be fulfilled with work in a number of diverse areas which reflect the main public health priorities in Europe related to foodborne diseases and nutrition, including, among others, meat inspection, transmissible spongiform encephalopathies, mercury, mycotoxins, zoonoses, dietary reference values and the cumulative risk assessment of chemical mixtures. The evaluation of regulated products and claims will continue to be a prominent feature of the work programme with the evaluation of enzymes and other applications in the areas of food and feed additives, novel foods, genetically modified organisms (GMOs) and pesticides. Increased efficiency in the evaluation of regulated products was one of the main drivers of the organisational restructuring introduced in 2011. It established a directorate to focus specifically on regulated products (Scientific Evaluation of Regulated Products) under which an Applications Desk Unit was established in late 2011 to facilitate interaction with stakeholders, particularly applicants, and to enhance the internal efficiency of this increasingly important aspect of our work. With the Directorate of Risk Assessment & Scientific Assessment focusing on generic public health issues, a third science directorate has also been introduced in the reorganisation, Science Strategy & Coordination, with a view to streamlining the coordination of EFSA's scientific and cooperation activities under one directorate. Its key objectives include the implementation of EFSA's *Science Strategy 2012-2016* and the coordination of EFSA's activities in the area of emerging risks in the food and feed chain.

Notable in 2012 are the renewal of eight of the Scientific Panels and the Scientific Committee and the move to EFSA's New Seat in Parma; a key priority is to ensure no loss of business continuity during the transition periods. The use of tele-meetings in EFSA's scientific work will continue to be promoted to reduce the travel burden of experts and the associated costs and it is expected that ultimately 20% of all "expert days" will be achieved via this mechanism. The independence of its scientific advice is a key priority for the organisation and EFSA will begin to implement its *Policy on Independence and Scientific Decision Making* possibly adopted in 2011.

Efficiency will continue to be a major priority and the e^3 programme[2] will continue with the objective of optimising organisational performance and preparing for future challenges. Three sub-programmes were initiated in 2011: business process mapping, organisational design and integrated performance management and EFSA will begin to see the benefits of these in 2012 with for example the new organisational chart in place, the establishment of a balanced scorecard to monitor organisational performance and enhance priority setting, and the optimisation of business processes. Development of the other components of the e^3 programme will continue in 2012: information technology (IT) management, further right-sizing of science and support activities, and the establishment of a human capital & knowledge management function. Already, an IT investment plan has been prepared covering the period 2012-2014 to facilitate improved strategic planning and monitoring in this critical aspect of EFSA's operations. A fully integrated quality management system will be introduced by 2016, recognising that quality is inherent in EFSA's core values. It will build on the existing INEX (self, internal, and external review) programme and standard operating procedures and will be fully compatible with the ISO 9001 standard. The system will initially cover EFSA's scientific outputs with a target completion date for this component of December 2013; it will then be extended to cover all activities with a view to overall completion by December 2016.

The external evaluation of EFSA currently in progress will provide future direction for the evolution of the working practices of the Scientific Panels, and the possible introduction of fees. The European Commission has included a legislative plan for fees in its work programme for 2012 and it 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 in the third quarter of 2012 and the recommendations will be adopted by the Management Board and implemented by EFSA. In addition, the results of the first phase of the impact assessment exercise will be known and will also provide insight into the future priorities of the organisation.

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 its 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 €9.22 million will be allocated to these activities in 2012, an increase of almost €1 million over last year. In line with the *Science Strategy 2012-2016* and the multiannual perspective provided therein, EFSA will undertake a review of its scientific

[1] Regulation (EC) No 178/2002

[2] EFSA Efficient & Effective

cooperation investment including its operational objectives, programming modalities and prioritisation with a view to adopting a more strategic and multiannual approach to the development of the contracts and grants programme. The programme will prioritise the scientific requirements, both short- and medium-term, for the evaluation of regulated products and the effectiveness of the annual work programme will be measured against the multiannual strategies that are being defined. 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. To facilitate this process, a rolling multi-annual work programme (Multiannual Plan) will be submitted to the Management Board at the end of the first quarter of 2012. 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 and the Platform will be renewed when its current mandate expires in mid-2012. Consultative workshops and technical meetings have proven to be very effective in interacting with stakeholders and, along with public consultations, will continue to be prioritised. One of the suggestions coming from the consultation on the policy was increased openness in the risk assessment process and EFSA is actively considering this proposal. To this end, a feasibility project will be initiated in early 2012 with observers to a limited number of Scientific Panel meetings and the outcomes reviewed.

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 to a wide range of interested parties in cooperation with its institutional partners. While EFSA will avail of the opportunities that arise in the course of the year to highlight its work, a dedicated risk assessment/risk communication event will be held in its New Seat in last quarter of the year as one of the key events to mark the occasion. In relation to risk communication, the focus will be on implementing EFSA's *Communications Strategy 2010-2013* with its emphasis on a more impactful and thematic approach to risk communication.

2. VISION, MISSION AND STRATEGY

2.1 Vision statement

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 statement

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.

2.3 Strategic framework

EFSA's activities are guided by its overarching *Strategic Plan 2009-2013*[3] along with two main specific strategies: *Science Strategy 2012-2016*[4] which lays out the vision of how EFSA will continue to support the European food safety system over the next five years; and the *Communications Strategy 2010-2013*[5] which sets out the long-term communication objectives for the Authority, outlining how these will be achieved and the measures implemented to evaluate success. The strategic objectives and targets from the *Strategic Plan 2009-2013* are listed in Annex D (p. 48).

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

3.1 Overview

The structural reorganisation introduced in 2011, and in particular the creation of the Risk Assessment & Scientific Assistance Directorate, will facilitate the efficient delivery of the work programme related to the core public health risk assessments. Renewal of eight of EFSA's Scientific Panels and Scientific Committee in 2012 will represent a significant

[3]EFSA Strategic Plan 2009-2013, http://www.efsa.europa.eu/en/corporate/pub/strategicplan.htm
[4]EFSA Science Strategy 2012-2016, www.efsa.europa.eu
[5]EFSA Communications Strategy 2010-2013, http://www.efsa.europa.eu/en/keydocs/docs/commstrategyperspective2013.pdf

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 harmonise its risk assessment approaches and to share best practices both internally between the Scientific Panels and externally with other risk assessment bodies. 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. The Scientific Committee, membership of which will be renewed in mid-2012, will provide guidance on a number of issues including the risk assessment of chemical mixtures (the so-called "cocktail effect") and endocrine active substances, hazard characterisation of low-dose effects and the harmonisation of methodologies for environmental risk assessment. EFSA will continue to use its procurement and Article 36 programmes to outsource mainly preparatory work to Member State organisations; in 2012 €2.53 million will be allocated to generic risk assessments.

In relation to the risk assessment work programme, specific features in 2012 will include the provision of animal welfare indicators. The European Commission has called for measurable animal welfare indicators to be assessed to reinforce the scientific basis of EU regulation in this field and EFSA is tasked with delivering opinions on all major farmed species by the end of 2012. The AHAW Panel is cooperating with scientific institutes in the Member States mandated to support EFSA with this major task. These welfare indicators will support decision-making on 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 of poultry will also be an important feature of the work programme; EFSA is assisting the Commission in providing the scientific basis for the modernisation of meat inspection in the EU with a view to introducing a risk-based approach to meat inspection at all relevant stages of the production chain. To fulfil this complex mandate, EFSA is drawing on its expertise in a wide range of fields within its scientific remit: biological hazards, zoonoses, chemical contaminants, and animal health and welfare.

The BIOHAZ Panel will work on several opinions related to transmissible spongiform encephalopathies (TSEs) to enable further adaptation of risk management measures in response to the reduced incidence of BSE. A microbiological risk assessment of fresh produce will be initiated in 2012, while the BIOHAZ and AHAW Panels will undertake a review of the EU Summary Report on Zoonoses and Foodborne Outbreaks. Other priorities will include the adoption 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. In the area of contaminants, risk assessments will cover mercury, natural toxicants and mycotoxins and the re-evaluation of the approximately 100 substances listed in the Annex to Commission Directive 1996/3/EC as acceptable previous cargoes for edible fats and oils. A request for an opinion on risk-benefit assessment of fish is expected and will be prioritised when received. In the plant health area, the PLH Panel will focus on EU-wide plant risk assessments (PRAs) and the evaluation of PRAs by Members States and third countries. In line with EFSA's crisis preparedness procedures, the units that carry out generic risk assessments will respond to urgent scientific requests, as required.

The risk assessment work will be supported by the Scientific Assessment Support (SAS), Biological Monitoring (BIOMO) and Dietary & Chemical Monitoring (DCM) units, all of which were established by the structural reorganisation implemented in 2011. The SAS unit will provide hands-on modelling support following good statistical and epidemiological practices and will continue to work on the development and harmonisation of risk assessment methods including the archiving and harmonisation of best coding practices for the development of statistical programmes and procedures to facilitate maintenance and reuse. The BIOMO unit will provide data for microbiological risk assessments and assist in the data analyses. The DCM Unit will assess dietary exposure to hazardous compounds using occurrence data on contaminants in food and feed and food consumption information stored at an individual level in the Comprehensive European Food Consumption Database. The application of IT tools allowing the effective collection of data in the area of chemical compounds, food consumption and zoonoses as well as the processing of scientific information will be prioritised in 2012 and subsequent years.

3.2 Key performance indicators Activity 1*

Objective	Indicator	Achieved 2010	Expected 2011	Target 2012
Effective delivery of work programme	Number of scientific outputs adopted[6]	66	67	74
Effective use of financial resources**	Proportion of original budget for Activity 1 committed/paid at year end	99%/80%	99%/86%	100%/87%

[6] For a full overview of scientific outputs planned for 2012, see Table 1, pp. 11-12.

Effective execution of grants and procurements programme***	Proportion of original budget for grants and procurements in Activity 1 committed/paid at year end	98%/84%	85%/68%	100%/98%

**For generic indicators for EFSA science activities, see section 5.3 (p. 10). **Global budget including operational, staff and infrastructure costs. ***Includes operational costs only.*

4. ACTIVITY 2: EVALUATION OF REGULATED PRODUCTS

4.1 Overview

The workload associated with the evaluation of regulated products and health claims will remain considerable in 2012. One of the key objectives of the review of EFSA's organisational structure implemented during 2011 is to reflect the prominence of evaluations of regulated products and health claims in the organisation's work programme. Efficiency is of paramount importance, without compromising the scientific quality of the evaluations. The e[3] programme has examined the working practices associated with applications with a view to optimising their efficiency and, in line with the *Science Strategy 2012-2016*, EFSA will allocate more staff in its scientific support units to the evaluation of applications. In addition, the strategic deployment of the contracts and grants programme in the evaluation of regulated products will be increased with a view to outsourcing more preparatory work for opinions while the core scientific skills and responsibilities remain with the Panels. In 2012, EFSA will allocate €1.92 million to contracts and grants in this area. A key development for 2012 is the establishment and full operation of the Applications Desk unit which has a dual purpose: (i) to act as a front office and support desk to enhance the dialogue and quality of service provided to applicants, Member States, stakeholders and other interested parties and (ii) to serve as a back office for the science units working on applications by coordinating and streamlining the registration and administrative tasks associated with applications. The Applications Desk unit will serve another important purpose in harmonising the use of the "stop the clock" mechanism across the EFSA Panels and ensuring that it is applied appropriately. The unit was launched in late 2011 and one of its first tasks has been the establishment of a new helpdesk service on EFSA's website where users can access information on applications and submit specific questions related to the legal and technical requirements for evaluations. 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. As with its generic public health work, 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.

