



---

**EXECUTIVE OFFICE**

**Management Board  
14 March 2013  
Parma, Italy**

<b>Meeting :</b>	<b>Management Board - Open Session</b>	
<b>Subject :</b>	<b>Draft Annual Activity Report 2012</b>	
<b>Document number:</b>	<b>mb 14 03 13 item 4 doc 3</b>	
<b>Document for :</b>		<b>Information</b>
	<b>X</b>	<b>Discussion</b>
	<b>X</b>	<b>Possible adoption</b>



**DRAFT ANNUAL ACTIVITY REPORT OF THE  
EUROPEAN FOOD SAFETY AUTHORITY  
FOR 2012**

**Document describing the activities of the Authority in 2012**

## TABLE OF CONTENTS

<b>I Highlights</b>	3
<b>II Summary</b>	4
<b>III Provide scientific opinions and advice and risk assessment approaches</b>	5
III.1 Overview	
III.2 Scientific Committee	
III.3 Scientific Panels/Units	
<b>IV Evaluation of products, substances and claims subject to authorisation</b>	9
IV.1 Overview	
IV.2 Scientific Panels/Units	
<b>V Data collection, scientific cooperation and networking</b>	12
V.1 Overview	
V.2 Scientific Committee	
V.3 Scientific Units	
V.4 International relations	
V.5 Stakeholder activities	
<b>VI Communication and dialogue</b>	22
VI.1 Overview	
VI.2 Relations with European institutions and agencies	
VI.3 Italian authorities	
<b>VII Governance and support</b>	25
VII.1 Overview	
VII.2 Human Resources	
VII.3 Finance and accounts	
VII.4 Legal and regulatory affairs	
VII.5 Information Technology	
VII.6 Executive Office	
VII.7 Audit	
VII.8 Corporate Services	
VII.9 Implementation of Independence Procedures	
<b>VIII Annexes</b>	32
Annex 1: Budget Execution	
Annex 2: Establishment Plan	
Annex 3: Declaration of Assurance	
Annex 4: Report on the Implementation of the Internal Control Standards	
Annex 5: List of Negotiated Procedures	
<i>Glossary</i>	52

**I Highlights 2012**

*January*

EFSA tenth anniversary begins  
Guidance on risk assessment of GM animals is published

*February*

Scenarios are presented for the spread of Schmallenberg virus  
Assessment of post-marketing data for Amflora GM potato is published

*March*

Joint report on antimicrobial resistance published with ECDC  
Stakeholder information session on implementing rules of independence policy held in Brussels  
Scientific Committee issues statement on Margin of Exposure approach  
Pilot project for observers to EFSA scientific meetings kicks off

*April*

Full re-evaluation of bisphenol A launched  
Post-market monitoring data for MON810 maize are analysed  
Reduction targets are established for Salmonella in turkeys

*May*

EFSA welcomes landmark CODEX Working Group to Parma  
State-of-the-art scientific review of the risks posed by pesticides to bees is published

*June*

Membership of eight Panels and Scientific Committee are renewed  
17<sup>th</sup> Scientific Colloquium on low dose response is held  
Council of the European Union appoints seven members to EFSA's Management Board  
Second opinion on meat inspection (poultry meat) is published

*July*

Call for additional data on aspartame is launched  
New guidance issued for food additive applicants  
Risk Communication Guidelines are issued by EFSA and Member States  
Scientific Committee publishes opinion on threshold of toxicological concern

*August*

Further guidance issued for health claim applicants

*September*

Independent external evaluation of EFSA released  
Public consultation launched on EFSA's draft guidelines for assessing the risk of pesticides to bees

*October*

Initial review of study on GM maize NK603 and glyphosate is published  
EFSA indicates that acrylamide levels in food are unchanged

*November*

Tenth Anniversary Scientific Conference and High-Level Conference held in Parma, new premises inaugurated  
EFSA hosts 6<sup>th</sup> annual meeting with GMO NGOs