In relation to the specific work of the various Scientific Panels and EFSA units, the newly formed Food Ingredients & Packaging (FIP) unit will provide the scientific secretariat for both the ANS and CEF Panels. In 2012, it will work with the ANS Panel to assess food additives as new products[7] and, in parallel, continue focusing on the re-evaluation of those already in the market[8]. Among the food additives being re-evaluated, the highest priority will be given to the re-evaluation of aspartame (E951). The new guidance on the submission for food additives evaluations will be finalised and the remaining resources will be allocated to the evaluation of nutrient sources. The priority activities for the CEF Panel, working with FIP, will include the following evaluations: plastic food contact materials[9]; recycled materials[10]; active and intelligent packaging[11]; processing aids, flavourings including the re-evaluation of FGE (Flavouring Group Evaluation) 19 and footnote 10 substances[12]; new flavourings[13]; and smoke flavourings[14]. Opinions will be adopted by the BIOHAZ Panel on the assessment of diagnostic tests for TSEs as well as on the efficacy and the development of antimicrobial resistance of substances to be used for the surface decontamination of food of animal origin[15]. The main activities of the FEEDAP Panel will include: the assessment of new feed additives; new uses of existing feed additives; the re-evaluation of existing feed additives; the modification of existing authorisations; and the provision of new/updated guidance for applicants[16]. EFSA will continue to assess applications for the use of GMOs in foods and feeds as well as for cultivation[17] in addition to assessing

[7] Regulation (EC) No 1333/2008
[8] Regulation (EC) No 257/2010
[9] Regulation (EC) No 1935/2004
[10] Regulation (EC) No 282/2008
[11] Regulation (EC) No 450/2009
[12] Article 3 of Regulation (EC) No 1565/2000
[13] Art 3 of Regulation (EC) No 1331/2008
[14] Art 8 of Regulation (EC) No 2065/2003
[15] Regulation 853/2004
[16] Regulation (EC) No 1831/2003
[17] Regulation (EC) No 1829/2003 and Directive 2001/18/EC

their safe use[18] and providing assessments of post-market environmental monitoring. A guidance document for applicants regarding genetically modified animals will be published and work will commence on a guidance document for the environmental risk assessment of GM animals. With regards nutrition, the NDA Panel will adopt opinions on Article 14 and 13.5 claims, novel foods, and the re-evaluation of some Article 13 heath claims. In addition, further guidance will be provided on the scientific requirements for health claims, beginning with an update of the guidance document for novel food applications.

The evaluation of regulated products and claims will be supported by the SAS and DCM units. In particular, SAS will provide statistical reviews of dossiers submitted to EFSA and will prioritise the development of guidance for statistical reporting and templates for reviewing. DCM will assist the Panels in evaluating exposure calculations submitted by industry in support of applications and will focus on harmonising existing exposure methodologies used by the various Panels as much as possible. The Pesticides unit (created in the reorganisation of 2011 by the merger of the former PRAPeR and PPR units) will finalise, in consultation with the Member States, the programme for the delivery of conclusions on substances of stage 4 of the review programme of existing active substances[19] for which EFSA has to deliver a conclusion by the end of 2012[20]. Another priority 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[21]. The first conclusions for new active substances[22] are expected in 2012. The development and revision of harmonised risk assessment methodologies and guidance documents for pesticides in the area of human and environmental toxicology will continue. Other priorities will include the cumulative risk assessment of pesticide residues and risk assessment methodology for bees and other pollinators.

4.2 Key performance indicators Activity 2*

Objective	Indicator	Achieved 2010	Expected 2011	Target 2012
Effective delivery of work programme	Number of scientific outputs adopted[23]	331	369	351
Effective use of financial resources**	Proportion of original budget for Activity 2 committed/paid at year end	99%/93%	99%/92%	100%/92%
Effective execution of grants & procurements***	Proportion of original grants and procurements budget for Activity 2 committed/paid at year end	94%/79%	89%/72%	100%/97%

**For generic indicators for EFSA science activities, see section 5.3 (p.10). **Global budget including operational, staff and infrastructure costs. ***Includes operational costs only.*

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

5.1 Overview

The principal objective of the new directorate of Science Strategy & Coordination is to implement EFSA's *Science Strategy 2012-2016* which lays out the vision of how EFSA will continue to support the European food safety system over the next five years and meet the demands that are placed upon it. To practically support the implementation of the strategy, a number of key initiatives are proposed, beginning in 2012, which include the provision of training in key risk assessment areas for both Panel members and staff and the introduction of an enhanced knowledge management programme. A review of investment planning in scientific cooperation will be undertaken with a view to adopting a more strategic and multiannual approach in line with the *Science Strategy 2012-2016*. Through the identification of strategic multiannual investment areas, based on the scientific requirements of both EFSA and Member States, the contracts and grants programme will be more effectively deployed with a focus on areas with particularly heavy workloads such as the evaluation of regulated products. The current Scientific Committee will finalise its work programme with a guidance document on terminology in risk assessment and it is anticipated that some of its ongoing activities (e.g. compendium of botanicals, technical guidance in the area of statistical approaches) will continue under the new Scientific Committee. The Scientific Committee will play an important role in several subjects of a cross-cutting nature including *inter alia* an update of its opinion on the risks of animal cloning; general guidance on the scientific aspects of evaluations of multi-sectoral issues; and the state of the science of

[18] Regulation (EC) No 1831/2003
[19] Included in Annex I to Directive 91/414/EEC
[20] Regulation (EC) No 2229/2004
[21] Evaluated under Regulation (EU) No 188/2011
[22] Evaluated under the new Regulation (EC) No 1107/2009
[23] For a full overview of scientific outputs planned for 2012, see Table 1, pp. 11-12.

emerging methodologies and alternative tools for risk assessment. In order to facilitate the development of a multi-annual programme for the Scientific Committee, internal task forces have been created to review the latest developments in the various areas, whereas other preparatory work has been outsourced in the areas of chemical mixtures and "-omics" technologies (e.g. genomics and proteomics). It is also anticipated that the Scientific Committee will play a more prominent role in the assessment of emerging risks with support from EFSA's Emerging Risks unit.

EFSA's activities in the identification of emerging risks will be based on the strategy outlined in the 2010 *Emerging Risks Report* and in the *Science Strategy 2012-2016*. The Emerging Risks 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. In the area of international cooperation, EFSA's activities will focus on the development of harmonised risk assessment methodologies, identification of emerging issues and participation in international data collection networks. In relation to crisis preparedness, a crisis training and simulation exercise will be organised with Member States. The procedures for responding to urgent requests will be tested and, if necessary, revised building on the experience gained from both simulation exercises and actual events. The Advisory Forum and Scientific Cooperation unit (AFSCO) will continue to strengthen scientific cooperation and networking with Member States and pre-accession countries in order to share workloads and exchange scientific data and information. This cooperation facilitates dialogue with the national food safety authorities and provides access to expertise and competent organisations within the Member States. The AFSCO Unit will organise scientific colloquia on relevant subjects and build awareness of EFSA's scientific outputs by seeking indexation of the *EFSA Journal* in more bibliographic databases. In addition, it will manage EFSA's 2011–2013 Pre-Accession Programme and initiate the 2012–2014 European Neighbourhood Programme. EFSA will continue to build networks of scientific excellence and strengthen electronic tools such as the Information Exchange Platform (IEP) to facilitate collaboration with Member States, engage their experts, avoid any duplication of effort and prevent any unnecessary divergence of views.

The EFSA Networks[24] 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 and the mandate of the Stakeholder Platform which expires in mid-2012 will be renewed. The Scientific Committee unit will organise meetings of the nanotechnology network and the network for the harmonisation of risk assessment. It will also lead an internal project to prepare a technical report on the state of the science of new and emerging methodologies and tools for risk assessment and their applicability to the human risk assessment of chemicals. This report will form one of the starting points for the development of a multi-annual work programme of the Scientific Committee.

The DCM unit will support the risk assessment work carried out by the Scientific Panels, in particular for CONTAM and in the evaluation of regulated products, by contributing to the collection and analysis of occurrence data and to the assessment of exposure. In addition, it will 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. The food classification system developed in 2010-2011 will be progressively implemented in EFSA activities and made available to the Member States. 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 relation to EU Menu, the pan-European food consumption survey project, the outcome of the pilot projects will be summarised and preparation activities in Member States will be supported. To further implement evidence-based, systematic and transparent approaches to risk assessment and in line with the guidance document on systematic reviews, the SAS unit will continue to allocate a significant amount of resource to providing methodological and hands-on support for systematic literature reviews including training for experts and staff. The SAS unit will also prioritise work on providing guidance for the development of a framework for expert knowledge elicitation, a crucial element of the risk assessment process. Additional priorities for SAS will be the continuation of its work, started in 2011, on the harmonisation and quality assurance of environmental monitoring and specific projects on the use of farmers' associations to detect adverse events.

One of the key mandates for the Biological Monitoring unit (also established in the recent reorganisation) is on meat inspection, specifically the task of proposing human health epidemiological indicators for biological hazards related to meat inspection; in 2012 this will focus on poultry, cattle, sheep and goats, horses and farmed game. During 2012, the analysis of results from the EU-wide baseline survey on *Listeria monocytogenes* in ready-to-eat foods will be started. Two annual EU

[24] For further information, see http://www.efsa.europa.eu/en/networks/supportingunits.htm.

summary reports on zoonoses and food-borne outbreaks and antimicrobial resistance will be produced, in close collaboration with ECDC. In 2012, the unit will take greater responsibility for the annual data analyses and 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 (extensible mark-up language) 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. The unit will also support the Commission in the development of harmonised monitoring schemes for antimicrobial resistance.

In relation to pesticides, the priority objectives for 2012 will include the timely delivery of reasoned opinions on proposals for new or the amendment of existing maximum residue levels (MRLs) and applications 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, the Pesticides unit will continue to support the preparatory work for the Codex Committee Meeting on Pesticide Residues (CCPR meeting).

5.2 Key performance indicators Activity 3

Objective	Indicator	Achieved 2010	Expected 2011	Target 2012
Effective delivery of work programme	Number of scientific outputs adopted[25]	111	154	175
Effective use of financial resources**	Proportion of original budget for Activity 3 committed/paid at year end	98%/80%	92%/78%	100%/89%
Effective execution of grants and procurements programme***	Proportion of original grants and procurements budget for Activity 3 committed/paid at year end	96%/75%	88%/71%	100%/95%

**For generic indicators for EFSA science activities, see section 5.3 (below). **Global budget including operational, staff and infrastructure costs. ***Includes operational costs only.*

5.3 Generic key performance indicators for science activities

Objective	Indicator	Achieved 2010	Expected 2011	Target 2012
Timeliness of scientific advice	Proportion of scientific outputs adopted within deadline	85%	85%	90%
	Proportion of scientific outputs[26] finalised and published in the *EFSA Journal* within 15 working days of adoption	70%	87%	90%
Compliance with declaration of interest (DOI) policy	Proportion of experts with approved annual DOI (aDOI) before first meeting invitation	99%	100%	100%
	Proportion of experts with approved specific DOIs (sDOI) before participation in an EFSA meeting	99%	100%	100%

From screening of aDOIs and sDOIs, 290 conflicts of interest were prevented from January to September 2011. Mitigation measures taken included exclusion of experts from working groups, meetings, meeting agenda items or other restrictions.

5.4 Risks to delivery of EFSA's scientific work programme

EFSA's ability to deliver its scientific work programme depends on a number of factors, in particular the timely receipt of mandates, the timely enactment of European legislation, the quality of the applications received, the number of "stop the

[25] For a full overview of scientific outputs planned for 2012, see Table 1, pp. 11-12.