*December*

EFSA advises on risks of mercury to public health  
Exposure to caramel colours found to be less than previously estimated  
Management Board adopts its recommendations derived from the second external evaluation of EFSA

## II SUMMARY

The year 2012 was a landmark one for EFSA for a variety of reasons, not least because it marked the tenth anniversary of the organisation. A number of events and communication opportunities were organised throughout the year to highlight EFSA's integral role in European food safety and its achievements over its first decade. It culminated in two corporate events organised in Parma in November which focused on the key future scientific and institutional challenges that the organisation faces. The scientific event attracted more than 600 leading experts in risk assessment from Europe and further afield and provided a stimulating platform for scientists from a range of disciplines relevant to EFSA's work. It made an important contribution to strengthening Europe's risk assessment capacity and the possibility of making it a regular event is under consideration. Much of the discussion at the high-level institutional conference centred on the outcomes of the second external evaluation of EFSA which were published in September. This valuable feedback was among the inputs utilised by EFSA's Management Board to formulate its recommendations which were agreed at its final meeting of the year. The recommendations form a definitive roadmap for the organisation in the coming years and plans for their implementation are described in EFSA's *Mutiannual Plan 2014-2016*.

The renewal of eight of EFSA's Panels and the Scientific Committee was one of the key milestones of 2012 and in June a consolidated list of members and reserves was adopted by the Management Board. The lists represent the culmination of more than 12 months preparatory work and the engagement of external expertise and observers to ensure the highest standards of transparency and effectiveness. The 2012 renewal process meant that the contribution of almost half the previous Panel members ended as they reached the end of their third term. The incorporation of the new members and the transition from old Panels to new was effectively managed and the Panels have continued to meet their targets. It also represented the first time that EFSA's *Policy on Independence and Scientific Decision Making* (2011) and its implementing rules (2012) were applied and a more detailed report of the outcomes is annexed to this report. The implementing rules were presented to a representative cross-section of stakeholders and interested parties at a dedicated information session in Brussels in March at which EFSA explained the application of the rules with practical examples. Related to this, independence continued to be a key theme for the organisation in 2012 with the publication of the European Court of Auditors report on a number of EU agencies and the deliberations in the European Parliament on the discharge of EFSA's 2010 budget. EFSA devoted significant resource to describing and explaining how its system works and one of the implications that can be drawn is that the organisation needs to communicate more effectively on the system it has in place to present conflicts of interest, particularly since it was significantly strengthened by the new policy and rules. Many useful suggestions have been derived from the Parliamentary and ECA inputs and all have been or are being addressed. Related to this, EFSA continued to build its stakeholder engagement with the renewal and strengthening of the Stakeholder Consultative Platform, dedicated workshops, technical meetings, public consultations and, for the first time, the inclusion of observers to EFSA's scientific meetings.

EFSA's scientific work programme continued to address issues of significant public health and environmental protection interest. While the overall number of scientific outputs (763) was generally on target, this total includes a greater number of supporting publications than predicted in Management Plan 2012. Output numbers were lower than expected in a number of areas, such as pesticides, food additives and packaging due to a range of factors including non-receipt of dossiers (food enzymes), overambitious deadlines (e.g. maximum residue levels (MRLs) for pesticides), reprioritisation (e.g. aspartame, bisphenol A) and use of the "stop the clock" the clock mechanism. These, along with other urgent requests such as the evaluation of the study on GM maize NK603 and glyphosate by Seralini et al., Schmallenberg virus and Salmonella Stanley, required reprioritisation and contributed to delays in other aspects of the work programme. Key scientific activities in 2012 included the re-evaluation of the safety of aspartame, a sweetener that EFSA has kept under constant review. After the call for data and the literature search of 2011, the ANS Panel\* began its full re-evaluation of the sweetener in 2012 only to find that the data on one metabolite (DKP) were insufficient; hence a further call for data was launched and a final opinion is now scheduled for May 2013.