[26] Excludes outputs released in batches; data for outputs with additional communications activities (e.g. press releases, web news items) are reported in section 6.3 on p.13.

clocks" (i.e. delays in the evaluation procedure to request additional information from the applicant) required during application assessments as well as the timely and efficient delivery of reports by external recipients of grants and contracts. In relation to the "stop the clock" procedure - one of the main causes of delays in delivery of scientific outputs - EFSA is assessing its use to ensure that the mechanism is being applied appropriately. This will enhance the predictability of outputs in the planning cycle. In addition, one of the objectives of the newly established Applications Desk is to harmonise the use of the mechanism across EFSA. In relation to progress tracking and reporting, EFSA will begin to implement its Balanced Scorecard in 2012, which will provide a better mechanism to monitor organisational performance and "work in progress" than previously and facilitate the identification of priorities. EFSA is faced with a number of requests for urgent advice or technical assistance such as the *E. coli* (STEC) outbreaks in 2011. While the Authority has put in place a policy for urgent advice as well as crisis preparedness procedures, such events can cause reprioritisation of work. Annex A of this Management Plan includes information on resource allocation for the delivery of urgent advice or assistance to facilitate planning activities.

6. ACTIVITY 4: COMMUNICATION AND DIALOGUE

6.1 Overview

The key objective for 2012 will be the continuing implementation of the *Communications Strategy 2010-2013* which emphasises EFSA's core communications remit and the adoption of a more proactive, thematic and impactful approach in areas such as zoonoses, GMOs, the safety of chemicals used in the food chain such as pesticides as well as corporate issues such as the independence of EFSA's scientific advice. The reorganisation of the Communications Directorate, and in particular the creation of two functional units (Editorial & Media Relations and Communication Channels), will streamline content development, editorial services and information dissemination and will be instrumental in enhancing efficiency and impact. EFSA will aim to reflect the more thematic approach on its website and to broaden the user base to include a wider range of stakeholders and interested parties. In line with the approach introduced in *Communications Strategy 2010-2013*, a video series – provisionally entitled *Understanding Science* – will be launched to cover key thematic areas such as zoonoses, GMOs and health claims, and aimed primarily at lay audiences with an interest in EFSA's work. 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 audiences. Furthermore, EFSA will continue to enhance dialogue with stakeholders and increase audience interactivity.

Table 1: Predicted scientific outputs and supporting publications 2012[27]

	APDESK	FEED	FIP	GMO	NUTRI	PRAS	AHAW	BIOHAZ	BIOMO	CONTAM	DCM	PLH	SAS	AFSCO	EMRISK	SCOM	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	-	5	4	-	9	-	14	9	-	12	-	12	-	-	-	4	**69**
Scientific Report of EFSA	-	-	-	-	-	-	-	-	1	-	-	-	2	-	-	-	**3**
Statement of EFSA	-	-	-	-	-	-	-	-	-	1	-	-	-	-	-	-	**1**
Total Activity 1	**-**	**5**	**4**	**-**	**9**	**-**	**14**	**9**	**1**	**13**	**-**	**13**	**2**	**-**	**-**	**4**	**74**
Activity 2 Evaluation of products, substances and claims subject to authorisation																	
Conclusion on Pesticide Peer Review	-	-	-	-	-	77	-	-	-	-	-	-	-	-	-	-	**77**
Guidance of the Scientific Committee / Scientific Panel	-	4	2	1	4	7	-	-	-	-	-	-	-	-	-	-	**18**
Opinion of the Scientific Committee / Scientific Panel	-	68	108	16	51	5	-	8	-	-	-	-	-	-	-	-	**256**
Total Activity 2	**-**	**72**	**110**	**17**	**55**	**89**	**-**	**8**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**351**

[27] For Scientific Panel and EFSA Unit acronyms see Glossary, p. 51.

Table 1: Predicted scientific outputs and supporting publications 2012 (*continued*)

	APDESK	FEED	FIP	GMO	NUTRI	PRAS	AHAW	BIOHAZ	BIOMO	CONTAM	DCM	PLH	SAS	AFSCO	EMRISK	SCOM	Total
Activity 3. Data Collection, scientific cooperation and networking																	
Guidance of EFSA	-	-	-	-	-	-	-	-	-	-	-	-	1	-	-	-	**1**
Reasoned Opinion	-	-	-	-	-	169	-	-	-	-	-	-	-	-	-	-	**169**
Scientific Report of EFSA	-	-	-	-	-	1	-	-	3	-	-	-	1	-	-	-	**5**
Total Activity 3	**-**	**-**	**-**	**-**	**-**	**170**	**-**	**-**	**3**	**-**	**-**	**-**	**2**	**-**	**-**	**-**	**175**
Other publications																	
Event report	4	-	-	3	-	-	4	3	-	-	-	-	-	1	-	-	**15**
External Scientific Report	-	-	-	-	4	4	3	4	7	1	14	2	3	1	2	-	**45**
Internal Report	1	-	-	3	-	-	-	-	8	-	8	-	30	17	-	-	**67**
Technical report	-	-	1	10	11	1	-	3	4	-	-	1	1	6	2	-	**40**
Total other publications	**5**	**-**	**1**	**16**	**15**	**5**	**7**	**10**	**19**	**1**	**22**	**3**	**34**	**25**	**4**	**-**	**167**
Total outputs	**5**	**77**	**115**	**33**	**79**	**264**	**21**	**27**	**23**	**14**	**22**	**16**	**38**	**25**	**4**	**4**	**767**

The dissemination of risk communication guidelines developed in collaboration with the Member States will support greater coherence in risk communication approaches. EFSA will also initiate work on the development of a lexicon of risk assessment terms, again in collaboration with national risk communicators. 2012 represents the 10th anniversary of EFSA's inception and this will be marked by activities throughout the year and, in particular, the organisation of a risk assessment/risk communication conference in Parma in the last quarter of the year in coincidence with 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. The use of social media which was introduced in late 2011 will continue with a view to increasing the outreach of EFSA news items via new routes such as Twitter. 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 EFSA's image and perception of its 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, consultative workshops, technical meetings and other means.

6.2 Risks to delivery of the communications and dialogue work programme

To ensure the effectiveness of its online communications and extend its outreach, the availability of effective IT support is crucial and EFSA will need to optimise the use of existing resources in this regard. The structural reorganisation carried out in 2011 is also critical to the delivery of the communications work programme and the effectiveness of the functions will be regularly monitored. A new framework contract for multimedia services will start at the beginning of 2011 and its implementation will also need to be closely monitored.

6.3 Key performance indicators for communication

Objective	Performance Indicator	Achieved 2010	Expected 2011	Target 2012
Effective use of financial resources*	Proportion of original Communications budget committed/paid at year end	66%/45%	81%/52%	99%/65%
Effective delivery of communication outputs/Enhanced simplicity	*Understanding Science* video series	NA	NA	35
Timeliness	Proportion of press releases/web news items accompanying scientific outputs delivered within 20 working days of adoption[28]	24%	45%	60%
Visibility/Outreach	Web visits	3.0 million	3.2 million	3.4 million
	Bibliographic databases indexing the *EFSA Journal*	3	4	5
	Newsletter subscriptions	27,000	28,000	29,000
Transparency	Number of public consultations	91	95	100
Effectiveness of communication	Message penetration and tracking[29]:			
	1. One key message taken up by media	95%	94%	90%
	2. Two key messages taken up by media	85%	57%	60%
	Based on the following outputs:			
	Number of press releases and web stories	75	77	80

*****O*perational costs only.*

[28] This indicator covers press releases and web news items on a number of key selected scientific outputs and does not include outputs released in batches such as health claim opinions.

[29] Data for 2011 refer to the period October to December only.

7. GOVERNANCE AND SUPPORT ACTIVITIES

7.1 Overview

Governance

One of the key objectives for 2012 is the completion of the next phases of the efficiency programme (e^3), focusing on phases 2 and 3 of the right sizing exercise covering scientific activities, resource management and centralised support activities; enhancement of EFSA's control environment; and documentation and harmonisation of science processes. Among the outcomes of the reorganisation of 2011 has been the strengthening of the planning and monitoring and quality functions at the levels of the Executive Office and Directorates. In addition to its strategic and institutional relations roles and the provision of the secretariat for the Management Board, the Office now embraces the centralised monitoring and reporting of organisational performance; in this task it is supported by Planning & Monitoring teams that have been established at directorate level. The Balanced Scorecard established in 2011 will be fully implemented and it will provide an effective basis for monitoring organisational performance and setting priorities. In 2012, EFSA will review its existing strategic initiatives to integrate these into an overall planning tool and will develop a Multi-Annual Workplan covering all its activities. The groundwork for establishing a fully integrated quality management system centred on EFSA's core values has been laid in 2011. It builds on the existing INEX (self, internal, and external review) programme and standard operating procedures and will be fully compatible with the ISO 9001 standard. An operating framework has been developed in 2011 and will be implemented in 2012 with a view to delivering a system that will initially cover EFSA's scientific outputs by December 2013. It will then be extended to cover all activities with a view to overall completion by December 2016.

Resources and Management of Risks

The principles of sound financial management and allocation of resources in accordance with policy objectives will continue to guide EFSA's financial activities and resource allocation. The control environment will be further adapted to: seek more proportionality to risks; adapt and support the deployment of Planning and Monitoring teams at directorate level; and monitor performance in the implementation of the control environment by the different actors through *ex-post* auditing. The management of the deployment of the Internal Control Standards framework will be integrated within the Financial and Contractual Management instrument in the Finance Unit. As regards accounting and treasury management, the Authority will continue to adhere closely 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 Commission's Internal Audit Service and other EU institutions. It will ensure efficient implementation of payment transactions, collection of revenue and recovery of amounts. 2012 will be a crucial year for activities related to managing Human Capital and Knowledge. Priority will be given to promoting a modern and efficient human capital policy, developing and making best use of all talents (internal and external workforces) in a healthy working environment. In addition, an integrated strategy will be implemented aimed at providing a strong basis for staff development through specialised training in order to acquire new knowledge and skills. To that end, a knowledge management strategy will be developed to support the internal and external workforce. The installation of a personal data repository and its integration with existing human resource workflows will greatly enhance efficiency and is one of key objectives for 2012.

The legal and regulatory challenges in 2012 in relation to scientific decision making processes will focus on ensuring the legal soundness of authorization procedures and other regulatory processes. A review of the legal compliance of the governance documents related to all EFSA processes will be carried out and new governance documents will be draw up covering, for example, the implementation of the *Policy on Independence and Scientific Decision Making Processes*, with a view of mitigating risks deriving from decisions based thereon. The implementing acts of the *Policy on Independence and Scientific Decision Making Processes* will be drafted in early 2012. This entails the provision of legal support for the implementation of the grant and procurement awarding procedures, contracts and agreements; the assurance of coherent legal processing related to transparency and access to document requests; the legal soundness and the provision of legal analysis for all decisions pertaining to human resources; and the reinforcement of the ethical advice function in-house to monitor and drive respect for EFSA's ethical standards.

The wide range of laws and regulated procedures applicable to EFSA in the area of regulated products, along with the adoption of new legislation and the increased scrutiny by stakeholders, require the enhancement of working processes regarding the identification, surveillance and mitigation of legal risks. This will be implemented by reinforcing the legal clearance processes for all relevant outputs and processes that will guarantee the identification and management of compliance issues in the legal and regulatory field. Further to the signature of the Final Purchase Agreement in December 2011, EFSA is expected to have moved to its New Seat building during the Christmas break in late 2011. EFSA staff will start operating from its new headquarters on 5 January 2012. The complete release of current premises will be achieved in February 2012. Operating from its own premises, EFSA has access to a larger and more versatile set of meeting rooms equipped to carry out audio, video and web conferences: this includes eight meeting rooms equipped with audio/video/web conference facilities and a Management Board room (40

seats) equipped for professional filming and broadcasting, high-end sound system, six translation booths, a display of up to 12 different television channels, and a centralised voting system. EFSA will consolidate its efforts to provide increased transparency in information technology (IT) governance, and will develop an IT strategy. The Authority will improve the capacity of conceptualization and definition of IT solutions before starting developments by establishing proper business analysis capabilities in the directorates, in order to support the objective that 92.5% of projects will be delivered within time and budget. EFSA will seek to increase the quality and customer satisfaction rating of IT solutions deployed with a target customer satisfaction rating of at least 80%. A disaster recovery site will be activated in the current premises (DUSB), making fully redundant the critical systems and in addition providing 40 workstations to fulfil peak requests of guest (external) workers and emergency office spaces.

Centralised support for scientific and communication activities

In January 2012, in line with the planning of the new EFSA organisational structure and with the objective of enhancing efficiency, previously de-centralised support services i.e. maintenance of the premises, logistic and general services, logistic aspects for the organisation of events and linguistic proofreading will be gradually centralised in the Corporate Services (CORSER) unit. Moreover, in the course of 2012, EFSA will pursue the development of technical tools that will allow the implementation of centralised support services for the organisation of meetings and travel.

7.2 Risks to delivery

The main risks to delivery of the work programme for governance and support activities in 2012 encompass timely implementation of the new organisational model, right-sizing of resources and system availability. While moving towards a new approach to Human Capital and Knowledge Management, it is crucial to ensure business continuity with the available capacity of knowledge workers and IT tools. In relation to IT, risks associated with the first release of the proposed personal data repository and its integration with existing human resources workflows will be mitigated by conducting a proof of concept phase, appointing a dedicated IT Requirement Specialist and IT Project Manager, and ensuring a phased migration of existing data. For the purpose of providing *a priori* verification of the legality and regularity of scientific outputs and processes and the monitoring of ethical standards, EFSA will review its workflows as part of the e^3 programme to ensure that legal input is provided at the appropriate junctures.

7.3 Key performance indicators for governance and support activities

Objective	Indicator	Achieved 2010	Expected 2011	Target 2012
Effective use of governance & support financial resources*	Proportion of original budget committed/paid at year end	100%/84%	100%/80%	100%/85%
Effective use of EFSA financial resources	Execution of overall EFSA budget:			
	• Commitments	98.8%	99.0%	99.0%
	• Payment credits requested from DG SANCO	98.7%	98.9%	99.0%
	• Carry forward of payments to following year	16.5%	20.0%	16.0%
Enhanced skill profile of staff	Ratio of knowledge workers** /support workers	0.60	0.60	0.62
Efficient use of IT resources	Projects delivered within budget and deadline	85%	90%	92.5%
Development of an integrated performance management system (IPM)	Milestones of implementation reached within deadline (e.g. in 2011 these represented the establishment of an agreed declaration of intent and operating framework)	Partially achieved	Achieved	Achieved

*****O*perational costs only. **Defined as staff at AD and FG4 grades and seconded national experts.*

Submitted for adoption in Warsaw, Poland
on 15 December 2011

For the EFSA Management Board

Prof. Diána Bánáti
Chair of the Management Board

ANNEXES

Annex A: Detailed deliverables per activity

Activity 1: Provision of scientific advice

Subject	Expected outcome	Number		FTE	Direct operational costs (€ k)
		Finalised in 2012	Ongoing		
AHAW					
Welfare risks associated with transport of fish (species specific)	Opinion of the Scientific Committee / Scientific Panel	3	4	1.5	138
Animal-based welfare indicators: beef and calves, laying hens and broilers	Opinion of the Scientific Committee / Scientific Panel	4	4	1.5	74
Vector borne diseases: leishmaniasis, Crimean-Congo haemorrhagic fever, African horse sickness and equine encephalosis, West Nile Virus	Opinion of the Scientific Committee / Scientific Panel	2	2	1.5	172
Risk assessment in support of the new animal health law: swine vesicular disease and vesicular stomatitis, foot and mouth disease, comment on the zoonosis summary report, bovine tuberculosis	Opinion of the Scientific Committee / Scientific Panel	4	6	4.25	145
Meat inspection revision, implications for animal health and welfare (poultry, solipeds, bovine, farmed games, small ruminants)	Opinion of the Scientific Committee / Scientific Panel	1	5	4	88
Aquatic animal health: Comparative risk of viral haemorrhagic septicaemia and infectious salmon anaemia strains	Opinion of the Scientific Committee / Scientific Panel	0	1	1	24
Ad hoc or urgent advice and scientific assistance		0	0	0.25	0
Total		**14**	**22**	**14**	**640**
BIOHAZ					
Foodborne zoonoses including antimicrobial resistance	Opinion of the Scientific Committee / Scientific Panel	1	6	3.8	192
Food hygiene including meat inspection	Opinion of the Scientific Committee / Scientific Panel	4	8	4	232
TSE opinions, e.g. mandates related to the TSE road map	Opinion of the Scientific Committee / Scientific Panel	3	5	1.5	83
Qualified presumption of safety (QPS)	Opinion of the Scientific Committee / Scientific Panel	1	1	0.5	40
Ad hoc or urgent advice		0	0	0.25	0
Total		**9**	**20**	**10.05**	**546**
Biological Monitoring Unit					
Meat inspection mandate - defining epidemiological indicators	Scientific Report of EFSA	1	5	3	107
Assistance to EFSA Panels	Internal Report	6	8	1	0
Total		**7**	**13**	**4**	**107**
CONTAM					
Contaminants in food and feed (mycotoxins and natural plant toxicants)	Opinion of the Scientific Committee / Scientific Panel	4	6	3.55	268
Contaminants in food (mercury, brominated flame retardants, mineral hydrocarbons, meat inspection, bottled seawater and previous cargoes)	Opinion of the Scientific Committee / Scientific Panel	7	10	7	417
Contaminants in feed	Opinion of the Scientific Committee / Scientific Panel	0	1	0.25	18
Pharmacologically active substances covered by Regulation (EC) 470/2009 Art. 19 (1)	Opinion of the Scientific Committee / Scientific Panel	1	1	0.25	21

Subject	Expected outcome	Number		FTE	Direct operational costs (€ k)
		Finalised in 2012	Ongoing		
Anticipated need for urgent requests on contaminants in food	Statement of EFSA	1	1	0.25	0
Total		**13**	**19**	**11.3**	**724**
Dietary & Chemical Monitoring					
Support for specific opinions	Internal Report	5	8	2	0
Total		**5**	**8**	**2**	**0**
FEED					
Feed additives: nutritional, sensory	Opinion of the Scientific Committee / Scientific Panel	5	10	1.5	18
Total		**5**	**10**	**1.5**	**18**
Food Ingredients & Packaging					
Anticipated need for urgent generic requests related to food additives and nutrient sources	Opinion of the Scientific Committee / Scientific Panel	2	2	0.4	27
Anticipated need for urgent generic requests (Art. 29)	Opinion of the Scientific Committee / Scientific Panel	2	2	1.5	69
Total		**4**	**4**	**1.9**	**96**
Nutrition					
Dietary reference values for energy, protein and micronutrients (plenary)	Opinion of the Scientific Committee / Scientific Panel	5	5	1.5	45
Dietary reference values for energy, protein and micronutrients (working group)	Opinion of the Scientific Committee / Scientific Panel	0	0	0	41
Public consultation on dietary reference value opinions for energy and protein	Technical report	2	2	0.5	0
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	1	1	0.5	12
Allergen risk assessment (thresholds for allergens)	Opinion of the Scientific Committee / Scientific Panel	0	1	0.5	13
Tolerable upper intake levels for certain micronutrients	Opinion of the Scientific Committee / Scientific Panel	3	3	1	37
Total		**11**	**12**	**4**	**147**
PLH					
Evaluation/peer review of pest risk assessments (PRAs) and other justification documents prepared by Member States or Third Countries	Opinion of the Scientific Committee / Scientific Panel	0	1	0.5	35
Preparation of PRAs and evaluation of risk reduction options for review of Annex II A of Directive 2000/29/EC (Liriomyza trifolii, Liriomyza huidobrensis, Erwinia chrysanthemi pv, dianthicola, Pseudomonas caryophylli, Phialophora cinerescens, Puccinia horiana, Scirrhia pini, Chrysanthemum stunt viroid)	Opinion of the Scientific Committee / Scientific Panel	8	8	3	219
Preparation of PRAs and evaluation of risk reduction options for the EU territory (Bemisia tabaci, potato cyst nematodes, tospoviruses, soil/growing media)	Opinion of the Scientific Committee / Scientific Panel	3	4	4.5	248
Evaluation of options to reduce pest risks	Guidance of the Scientific Committee / Scientific Panel	1	1	0.75	36
Update of the guidance document on harmonised framework for pest risk assessment	Guidance of the Scientific Committee / Scientific Panel	0	1	0.75	64

Subject	Expected outcome	Number		FTE	Direct operational costs (€ k)
		Finalised in 2012	Ongoing		
Ad hoc or urgent advice and scientific assistance	Opinion of the Scientific Committee / Scientific Panel	1	1	0.25	0
Total		**13**	**16**	**9.75**	**602**
Scientific Assessment Support					
Support for generic opinions	Internal Report	10	15	2	23
	Scientific Report of EFSA	2	2	1	21
Total		**12**	**17**	**3**	**44**
Scientific Committee Unit					
Preparation of scientific advice on horizontal subjects and risk assessment approaches (animal cloning, statistical approaches, risk assessment terminology, thresholds of toxicological concern, compendium of botanicals, etc.)	Opinion of the Scientific Committee / Scientific Panel	4	6	8	600
Workshops/meetings on horizontal issues	Workshop/meeting reports	0	2	1.5	62
Editorial Board meeting		0	0	0	5
Mandates Review Committee teleconferences (Chair of Scientific Committee)		0	0	0	5
Total		**4**	**8**	**9.5**	**672**
Information Technology					
Develop IT tools to support reporting risk assessment activities (Risk Assessment Workflows, Declaration of Interest tool)	Development of IT tools to support reporting and monitoring for risk assessment	0	0	1.5	957
Maintain IT tools to support risk assessment activities	Maintenance of existing IT applications	0	0	1.5	338
Total		**0**	**0**	**3**	**1295**

Activity 2: Evaluation of regulated products

Subject	Expected outcome	Number		FTE	Direct operational costs (€ k)
		Finalised in 2012	Ongoing		
Applications Desk					
Meetings with applicants	Event report	3	3	6	53
Launching of Applications Desk Unit Phase 2	Event report	1	1	3	37
Total		**4**	**4**	**9**	**90**
BIOHAZ					
TSE diagnostic tests	Opinion of the Scientific Committee / Scientific Panel	2	2	0.2	15
Animal by-product (ABP) applications	Opinion of the Scientific Committee / Scientific Panel	4	4	3	130
Decontamination dossiers	Opinion of the Scientific Committee / Scientific Panel	2	3	1	49
Total		**8**	**9**	**4.2**	**194**
Dietary & Chemical Monitoring					
Support for the evaluation of products, substances and claims	Internal Report	3	3	2	0
Total		**3**	**3**	**2**	**0**