---

\*For a full list of Panel and Unit abbreviations, see Glossary on pp. 52-53.

EFSA issued another call for data on bisphenol A, a food contact material that has aroused public concern, and brought together national experts in Parma in October to exchange information and views. An opinion on BPA will be issued in May 2013. In December, EFSA issued conclusions on three neonicotinoid pesticides (published in January 2013) linked with the decline in bee numbers in the EU which will guide the Commission recommendations on their continued usage.

European risk communication on food and feed safety was given a significant boost in 2012 with the publication of the multilingual *Risk Communication Guidelines* a joint product of EFSA and the Advisory Forum Working Group on Communications. This living document will be updated annually with case studies and will serve as a reference for Member States and EFSA in the coming years. EFSA continued to enhance its communications portfolio with the addition of significant new multimedia and social media functionalities.

From an organisational perspective, EFSA continued to build an integrated management system that enables planning and monitoring of activities and resources. This will be enhanced in 2013 with a Multiannual plan based primarily on the medium-term planning agreed with the Commission and Member States. The centralisation of planning and monitoring has been fully deployed and has contributed to more efficient financial management: budget execution in 2012 is the best recorded for the organisation (99.3% committed, 88% paid and a carry forward of 12%). Personnel engaged in governance and support activities has been reduced by 4% as a result of efficiency gains and, in addition to the €1.98 of savings in 2011, a further €3.94 m was achieved in 2012; these savings have been redeployed in scientific cooperation and IT development. The external evaluation of the organisation was successfully delivered and the Management Board adopted its recommendations for EFSA and its institutional partners.

In addition to the already described delays in some areas of the science work programme, other notable delays in delivery against the 2012 Annual Management Plan included: (i) Information Technology (IT) Strategy which has been brought forward to 2013 pending the arrival of a new Head of the IT unit; and (2) the IT component of the new document management system where difficulties existed with the supplier. The discharge of EFSA's 2010 budget also raised a number of difficulties for the organisation in 2012 and resources had to be allocated to address the issues raised.

### **III PROVISION OF SCIENTIFIC OPINIONS AND ADVICE AND RISK ASSESSMENT APPROACHES**

#### **III.1 Overview**

One of the key 2012 achievements was the successful renewal of the Scientific Panels with the renewed Panels holding their inaugural meetings in July. From a strategic perspective, the introduction of a project management approach to the delivery of scientific advice represented an important milestone for the organisation. The implementation is ongoing but has already required a significant change in culture for the scientific units with more focus on timeliness, meeting customer expectations, and fitness for purpose. An important deliverable in 2012 related to meat inspection, a complex mandate that has required effective cooperation between the AHAW, BIOHAZ and CONTAM Panels and units. The European Commission requested EFSA's assistance in 2010 in providing the scientific basis for the modernisation of meat inspection in the EU. EFSA is charged, together with the European Centre for Disease Prevention and Control (ECDC), with helping to introduce a risk-based approach to meat inspection, at all relevant stages of the meat production chain. In 2011, EFSA published the first of six opinions on public hazards linked to meat inspection, which was accompanied by a scientific report proposing epidemiological indicators, and the second opinion on inspection of poultry meat was published in June 2012. The latter suggests that traditional poultry meat inspection may not suffice to fully address the most relevant biological hazards to public health such as *Campylobacter* and *Salmonella*. EFSA's opinion will have far-reaching implications for European meat inspection and public health. It proposes that risk-based interventions coupled with the improved use of information shared between farms and abattoirs are more effective and that such information would also play

an important role in identifying animal health and welfare issues. It also concludes that chemical substances found in poultry meat are unlikely to pose an immediate or acute health threat to consumers.