Subject	Expected outcome	Number		FTE	Direct operational costs (€ k)
		Finalised in 2012	Ongoing		
FEED					
New additives or new uses for a feed additive (Article 4 of Regulation (EC) 1831/2003)	Opinion of the Scientific Committee / Scientific Panel	11	12	2	58
Re-evaluation of existing feed additives (Article 4 and Art 10 of Regulation (EC) 1831/2003)	Opinion of the Scientific Committee / Scientific Panel	46	65	10.15	704
Modification of existing authorisations (Article 13 of Regulation(EC) 1831/2003)	Opinion of the Scientific Committee / Scientific Panel	6	7	1.75	49
Requests associated with negative/inconclusive opinions under Regulation (EC) 1831/2003	Opinion of the Scientific Committee / Scientific Panel	5	7	1.75	30
New guidance on support for applicants in the preparation and presentation of applications (covering additional issues not included in previous guidance documents) and one administrative guidance document	Guidance of the Scientific Committee / Scientific Panel	4	5	1.75	26
Total		**72**	**96**	**17.4**	**867**
Food Ingredients & Packaging					
Additives: new applications	Opinion of the Scientific Committee / Scientific Panel	3	4	0.9	59
Additives: re-evaluation	Opinion of the Scientific Committee / Scientific Panel	15	30	6.4	320
Additives: Guidance on submission for food additives evaluations	Guidance of the Scientific Committee / Scientific Panel	1	1	0.25	23
Additives: Aspartame	Opinion of the Scientific Committee / Scientific Panel	1	1	2.2	66
Evaluation of nutrient sources and other substances	Opinion of the Scientific Committee / Scientific Panel	4	4	0.9	65
Plastic food contact material substances (Regulation 1935/2004)	Opinion of the Scientific Committee / Scientific Panel	13	13	2	112
Recycling of food contact materials: existing and new processes (Regulation 282/2008 Art 5)	Opinion of the Scientific Committee / Scientific Panel	21	21	3.5	96
Active and intelligent packaging materials (Regulation 450/2009 Art 8)	Opinion of the Scientific Committee / Scientific Panel	2	2	0.75	18
Processing aids/Decontaminants	Opinion of the Scientific Committee / Scientific Panel	2	2	0.75	18
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	2	258
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	64
Plastic food contact material substances: revision of guidance	Guidance of the Scientific Committee / Scientific Panel	1	1	1	25
Total		**110**	**126**	**21.65**	**1123**
GMO					
Applications received under Directive 2001/18/EC, Regulation 1829/2003, 1831/2003 and 1331/2008 and renewal of GM plant application.	Opinion of the Scientific Committee / Scientific Panel	10	80	16.25	584

Subject	Expected outcome	Number		FTE	Direct operational costs (€ k)
		Finalised in 2012	Ongoing		
EC requests related to new techniques and post-market environmental monitoring reports	Opinion of the Scientific Committee / Scientific Panel	5	5	2.5	188
Guidance on applications relating to the environmental risk assessment of GM animals	Guidance of the Scientific Committee / Scientific Panel	1	1	3	217
EC requests related to applications including safeguard clauses	Opinion of the Scientific Committee / Scientific Panel	1	3	0.5	21
EFSA overall opinions on applications (Regulation 1829/2003)	Technical report	9	9	0.5	0
Public consultation on guidance document (GD) for environmental risk assessment of GM animals	Technical report	1	1	0.5	0
Scientific workshop on allergenicity	Event report	1	1	0.25	8
Total		**28**	**100**	**23.5**	**1019**
Nutrition					
Safety assessment of Novel Foods (EC 258/97)	Opinion of the Scientific Committee / Scientific Panel	5	5	1.5	63
Novel Foods (EC 258/97): update of guidance document for preparation of Novel Foods application	Guidance of the Scientific Committee / Scientific Panel	0	0	0.5	30
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	0	0	0	21
Article 14 and 13.5 claims (Health Claims Regulation, EC 1924/2006)	Opinion of the Scientific Committee / Scientific Panel	15	15	4.5	148
Response to comments on published health claims applications	Technical report	5	5	0.5	0
Re- evaluation Article 13 claims (EC 1924/2006)	Opinion of the Scientific Committee / Scientific Panel	30	30	5	102
Guidance on scientific requirements for health claims	Guidance of the Scientific Committee / Scientific Panel	4	4	2	59
Public consultation on guidance on scientific requirements for health claims	Technical report	4	4	0.5	0
Other applications (allergies, infant formulae; Directive 2000/13/EC; Directive 2006/141/EC)	Opinion of the Scientific Committee / Scientific Panel	1	1	0.5	42
Meetings with Stakeholders on health claims	Event report	0	1	0.2	11
Total		**64**	**65**	**15.2**	**476**
Pesticides Unit					
Update and development of risk assessment methodology and guidance (opinion of the Panel)	Opinion of the Scientific Committee / Scientific Panel	5	13	4	269
Update and development of risk assessment methodology and guidance (guidance of the Panel and of EFSA)	Guidance of the Scientific Committee / Scientific Panel	7	14	4	271
Reg. 1107/2009, Art. 12 (placing of plant protection products on the EU market)	Conclusion on Pesticides Peer Review	0	5	1	0
Reg. 188/2011, Art. 8 (assessment of active substances)	Conclusion on Pesticides Peer Review	48	69	22	275
Reg. 2229/2004, Art. 25a (implementation of the fourth stage of the programme for placing plant protection products on the EU market)	Conclusion on Pesticides Peer Review	23	23	5.4	100

Subject	Expected outcome	Number		FTE	Direct operational costs (€ k)
		Finalised in 2012	Ongoing		
Reg. 1107/2009, Art. 23(4) ((placing of plant protection products on the EU market)	Conclusion on Pesticides Peer Review	3	4	1	0
Post-approval activities	Conclusion on pesticide peer review	3	4	0.5	0
Pesticide Steering Committee	Technical report	1	1	0	37
Total		**90**	**133**	**37.9**	**952**
Scientific Evaluation of Regulated Products					
Support Service for applicants	Enhancement of the services provided by EFSA to applicants	0	3	0	NA
Total		**0**	**3**	**0**	**NA**
Scientific Assessment Support					
Support for the evaluation of products, substances and claims	Internal Report	10	15	2.75	1
Total		**10**	**15**	**2.75**	**1**
Information technology					
Development of IT tools to support Application Desk processes	IT tools successfully developed	0	0	1.5	1190
Maintenance of IT tools to support Application Desk processes	IT tools successfully maintained	0	0	1.5	338
Total				**3**	**1528**

Activity 3: Data collection, scientific cooperation and networking

Subject	Expected outcome	Number		FTE	Direct operational costs (€ k)
		Finalised in 2012	Ongoing		
Applications Desk					
Development of questionnaires targeted for APDESK	Internal Report	1	1	1	170
Total		**1**	**1**	**1**	**170**
AHAW					
Systematic reviews as preparatory work for AHAW mandates	External Scientific Report	2	2	0.4	60
Member State collaboration with AHAW network	Technical report	0	1	0.75	62
Proofreading of opinions		0	0	0	22
Workshop on methodological approach of Risk Assessment for emerging issues in animal and plant health	Event report	1	1	0.75	16
Methodological aspects of validation of indicators for animal welfare (dependent on available resources)	External Scientific Report	NA	NA	NA	NA
Stakeholder consultation and technical meetings (fish welfare during transport)	Event report	1	1	0.5	19
Update and upgrade of AHAW database on vector borne diseases	External Scientific Report	1	1	0.3	50
Data collection to characterise the impact of canine leishmaniasis and modelling of the role of animals in spreading Leishmania infantum within the European Union	External Scientific Report	0	1	0.3	200

Subject	Expected outcome	Number		FTE	Direct operational costs (€ k)
		Finalised in 2012	Ongoing		
Animal-based welfare indicators (technical hearing)	Event report	2	2	1	33
Total		**7**	**9**	**4**	**463**
BIOHAZ					
Proofreading and scientific editing of adopted opinions		0	0	0	5
Preparatory work to support the BIOHAZ Panel in particular on the risk of intestines for casings and on fresh produce	External Scientific Report	4	6	1.2	356
Member State collaboration with microbiological risk assessment (MRA) and TSE networks	Technical report	3	3	0.4	60
Workshops with stakeholders on food hygiene issues	Event report	3	3	0.15	11
Total		**10**	**12**	**1.75**	**432**
Biological Monitoring Unit					
Community Summary Reports on zoonoses and food-borne outbreaks	External Scientific Report	4	4	0.8	220
	Scientific Report of EFSA	1	2	3.5	51
Community Summary Reports on antimicrobial resistance	External Scientific Report	1	1	0.3	233
EU Summary Reports, reporting manuals	Technical report	2	2	0.5	0
Baseline survey preparation and analyses	External Scientific Report	0	1	0.2	100
	Scientific Report of EFSA	0	3	2	35
		1	2	2	28
Other data analyses reports	External Scientific Report	1	1	0.1	0
Database and reporting applications	External Scientific Report	0	11	0.6	400
	Technical Report	1	1	0.5	18
	Web reporting application, data warehouse, XML schemas	0	0	0.25	20
	Internal Report	2	2	0.7	7
Meat inspection mandate: defining epidemiological indicators	External Scientific Report	1	4	0.3	0
Proof reading		0	0	0	30
Harmonisation of monitoring and reporting	Scientific Report of EFSA	1	2	1	32
Development of analytical methods for the annual data	Scientific Report of EFSA	0	1	0.5	1
Coordination of networks of Zoonoses Data Collection	Technical report	1	1	0.5	51
Ad hoc or urgent advice and scientific assistance		0	0	0.25	0
Total		**16**	**38**	**14**	**1225**
CONTAM					
Alternaria toxins - data needs identified in order to refine risk assessment (genotoxicity test)	External Scientific Report	0	1	0.3	227

Subject	Expected outcome	Number		FTE	Direct operational costs (€ k)
		Finalised in 2012	Ongoing		
Influence on processing on nitrate levels in vegetables	External Scientific Report	1	1	0.1	54
Proofreading and scientific editing of adopted opinions		0	0	0	3
Mineral hydrocarbons toxins - data needs identified in order to refine risk assessment	External Scientific Report	0	1	0.3	209
Total		**1**	**3**	**0.7**	**493**
Dietary & Chemical Monitoring					
Access to high performance probabilistic calculation computer service	External Scientific Report	4	5	0.2	50
EU Menu: IARC (International Agency for Research on Cancer) support phase 3	External Scientific Report	1	1	0.3	114
Support to Member States 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	0.4	220
Harmonisation of exposure assessment methodology expert meetings	Internal exposure methodology report	0	0	4.75	76
Updating and completing the standard sample description (SSD) catalogues, including methods of analysis	External Scientific Report	1	1	0.2	50
Harmonisation of exposure assessment methodology maintenance	Internal exposure methodology report	0	0	4	101
Preparation for the EU Menu project on food consumption data collection methods, including capacity building	External Scientific Report	1	3	0.8	600
Exposure calculations using high performance IT tools	Internal Report	0	0	1	0
Assistance to Member States to map database structures to EFSA requirements and to submit data using the XML protocol.	External Scientific Report	3	5	0.6	180
Ad hoc or urgent advice and scientific assistance	Internal exposure assessment report	0	0	0.25	0
Updating the comprehensive food consumption database by incorporating recently collected data in adults and children	External Scientific Report	3	3	1	240
Post marketing monitoring chemicals: framework contract (dependent on available resources)		NA	NA	NA	NA
2012 specific contract under framework contract for post marketing monitoring	External Scientific Report	1	1	0.3	155
Dietary monitoring tool for risk assessment	External Scientific Report	0	1	0.2	250
Total		**14**	**23**	**14**	**2036**

Subject	Expected outcome	Number		FTE	Direct operational costs (€ k)
		Finalised in 2012	Ongoing		
FEED					
Proofreading of opinions	External Scientific Report	0	0	0.2	15
Systematic literature review on the bioavailability of trace elements combined or as a component of animal diet	Technical report	0	0	0.5	85
Feed additive/feed material applications in the area of nanotechnologies. Preparatory documents for the Guidance on the Risk Assessment of Feed Additives derived from Nanotechnologies	Technical report	0	0	0.4	80
Feed additives that have direct beneficial effects on the environment	Technical report	0	0	0.5	100
Bibliographic review on the effects of additives/substances on the immune system of animals. Parameters to measure efficacy for additives which have a “beneficial effect” on the animal’s immune system	Technical report	0	0	0.5	100
Total		**0**	**0**	**2.1**	**380**
Food Ingredients & Packaging					
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	1.9	0
Outsourcing: Editing and proofreading of draft opinions	Proof reading of draft opinions	15	15	0.2	15
Outsourcing: Bibliography reports on BPA	Preparatory work	0	0	0.5	NA
Outsourcing: Preparatory work to support the ANS Panel 2nd specific contract under multiple framework contract 2011	Preparatory documents to serve as basis for opinions	0	5	0.4	120
Additives: Calls for data in accordance with regulation (EU) 257/2010		0	8	0.9	0
Outsourcing: Preparatory work to support the ANS Panel - 3rd SC under the Multiple FWC 2011	Preparatory documents	0	6	0.4	145
Additives: Public consultation on the draft guidance on submission for food additives evaluations by the ANS Panel	Technical report	1	1	0.15	1
Outsourcing: CEF bibliography reports on BPA	Preparatory work	0	0	0.5	0
Outsourcing: CEF literature screening on phtalates	Preparatory work	0	0	0	15
Outsourcing: CEF food contact materials - preparation of non-toxicological summary data sheets	Preparatory work	0	0	1.25	35
Outsourcing: CEF – food contact materials: preparation of toxicological summary datasheets	Preparatory work	0	0	1.25	40

Subject	Expected outcome	Number		FTE	Direct operational costs (€ k)
		Finalised in 2012	Ongoing		
Outsourcing: CEF Methodological support to risk assessment approaches	External Scientific Report	0	0	0	40
Outsourcing: CEF Food Enzymes: preparation of Summary Documents including toxicity and non-toxicity data	Preparatory work	0	0	0	40
Outsourcing: CEF Collection of data on flavourings and preparation of summaries	Preparatory work	0	0	1	200
Outsourcing: CEF electronic archiving of Flavis files	Archiving	0	0	0	20
Outsourcing: CEF Scientific proofreading of FGEs	Opinion of the Scientific Committee / Scientific Panel	0	0	0	20
Total		**16**	**55**	**8.45**	**691**
GMO					
Data collection and methodology support in risk assessment of GM animals	External Scientific Report	0	1	0.5	150
Procurement: initial risk assessment of renewal applications to be received under regulations 1331/2008 & 1332/2008 as well as regulation 1831/2003 art 10	Internal Report	3	11	0.5	30
Statistical support for evaluation of risk assessment of GMO dossiers	Internal Report	0	12	0.5	45
Proofreading of opinions		9	9	0	15
Support for workshop (moderation, report preparation)	Event report	1	1	0	5
Literature review of Allergenicity related studies focusing on non-IgE mediated food allergy and in vitro digestibility tests	External Scientific Report	0	2	0.25	60
Review of the criteria for the comprehensive food and feed safety and nutritional assessment of GM plants	External Scientific Report	0	1	0.25	65
EFSA-Member State GMO scientific risk assessment network	Event report	1	1	0.5	36
Total		**14**	**38**	**2.5**	**381**
Nutrition					
Outsourcing Scientific Cooperation related to data collection on novel foods	External Scientific Report	0	1	0.2	80
Outsourcing for Preparatory work for allergen risk assessment	External Scientific Report	0	1	0.2	80
Outsourcing: Preparatory work related to dietary reference values for micronutrients	External Scientific Report	4	7	0.2	40
Outsourcing: Preparatory work for health claims application	External Scientific Report	0	0	0.2	25
Total		**4**	**9**	**0.8**	**225**

Subject	Expected outcome	Number		FTE	Direct operational costs (€ k)
		Finalised in 2012	Ongoing		
Pesticides Unit					
Scientific support, literature and data collection for RA on microbial organisms used as Plant Protection Products	External Scientific Report	0	5	1	120
Outsourcing : Support for preparing guidance documents for pesticide risk assessment	External scientific report	0	0	0.5	NA
Collection of pesticide application data in view of performing environmental risk assessments for pesticides	External Scientific Report	0	1	1	240
Toxicological data analysis supporting establishment of cumulative assessment group of pesticides	External Scientific Report	3	3	0.5	72
Literature review on epidemiological studies linking exposure to pesticides and health effects	External Scientific Report	0	1	0.5	80
Reg. 396/2005, Art. 32 (maximum residue levels of pesticides in food and feeds)	Scientific Report of EFSA	1	4	2	94
Reg. 396/2005, Art. 12	Reasoned Opinion	89	156	2.5	155
Reg. 396/2005, Art. 10	Reasoned Opinion	75	75	3	0
Reg. 396/2005, Art. 43	Reasoned Opinion	5	5	0.5	0
Outsourcing: use of guidance peer reviewed open literature	External Scientific Report	1	1	0.1	90
Development of software models in support of the guidance document estimating predicted environmental concentrations in soil	External Scientific Report	0	1	0.5	125
Total		**174**	**252**	**12.1**	**976**
PLH					
Outsourcing: extensive literature searches and data collection activities to support pan-European pest risk assessments for PLH Panel scientific opinions	External Scientific Report	1	2	0.4	195
Proofreading and scientific editing of adopted opinions		0	0	0	5
Development of pest risk assessment methodologies to support PLH scientific opinions - new call 2012	External Scientific Report	0	1	0.3	293
Art 36 project: Pest risk assessment for the European Community plant health: A comparative approach with case studies Project acronym: Prima phacie	External Scientific Report	1	1	0.2	0
Art 36 project: “Plant health pest surveys for the EU territory: an analysis of data quality and methodologies and the resulting uncertainties for pest risk assessment”. Project acronym: Perseus	External Scientific Report	0	1	0.3	0

Subject	Expected outcome	Number		FTE	Direct operational costs (€ k)
		Finalised in 2012	Ongoing		
Procurement: CFT/EFSA/PLH/2011/03 on "Development of probabilistic models for quantitative pathway analysis of plant pest introduction for the EU territory"	External Scientific Report	0	2	0.6	0
Service level agreement with the Joint Research Centre Institute for Environmental Sustainability to support EFSA PLH Panel scientific opinions for the assessment of the EU environmental suitability for exotic plant pests	External Scientific Report	0	1	0.2	0
Member state collaboration with PLH Network	Technical report	1	1	0.25	48
Total		**3**	**9**	**2.25**	**541**
Scientific Assessment Support					
Assistance for statistical analyses and ad hoc consultation on statistics; framework contract ongoing from previous year	External Scientific Report	2	3	0.4	46
Access to databases and publications	Scientific papers, subscriptions to e-journals, e-databases and other science reviews	0	0	1	250
Further implementation of systematic approaches to support risk assessment: framework contract to be launched in 2012.	External Scientific Report	0	3	0.6	250
Approaches in environmental monitoring	External Scientific Report	0	2	0.6	155
Development of new and harmonised risk assessment methods (dependent on available resources)	External Scientific Report	NA	NA	NA	NA
Harmonisation of risk assessment methods	Guidance of EFSA	1	1	0.75	26
	Scientific Report of EFSA	1	2	1.25	6
	Technical report	1	1	0.5	0
List scientific literature relevant to food and feed safety research and training on searching techniques for systematic reviews	External Scientific Report	1	1	0.4	100
Extensive literature searches and systematic review support	Internal Report	10	12	3.5	1
Working Group on guidelines for expert knowledge elicitation in food and feed safety risk assessment.	Guidance of EFSA	0	1	2	34
Ad hoc urgent advice and scientific assistance		0	0	0.25	0
Total		**16**	**26**	**11.25**	**868**

Subject	Expected outcome	Number		FTE	Direct operational costs (€ k)
		Finalised in 2012	Ongoing		
Information technology (IT)					
Develop IT tools to support data collections and support for scientific opinions (Data Collection Framework, Zoonoses Community Report, Pesticides Community Report, Data Warehouse, Databases deriving from Art. 36 grants and procurements).	Development of existing IT tools (Data Collection Framework, Zoonoses Community Report, Pesticides Community Report, Data Warehouse, Databases deriving from Art. 36 grants and procurements)	0	0	2	1560
	Maintenance of existing IT tools Data Collection Framework, Zoonoses Community Report, Pesticides Community Report, Data Warehouse, Databases deriving from Art. 36 grants and procurements)	0	0	1	344
IT tool development and maintenance to support organisational networking	Maintenance of existing IT tools (Information Exchange Platform, Article 36 database, expert database)	0	0	0	328
Total		**0**	**0**	**3**	**2232**
Advisory Forum and Scientific Cooperation Unit					
Advisory Forum plenary meetings	Minutes of the meetings	4	4	2.5	240
Management of 29 contracts with EU/EEA/EFTA Member States	Technical report	1	1	1	760
Focal Point plenary meetings and management of the network	Minutes of the meetings	0	0	1.75	73
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.	0	0	2.5	0
European Neighbourhood Policy (ENP)	Support ENP countries in developing risk assessment and in starting cooperation with EFSA	0	0	0.5	0
Other Advisory Forum related meetings	Minutes of the meetings	2	2	0.5	30
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	0
	Internal Report	12	12	0.5	0
	Technical report	1	1	0.5	5
Organisation of scientific events	Event report	1	1	0.5	0
Training Sessions, Guest Lectures	Technical report	1	1	0	149
Recognition and visibility of EFSA's scientific work	EFSA Journal indexation in databases	0	0	1	0
	Technical report	1	1	0.5	0

Subject	Expected outcome	Number		FTE	Direct operational costs (€ k)
		Finalised in 2012	Ongoing		
Article 36 network	Management of List of Art. 36 competent organisations (updated)	0	0	0.5	0
	Management of two IT tools: (1) Art 36-NET on ScienceNet and (2) Art 36 database	0	0	0.5	0
Article 36 and procurement WP	Technical report	1	1	1.5	0
Ad hoc or urgent advice and scientific assistance	Internal Report	1	1	0.25	0
Training activities under Science Strategy	External Scientific Report	1	1	0.5	218
Total		**31**	**31**	**17.5**	**1475**
EMRISK					
Crisis assistance	External Scientific Report	0	0	0.3	85
	Technical report	1	1	0.7	14
Development of the Emerging Risks identification process	Technical report	1	2	2.3	32
Data sources and hazard databases	External Scientific Report	0	1	0.3	90
Emerging risks exchange with MS	External Scientific Report	1	1	1	46
Emerging Risk Identification	External Scientific Report	0	1	0.3	250
Emerging Risks exchange with Stakeholders	External Scientific Report	1	1	0.3	9
Standing Working Group of the Scientific Committee	Scientific Report of EFSA	0	1	4.8	30
Total		**4**	**8**	**10**	**555**
Scientific Strategy & Coordination					
Stakeholder Consultative Platform (Brussels)	Strengthen stakeholder consultation processes	0	0	0.4	29
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	0	0	1	17
Stakeholder Platform (Parma)	Strengthen stakeholder consultation processes	0	0	0.4	14
Stakeholder WG	Strengthen stakeholder consultation processes	0	0	0.2	7
Total		**0**	**0**	**2**	**67**
Scientific Committee Unit					
Annual meeting of the nanotechnology network	Event report	0	1	0.25	30
Network for harmonisation of risk assessment and related WG	Event report	0	1	0.25	30
Total		**0**	**2**	**0.5**	**60**

Activity 4: Communication and dialogue

Subject	Expected outcome	Performance indicator	FTE	Direct operational costs (€ k)
Communication Channels				
Improve overall understanding of EFSA work within context of EU food safety system	Corporate multimedia products	1 video	0.5	60
	"Understanding Science" video clips	35 video clips	0.2	25
Enhance simplicity and usability of EFSA website and online services	Ensure technical accessibility	22 projects	0.4	0
	Increase availability, relevance and understanding of digital information	108 projects	1.75	76
	Monitoring and evaluation of online communications	24 evaluation reports	0.4	0
	Multimedia, publications and image management	11 projects	0.2	0
Enhance transparency, visibility and understanding of EFSA's operations and outputs through online media	Audio/webcasting of Management Board and other key meetings	7 audio/ webcasts	0.5	0
	Raise visibility and increase reach of digital information	81 projects	1.25	0
	Website content management and publishing	7500 updates	2.8	0
Internal communications support	Intranet management Portal content managed by Editorial Committee Enhanced internal communication through the use of appropriate tools	1000 updates Portal user satisfaction survey rating increased Reduced queries to human resources functions	1	0
Visibility and recognition of EFSA's work	Newsletters	50 issues	0.5	70
	Scientific publications (reports, colloquium reports, posters etc.)	45 publications	1.5	157
Improve overall understanding of EFSA activities within context of EU food safety system	Corporate publications (including all EU languages versions)	60 publications	2	154
Total			**13**	**542**
Core communication activities				
Evaluation of EFSA-related media coverage	Media monitoring and analysis reports (monthly and annual)	14 (12 monthly reports + 2 ad hoc reports)	0	242
Enhanced understanding of EFSA's target audiences and consumer risk perception	Quantitative and qualitative target audience research; research on communication outputs	1 study	0.5	100
Support for development of EFSA's communications strategy	Advisory Group on Risk Communication (AGRC) meetings	3 meetings	0.8	24