In the animal health and welfare arena, EFSA continued to play an active role in the Schmallenberg disease situation, providing scenarios for the spread of the disease, epidemiological analyses, likely impacts and regular updates for risk managers. Scientific opinions were finalised on major infectious diseases in food-producing animals such as foot and mouth disease and swine vesicular disease/vesicular stomatitis as well as the use of animal-based measures to assess the welfare of farm animals, with specific focus on dairy cows, pigs, and broilers. In addition to meat inspection, other achievements related to biological hazards included opinions on food hygiene, development of a risk-ranking framework and a review of the Summary Report on Zoonoses. In relation to contaminants, the main activities in 2012 included brominated food retardants, mercury and substances regarded as acceptable previous cargoes for edible fats and oils. As in previous years, EFSA was asked to respond rapidly on a number of occasions: in particular in relation to a multi-country outbreak of Salmonella Stanley and to assess the implications of a long-term feeding study of GM maize NK603 and glyphosate. In relation to the latter, EFSA produced a two-phased response: the first urgent response was issued within a week of the publication of the study and identified a number of issues in relation to the design and methodology. The second evaluation in December took into the consideration the opinions of other Member State authorities and confirmed that the study did not meet acceptable scientific standards. Hence, no reason to re-examine previous safety evaluations of genetically modified maize NK603 was identified. As well as its pest risk assessments and provision of mitigation options, EFSA made an important contribution to European plant health with its participation in the Better Training for Safer Foods programme with the European Commission.

Significant progress has been made in data collection, in particular in the establishment of the data warehouse, an essential tool in providing access to data to Member States and other external parties. Software development continued throughout 2012 and EFSA will shortly be in a position to initiate a pilot project. Significant progress was also made in the development of EFSA's Virtual Library project which aims at making the relevant scientific literature accessible to EFSA scientists, both internal and external, and which will greatly enhance efficiency. EU Menu, a multiannual programme that aims to harmonise data collection on food consumption and the collection of comparable food consumption data across the EU, continued in 2012 with the publication of an external report on a pilot project for the assessment of food consumption among children in Europe. Two other pilot studies in adolescents and adults are ongoing. Support was granted to five Member States to collect food consumption data in accordance with the EU Menu programme. In relation to monitoring of chemicals in the food chain, the main activities in 2012 centred on mercury, polychlorinated biphenyls (PCBs), alkaloids, mineral oil hydrocarbons, citrinin, phomposins and brominated flame retardants. Methodological and modelling support was provided on the epidemiological data collected for the Schmallenberg virus in Europe, the risk of swine vesicular disease in imports, and strategies for the early detection of foot and mouth disease in a wild boar population.

### **III.2 Scientific Committee**

Three scientific opinions were adopted by the Scientific Committee (SC), including a statement on the applicability of the margin of exposure approach for the safety assessment of impurities which are both genotoxic and carcinogenic as well as opinions on the threshold of toxicological concern and risk assessment terminology. The Committee finalised and published its work on the guidance document on default values to be used by EFSA scientific bodies in the absence of actual measured data. A statement was provided on the animal health and welfare aspects and environmental impact of animals derived from somatic cell nuclear transfer cloning and their offspring as well as the safety of products obtained from those animals. A European Commission mandate of September 2012 asked EFSA to define scientific criteria for identifying endocrine disruptors and to review whether existing toxicity methods are appropriate to identify and characterise potential endocrine activity and/or endocrine disruption in humans and the ecosystem. Adoption of the opinion is scheduled for the first quarter of 2013. Work started on the development of a generic assessment system to enable priority setting for the botanicals to be evaluated by EFSA. A standing

## mb 14 03 13 item 4 doc 3 - Draft Annual Activity Report 2012

working group on guidance review was established in late 2012 and will continue to work in 2013 and 2014. The mandate of this working group is to establish the priorities for the review of existing guidance documents and the preparation of new ones. It will also assist in the implementation and further use of the guidance documents across EFSA.