Subject	Expected outcome	Performance indicator	FTE	Direct operational costs (€ k)
Ensure coherent risk communications through close liaison with EU institutions, national food safety authorities and international partners	Advisory Forum Communications Working Group (AFWGC) meetings	4 meetings	1.2	92
	Exchanges with relevant partners on pre-notification of opinions	50 pre-notifications	0.2	0
Co-ordinate strategic and operational planning and budgeting	Communications calendars, plans, procurements and budget	20 procedures, meetings	4.3	0
Ensure effective implementation of Communications Strategy 2010-2013, including thematic approach	Thematic and other communication plans	85 press releases, web news items and handling plans	1	0
Total			**8**	**458**
Editorial & Media Relations				
Evaluation of EFSA-related media coverage	Analyses of media coverage	14 analyses	1.25	NA
Build media relationships to achieve better understanding and coverage of EFSA	Media training for scientists	4 training sessions	0.2	NA
	Press contacts database	1 database	0.3	NA
Communicate EFSA scientific advice to the media	Media responses to questions/interviews	800 responses	2	NA
	Media relations / face-to-face meetings / press briefings	8 meetings	2.25	NA
Development of communications handling plans and content	Scientific content	30 outputs	1.5	NA
	Corporate content	10 outputs	1	NA
	Thematic approach	8 outputs	2	NA
	Internal Communications	100 outputs	0.2	NA
	Ask EFSA	1000 queries	0.3	NA
Total			**11**	**NA**
Corporate Services Unit				
Media relations events	Face-to-face meetings with the media	6 meetings	0	12
	Press briefings	2 press briefings	0	20
Scientific events	EFSA participation in scientific conferences	4 conferences	0.3	80
	Scientific Colloquia	2 meetings	0.5	160
Events with Member States	Joint events with National Food Agencies	4 events	0.75	50
Local/community events	Festa dell'Europa	1 event	0.2	30
Other corporate events	Social events/VIP events	5 events	0.3	30
10 year anniversary event	Inauguration new building / 10 year anniversary (including events, corporate brochure etc.)	1 event	1.5	95
Stakeholder events	Workshop with stakeholders	1 workshop	0.3	40
Events communications tools	Photo-shooting	25 photo services	0.1	5
	Production of EFSA promotional event materials	25,000 items	0.05	50

Subject	Expected outcome	Performance indicator	FTE	Direct operational costs (€ k)
Events audio/webcasting	Audio/Webcasting of Management Board and other key meetings		0	180
Total			**4**	**752**
Information Technology				
Develop IT tools to track the interactions with EFSA audiences	Develop IT tracking tools	N/A	1.5	130
Maintain Web presence	Maintain web presence	N/A	1.5	328
Total			**3**	**458**

Governance and support activities

Subject	Expected outcome	Performance Indicator	FTE	Direct operational costs (€ k)
Executive Office				
Management Board (MB) meetings	Organisation of four Management Board meetings	Timely delivery of the MB documents, meeting minutes and publication according to agreed guidelines	1.1	136
MB members attending other meetings	Attendance at non-MB meetings	Effective organisation of attendance to meet requirements of members	0	14
Research in the area of Quality Management/ISO 9000/EFQM	Development and implementation of an Integrated Quality Management System	Number of implemented standard operating procedures (SOPs), work instructions (WINs)	0	15
Foresight and associated studies	Ensure that EFSA is aware of its changing environment and can prepare accordingly Identify issues of relevance to EFSA's future planning	Five in-depth reports Associated studies Planning exercise successfully carried out	2	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	18 "What's Next" reports delivered Impact assessment tools reviewed and progress delivered to Management Board in 2012	1	40
Total			**4.1**	**235**
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	Adoption of the audit plans by the Audit Committee	0.5	NA

Subject	Expected outcome	Performance Indicator	FTE	Direct operational costs (€ k)
Perform internal audit engagements	Advise EFSA on managing risks to improve the implementation of operations and promote sound financial management Provide independent opinions and recommendations on the quality of management and control systems	Percentage of audit reports reviewed by the Audit Committee	0.5	NA
Follow-up of audits	Follow up and report at each Audit Committee meeting on the level of completion of accepted audit recommendations	Percentage of recommendations implemented/closed for the Internal Audit Service of the European Commission (IAS), European Court of Auditors (ECA) and the EFSA Internal Audit Capabilities	0.5	NA
Liaison function	Coordinate audit activities with external auditors and audit bodies including the IAS and ECA Provide the contact point between EFSA and OLAF (European Anti-Fraud Office).	Feedback from auditees and auditing bodies obtained through a satisfaction survey	0.5	NA
Total			**2**	**NA**
Accounts				
Execution of payments and collection of revenue Accounting Management	Efficient execution of payments Monitor and report to Management	Payment delays less than 3.0 days	2.7	NA
Establishment of EFSA accounts	EFSA annual financial accounts report	Publication of EFSA final accounts in the Official Journal	0.5	NA
Liaison with Court of Auditors (CoA)	Accounts prepared in accordance with the Financial Regulation and Commission accounting rules	CoA findings free of material misstatement Positive statement of assurance on EFSA annual accounts	0.3	NA
ABAC (accrual-based accounting) implementation	ABAC implementation	Successful implementation	0.5	NA
Total			**4**	**NA**
Finance				
Maintenance of Financial systems	ABAC annual fee, data warehouse fee - LEF and BAF fees	Readily access to data warehouse and on-time registration of LEF BAF	0	125
Efficiency Initiative	Critically review EFSA workflows and working processes, review organisational structure, implement improvements	Reports on efficiency discussed in the Steering Committee and recommendations implemented	0	100
Workshop on Internal Control standards	High level Risk Management Workshop	Action plan on risk mitigation	0	30

Subject	Expected outcome	Performance Indicator	FTE	Direct operational costs (€ k)
Budgetary & Financial Management	Management of budgetary and financial cycles Optimisation of the commitment, invoicing and payment operations Realise efficiency gains in the management of the centralised budget lines and enhance support to the organisation Ensure integration of local systems with ABAC financial system	Definition of budget requirements, elaboration of budget planning in support of the multiannual work plan Monitoring of optimum allocation of financial resources Further development of supporting IT applications, ensuring legality and regularity of budget planning, execution and monitoring Efficient and timely execution of financial operations Preparation of local systems for automatic upload of payments in the financial system	8	NA
Financial control	Development and implementation of Financial Regulations, policies and procedures Supervision of budgetary expenditure and financial operations in line with sound financial management Financial verification and control Internal Control Standard monitoring Financial training	Ensure full compliance with the Financial Regulation and related guides or procedures and train the staff Monitoring of effective utilisation of the financial resources Provide efficient, effective and timely financial verification Review, monitoring and reporting on the internal control systems Maintain liaison and cooperation with audit structures	7	NA
Procurement & Grant Management	Provide support and guidelines to the organisation with regards to all aspects of procurement and grants Ensure legality and regularity of procurements and grants procedures Disseminate knowledge and best practice through training and streamlined procedures Management of the procurement and grant database Delivery of comprehensive reporting	Ensure compliance and coherence of call for tenders, contract management with regulations Implementation of Public Procurement Committee recommendations Integration of all procurement procedures in the procurement and grant database	5	NA
Total			**20**	**255**

Subject	Expected outcome	Performance Indicator	FTE	Direct operational costs (€ k)
Human Capital & Knowledge Management (HUCAP)				
Manage rights and obligations	Further streamline and enhance efficiency in the internal processes and procedures to ensure a coherent implementation of and effective compliance with the rules laid down in the Staff Regulations and respect of data protection rules	Payroll processing error rate <= 0.5% Proportion (%) of agreed audit recommendations on which actions have been implemented Standard staff requests executed within 5 working days Average number of days of sick leave	5	248
Further develop and update of the individual job descriptions and EFSA's competency catalogue	Facilitation of the process for the harmonisation of job descriptions Inventory of staff competencies (e.g. update of e-CVs)	At least 80% of individual job descriptions updated in the revised format	2	30
Enhance the "added value" of the Human Capital and Knowledge Management unit	Manage social dialogue and health and safety at work Move closer to customers and stakeholders in order to better understand their needs by fostering a commitment to being a service partner, advisor and consultant and by focusing on the delivery of effective and efficient services Further develop the professionalism of HUCAP	100% Staff Committee requests are considered and initiated within 5 working days Release of HUCAP Scorecard as part of the development of more comprehensive and accurate metrics helping the planning and decision-making process Publication of HUCAP newsletter Define an 'HR Academy"	3.5	30
Setting up of a modern and effective e-HR tool	Launch of the e-HR tool for human capital management Business needs development of the e-HR tool for Knowledge Management	Improved integration and efficiency through the use of e-HR tool services helping to reduce the administrative burden and to improve organisational processes. Information and services are integrated in order to optimise their cost-benefit ratio	1.5	15
Manage deployment of staff within the zero-growth context	Define a workforce planning approach Manage around 20 recruitment procedures /internal mobility to further accompany the EFSA reorganisation Manage secondment procedures to EFSA for seconded national experts (ENDs) and national experts in professional training (NEPTs)	95% of posts in the Establishment Plan are filled Bridge-building towards the objective of 70% knowledge worker-30% administrative worker Average length of time to fill vacancies (months) 80% of satisfied declared staff of the induction process	4	155

Subject	Expected outcome	Performance Indicator	FTE	Direct operational costs (€ k)
	Manage selection of experts/renewal of Panels Review the induction and integration process, in particular introducing mentoring/induction buddies			
Motivate, care and retain staff	Further clarify and develop appraisal and promotion policies according to the new Commission Guidelines Foster staff welfare	Objective setting and performance appraisal closed within the deadlines for at least 80% of staff Staff survey satisfaction index Turnover rate = 8% Percentage of use of tele-working arrangements	3	280
Leverage competencies and knowledge	Reengineer the learning framework and development strategy, including the development of a knowledge management strategy Incorporate learning and training initiatives aligned to the science strategy Review/develop/improve the knowledge development tools	Adoption of a career path policy for knowledge worker Experts Database incorporated in knowledge management strategy Average annual number of learning and training days per staff = 8 days	5	716
Total			**24**	**1474**
Information Technology				
Software maintenance	Maintenance and small acquisitions of software licences	Effective maintenance of all software in use	1	245
Develop IT tools to support streamlining and cost reduction of EFSA Administrative Processes	Application development	Additional development to meet corporate needs	0	217
	Application maintenance of existing custom IT tools (financial workflows, human resources workflows, expert management tool, meeting organisation)	Effective maintenance support for custom applications	0.5	150
	Application development of existing custom IT tools		1.5	1350
	Infrastructure assistance	Infrastructure maintained according to service level agreements	1	300
Total			**4**	**2262**
Legal & Regulatory Affairs				
Identify legal risk	Prevent litigation and if necessary provide appropriate defence	Positive outcome of court cases for EFSA	3.5	100