### III.3 Scientific Panels/Units

#### *Animal health and welfare*

In relation to animal welfare, the European Commission has called for measurable animal welfare indicators to be assessed to reinforce the scientific basis of EU regulation. The AHAW Panel has delivered opinions on the use of animal based measures (ABMs) to assess the welfare of farm animals, with specific focus on dairy cows, pigs, and broilers. The previous opinions on the welfare of beef cattle were updated to prepare for an assessment of ABMs. The AHAW Panel also issued a statement on the use of ABMs, providing a general framework for future scientific opinions and for a wider range of animal species. In particular, the statement highlighted the potential of collection of validated ABMs towards quantitative risk assessment. Another important scientific opinion in the field of animal welfare has been on the electrical requirements for water-bath stunning equipment applicable to poultry. Together with BIOHAZ and CONTAM Panels, AHAW contributed to the scientific opinion on meat inspection for poultry. In the area of major infectious diseases of food producing animals, scientific opinions were finalised on foot and mouth disease in relation to outbreaks in Thrace (Bulgarian-Turkish border region) and role of wildlife, the impact of swine vesicular disease and vesicular stomatitis, the testing for bovine tuberculosis, and risk posed by specific strains of Infectious salmon anaemia virus (ISAV HPR0). The Commission also requested EFSA to analyse and critically assess the surveillance strategy considered by Member States for the zoonotic parasite *Echinococcus multilocularis* and a first report was published on the topic. The AHAW unit has been heavily involved in the scientific and technical assistance to the European Commission in response to the emergence of the Schmallenberg virus, with four reports addressing the epidemiological situation and providing an overall assessment of the impact of this emerging disease. The European Union Summary Report on Trends and Sources of Zoonoses, Zoonotic Agents and Food-borne Outbreaks (a joint EFSA/ECDC report) was evaluated by the AHAW Panel with regard to data needs and subsequent analyses that will minimise the impact of existing data gaps and inconsistencies.

#### *Biological hazards*

The BIOHAZ Panel adopted nine scientific opinions in 2012. In relation to food hygiene, the Panel adopted five opinions on the following mandates: public health hazards to be covered by inspection of meat – poultry; public health risks in composite products containing food of animal origin; hygiene criteria for clean sea water; the development of a risk ranking framework on biological hazards; and the risk posed by pathogens in food of non-animal origin. Work continued on the opinions on the revision of meat inspection of bovines, sheep and goats, farmed game and solipeds, due to be finalised in 2013. In relation to foodborne zoonoses, the Panel adopted three opinions on an estimation of the public health impact of setting a new target for the reduction of *Salmonella* in turkeys; a review on the Summary Report on trends and sources zoonoses, zoonotic agents and food-borne outbreaks in 2009 - specifically for food-borne zoonosis and food-borne outbreaks; and experience and lessons learnt from modelling biological hazards. In addition, the list of QPS (qualified presumption of safety) microorganisms was updated in 2012. Four scientific reports were issued: clarifications on the interpretation of technical issues about the opinion on a summary of scientific studies undertaken by the UK Food Standards Agency (FSA) to support a proposed production method for smoked "skin-on" sheep meat; a joint report with the European Centre for Disease Prevention and Control (ECDC) on an outbreak assessment on *Salmonella* Stanley; minimum sample size for the BSE monitoring of healthy slaughtered cattle; and the provisional results of the study on genetic resistance to classical scrapie in goats in Cyprus. An opinion on the quantitative risk assessment of tallow was published and issues raised by the German authorities in relation to the assessment model EFSA used were successfully resolved.

*Biological monitoring*

In the context of the meat inspection modernisation mandate, the BIOMO unit issued a scientific report on epidemiological indicators for meat inspection of poultry which complemented the corresponding opinion on public health hazards. Similar work was started related to meat inspection of bovines, small ruminants, solipeds and farmed game. The unit also issued in collaboration with BIOHAZ unit and ECDC a rapid risk assessment on the multi-country *Salmonella* Stanley outbreak. In addition, the unit provided support to the scientific panels in their work with mandates on zoonoses.

*Contaminants*

The CONTAM Panel adopted 12 scientific outputs in 2012, all scientific opinions. In relation to contaminants in food, the Panel adopted nine opinions including the last two of the series of six opinions on brominated flame retardants (brominated phenols and their derivatives in food, and emerging and novel brominated flame retardants (BRFs) in food), the last two of the series of three opinions on the re-evaluation of acceptable previous cargoes for edible fats and oils, opinions on mineral oil hydrocarbons in food, on mercury and methyl mercury in food and one opinion on meat inspection of poultry (with AHAW and BIOHAZ Panels). In addition, three opinions on contaminants in food and feed were risk assessments on various mycotoxins in food and feed. Four external scientific reports supporting the production of scientific opinions were published; these related to toxicokinetics, toxicity and allergenicity data on substances to be evaluated as acceptable previous cargoes for edible fats and oils and toxicity data on mercury in experimental animals and humans.

*Plant health*

The main activities in 2012 concerned the assessment of the risk to EU plant health of a range of harmful organisms. Pest risk assessments, evaluation of the available options to reduce the level of risk and the potential consequences of amending or removing current regulatory requirements were delivered for nine regulated harmful organisms that infect various crops namely: *Chrysanthemum stunt viroid*, *Scirrhia pini*, *Puccinia horiana*, *Phialophora cinerescens*, *Pseudomonas caryophyllii*, *Erwinia chrysanthemi*, *Liriomyza huidobrensis* and *Liriomyza trifolii*. These assessments represent the first batch of such requests from the revision of the EU plant health regime, part of which is aimed at better targeting of phytosanitary resources. Pest risk assessments were delivered for the Tospoviruses, a group of harmful plant viruses; an opinion on pest categorisation for 23 of the Tospoviruses followed by a pest risk assessment for *tomato spotted wilt virus* including evaluation of the options available to reduce the level of risk. Other outputs issued by the Panel included supplementary scientific advice on snails from the genus *Pomacea* and emerald ash borer *Agrilus planipennis* to augment previously issued scientific advice. The PLH Panel also delivered a guidance document on the evaluation of options to reduce the level of the risk of introduction and spread of harmful organisms in the EU territory. The guidance contains a checklist to be used by the Panel to evaluate a proposed risk reduction option and the document supplements the other guidance already issued by the PLH Panel.

*Dietary and chemical monitoring*

The DCM unit contributed to seven scientific opinions adopted by the CONTAM Panel: mercury and methyl mercury in food, dioxins and dioxin-like polychlorinated biphenyls in foods for infants and young children, ergot alkaloids in food and feed, mineral oil hydrocarbons via food, citrinin in food and feed, phomopsins in food and feed and brominated flame retardants. The unit's input related to the collection and analysis of chemical occurrence data, the estimation of dietary exposure, as well as participation in working group meetings. The DCM unit also contributed to a scientific opinion adopted by the BIOHAZ Panel on the risk posed by pathogens in food of non-animal origin by providing food consumption statistics.

*Dietetic products, nutrition and allergies*

The NDA Panel issued after public consultation scientific advice related to energy requirements and a further opinion on protein requirements. The Panel also adopted one scientific opinion on Tolerable Upper Intake Levels (UL) for omega-3 long-chain polyunsaturated fatty acids and two revised opinions on ULs for calcium

and vitamin D in response to requests from the Commission in the context of establishing conditions of use for the authorisation of health claims for certain nutrients.

*Scientific assessment support*

In 2012, the SAS unit continued to provide hands-on methodological and modelling support to the Scientific Committee and several Panels. In particular SAS supported AHAW to publish the reports on the analysis of the epidemiological data collected in the Member States with regard to the Schmallenberg virus and SAS published a scientific report on the assessment of the impact of Schmallenberg virus in Europe. Scientific reports on assessing the swine vesicular disease risk via import and on strategies for early detection of foot and mouth disease incursion in a wild boar population area were published in order to support the specific AHAW opinions.