Subject	Expected outcome	Performance Indicator	FTE	Direct operational costs (€ k)
Legal and regulatory advice	Maintain current knowledge and awareness of all relevant legislation Maintain uniform application and interpretation of relevant legislation Provide input for the Legislator when relevant Development of internal rules	Avoid inconsistencies in EFSA's application of the regulatory framework Feedback from Units on responsiveness Increased awareness and compliance with internal rules	2.5	NA
Total			**6**	**100**
Scientific Assessment Support				
Library stocks, purchase and preservation of non-science items	Maintenance of non-science library stocks	Library stocks meet user needs	0	12
Miscellaneous library items, documentation and equipment	Generic equipment (e.g. shelves and other miscellaneous Library items)	Library is professionally maintained	0	18
Subscriptions, purchase of information media	Information media, newspapers, subscriptions to institutional information services	Library subscriptions meet user needs	0	9
Total			**0**	**39**
Resources & Support				
Data Protection	Notifications to Data Protection Officer 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	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	0.5	NA
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	Perform one walk-through and one simulation of the business continuity plan and crisis management procedure in 2011	1	NA
Security policy implementation	Complete second level policies for the implementation of EFSA's Security Policy	Draft identified second level policies by the end of 2011	0.2	NA

Subject	Expected outcome	Performance Indicator	FTE	Direct operational costs (€ k)
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	Policy enforced in all units by end of 2011 Plan for implementation of IT tools to automate enforcement of policy by end of 2011	0	NA
Total			**1.7**	**NA**
Corporate services unit				
Linguistic editing & proofreading	Review of approx. 150 documents e.g. annual report, newsletters etc.	High-quality corporate publications	0	15
Total			**0**	**15**

Annex B: Resources

EFSA's resources for 2012 due to be decided by the Budgetary Authority are as follows:

- A global EUR 78.76 million subvention, including the contribution of EFTA countries (EUR 1.9 million) and DG ENLARG Pre-Accession Programme (EUR 0.5 million) distributed as follows:
  - (a) EUR 78.76 million of Commitment Appropriations
  - (b) EUR 75.86 million of Payment Appropriations broken down as follows:
    - (i) EUR 69.54 million to cover new 2012 commitments made for non-dissociated type of expenditures
    - (ii) EUR 6.32 million to cover payments under the Scientific Cooperation activities launched in 2009, 2010, 2011 and 2012 operating under the regime of dissociated expenditures.

- An Establishment Plan stable at 355 Temporary Agents/Official and appropriations for 110 Contract Agents and 29 Seconded National Experts.

Financial resources 2012

Compared to 2011, the budget for 2012 will increase by 1.2% or EUR 0.93 million and will be distributed over the activities as follows:

Activity (in M EUR)	Executed 2010	Budgeted 2011	Budgeted 2012	%	Variation vs 2011
A1 Scientific opinions & advices	13.05	12.24	12.98	16%	0.74
A2 Evaluation of products	18.55	20.14	20.64	26%	0.50
A3 Data collection & scientific cooperation	23.06	22.88	24.80	31%	1.92
A4 Communication & dialogue	7.85	7.51	6.06	8%	-1.45
G5 Governance & Administration	11.30	15.05	14.28	18%	-0.77
TOTAL	**73.81**	**77.83**	**78.76**	**100%**	**0.93**

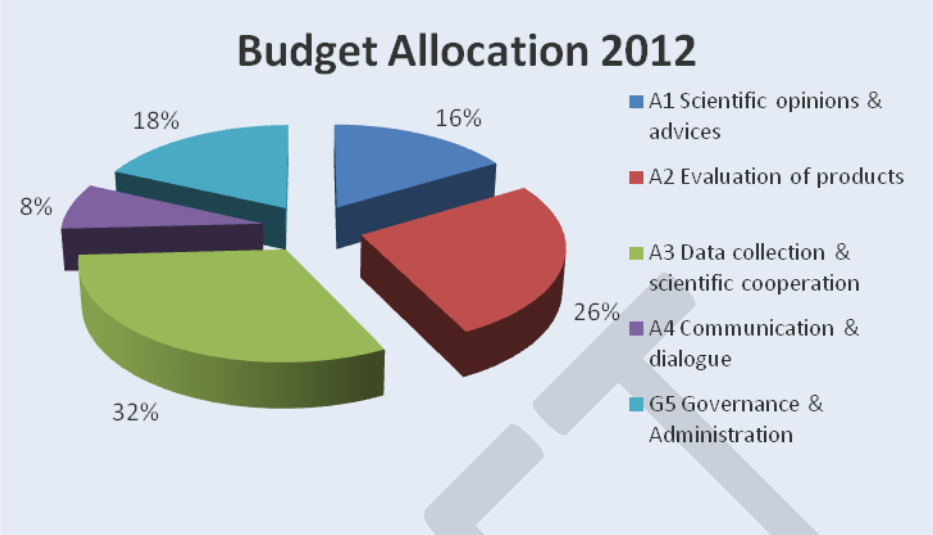
In 2012, scientific activities will be allocated EUR 58.42 million in total, representing 74% of EFSA budget. This represents an increase of EUR 3.16 million over the 2011 allocation.

The contribution of the Directorates to the different activities and the financial resources allocated to them is as follows:

Activity (in M EUR)	REPRO	RASA	SCISTRAT	COMMS	Exec. Office*	RESU	Staff & Infrastructure	Total
A1 Scientific opinions & advices	0.26	2.66	0.67			1.30	8.08	**12.98**
A2 Evaluation of products	4.53	0.19				1.53	14.39	**20.64**
A3 Data collection & scientific cooperation	2.82	6.06	2.65			2.23	11.03	**24.80**
A4 Communication & dialogue				1.00	0.02	1.21	3.84	**6.06**
G5 Governance & Administration		0.04			0.24	4.68	9.33	**14.28**
TOTAL	**7.61**	**8.95**	**3.32**	**1.00**	**0.26**	**10.95**	**46.67**	**78.76**

**Including the Executive Office Unit, the Executive Director and Internal Audit.*

The relative weight of the activities is shown below and illustrates the prominence of activities associated with scientific cooperation and the evaluation of regulated products, representing close to 60% of EFSA's 2012 budget.

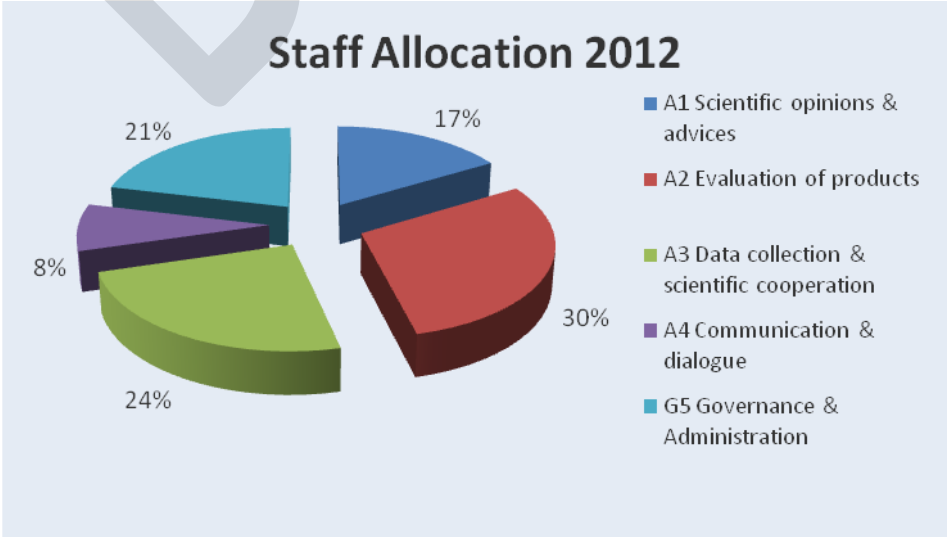


Human resources 2012

The allocation of human resources (494 staff in total) to the various activities shows that 70% is allocated to the core scientific activities and 8% to communication and dialogue activities.

Activity (in FTE)	REPRO	RASA	SCISTRAT	COMMS	Exec. Office*	RESU	Total	%
A1 Scientific opinions & advices	8	58	10		2	**4**	81	**16%**
A2 Evaluation of products	132	9			3	**3**	147	**30%**
A3 Data collection & scientific cooperation	29	51	34		3	**4**	120	**24%**
A4 Communication & dialogue				32	2	**7**	41	**8%**
G5 Governance & Administration		0			11	**95**	105	**21%**
TOTAL	**169**	**118**	**43**	**32**	**20**	**112**	**494**	**100%**

**Including the Executive Office Unit, the Executive Director and Internal Audit.*



Annex C: Legislation in force relevant to EFSA and legislation in preparation likely to have an impact on EFSA[30]

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]*

[30] 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)

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 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation).

Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from

veterinary checks at the border under that Directive (as last amended by Commission Regulation (EU) No 749/2011 of 29 July 2011).

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 189/2011].*

Regulation (EC) No 2073/2005 on microbiological criteria in foodstuffs as amended by Regulation (EC) No 1441/2007.

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; Official Journal of the European Union L 325/31. (In order to obtain information on antimicrobial resistance that is comparable between Member States and in time, Commission Decision 2007/407/EC on a harmonised monitoring of antimicrobial resistance in Salmonella in poultry and pigs was adopted on 12 June 2007).

Food hygiene package:

- Regulation (EC) 852/2004 on the hygiene of foodstuffs, 29 April 2004
- Regulation (EC) 853/2004 laying down specific hygiene rules for food of animal origin, 29 April 2004
- Regulation (EC) 854/2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption, 29 April 2004
- Directive 2004/41/EC repealing certain Directives concerning food hygiene and health conditions for the production and placing on the market of certain products of animal origin intended for human consumption and amending Council Directives 89/662/EEC and 92/118/EEC and Council Decision 95/408/EC, 21 April 2004

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]*

Directive 2002/32/EC of the European Parliament and of the Council on 7 May 2002 on undesirable substances in animal feed (OJ L 140, 30.5.2002, p. 10) *[last amended by Commission Regulation (EU) No 574/2011 of 16 June 2011]*

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
AFSCO – Advisory Forum and Scientific Cooperation Unit
AGRC – Advisory Group on Risk Communication
AHAW Panel – Panel on Animal Health and Welfare
ANS – Panel on Food Additives and Nutrient Sources Added to Food
APDESK – Applications Desk Unit
BIOHAZ Panel – Panel on Biological Hazards
BIOMO – Biological Monitoring Unit
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
CORSER – Corporate Services Unit
CRL – Community Reference Laboratory
CVO – Chief Veterinary Officer
DCM – Dietary & Chemical Monitoring Unit
DG ENV – Directorate General Environment
DG SANCO – Directorate General for Health and Consumers
DOI – Declaration of Interest
ECDC – European Centre for Disease Prevention and Control
ECHA – European Chemical Agency
EDPS – European Data Protection Supervisor
EEA – European Environment Agency
EMA – 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
ESCO – EFSA Scientific Cooperation projects
FAO – Food and Agriculture Organization
FEED – EFSA Feed Unit
FEEDAP Panel – Panel on Additives and Products or Substances Used in Animal Feed
FGE – Flavouring Group Evaluation
FIP – Food Ingredients & Packaging Unit
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
JRC – Joint Research Centre of the European Commission
MRL – Maximum residue level
MS – EU Member States
NA – Not applicable
NDA Panel – Panel on Dietetic Products, Nutrition and Allergies
NGO – Non-Governmental Organisation
NUTRI – EFSA Nutrition Unit
OIE – Office International des Epizooties
OECD – Organisation for Economic Cooperation and Development
OJ – Official Journal
PEST – Pesticides Unit
PLH Panel – Panel on Plant Health
PPR Panel – Panel on Plant Protection Products and Their Residues
PRAS – EFSA Pesticides Unit
QMRA – Quantitative Microbiological Risk Assessment
QPS – Qualified Presumption of Safety
SAS – Scientific Assessment Support Unit
SC – Scientific Committee
SCOM – Scientific Committee Unit
SOP – Standard Operating Procedure
TSE – Transmissible Spongiform Encephalopathy