**Table 1: Resource summary Activity 1**

Staff number	Staff costs	Infrastructure costs	Operational Budget (incl. grants & procurements)	Execution Grants / Procurement 2012	Total Budget 2012	Budget Execution 2012
82	5,904	1,439	5,637	2,845	12,980	12,954

#### IV EVALUATION OF PRODUCTS, SUBSTANCES AND CLAIMS SUBJECT TO AUTHORISATION

##### IV.1 Overview

While the renewal of the Scientific Panels and Scientific Committee represented an important milestone for the organisation, one of EFSA's other key achievements in the regulated products area was the ongoing development of the Applications Desk unit. Newly established in 2011, in its first full year of operation the staffing of the unit was completed and the harmonisation of administrative procedures was started. The Helpdesk function was launched on EFSA's website; it provides structured guidance to applicants and enables them to submit questions on the application process. The unit organised four information sessions on pesticides, food additives, GMOs and flavourings to ensure that commercial operators and other stakeholders were fully informed of the evaluation process. EFSA continued to analyse its use of the "stop the clock" mechanism, a legal provision whereby an application is suspended while awaiting additional information from applicants. An internal taskforce within the Directorate of the Evaluation of Regulated Products has analysed the use of the mechanism and will use this analysis in its dialogue with the Commission with a view to rationalising the application of this tool.

In the area of chemical risk assessment, three substances stand out in 2012: bisphenol A (BPA), aspartame and neonicotinoid pesticides. In light of EFSA's ongoing monitoring of scientific research on BPA and the CEF Panel's consideration of new scientific studies, EFSA began a full risk assessment of this commonly used food contact material. Two multidisciplinary working groups are working on hazard characterisation and exposure assessment of BPA respectively with scientific input of experts from Member States and internationally and an opinion is scheduled to be delivered in 2013 following a public consultation. A lack of available data on 5-benzyl-3,6-dioxo-2-piperazine acetic acid (DKP), a breakdown product of aspartame, was identified during the course of the assessment; a call for data was launched in July 2012 and the outcomes were considered in the risk assessment. EFSA has been working on issues associated with healthy bee stocks in Europe for a number of years and in late 2012 finalised conclusions on three neonicotinoid pesticides – clothianidin, imidacloprid and thiamethoxam – which identify a number of risks to bee health. As well as assessments of safety, requests for efficacy, benefit and environmental risk assessments – both pre- and post-marketing – continue to grow. In 2012, post-market evaluations were delivered on GM maize MON810 and the Amflora GM potato, both of which made recommendations on how to improve monitoring systems. In addition, an opinion on the safety of MON810 pollen was adopted and

## **mb 14 03 13 item 4 doc 3 - Draft Annual Activity Report 2012**

draft guidance on the risk assessment of GM animals was issued after a public consultation. In response to this growing aspect of the work programme, EFSA's Scientific Committee established a Working Group to review environmental risk assessment guidelines. In the area of food flavourings, an important milestone was reached when EFSA finalised three opinions on smoke flavourings, bringing to an end this particular portfolio.

In a series of 24 scientific opinions, EFSA completed a further 91 "general function" health claims which were eligible for further assessment, i.e. which were considered initially to be insufficiently characterised or for which the evidence provided was not sufficient to establish a cause-and-effect relationship. EFSA's work on pesticides addressed the prediction of environmental concentrations of pesticides in soil, the emission of pesticides from protected crops to the environment, the toxicological relevance of metabolites of pesticides in food and the state of the science regarding the risk assessment of pesticides for bees. In the feeds area, EFSA's main activities focused on the re-evaluation of additives currently on the market. While many evaluations were positive, in some cases, EFSA made specific recommendations.

### **IV.2 Scientific Panels/Units**

#### *Applications desk*

The APDESK unit is centralising and processing the initial administrative steps of all applications received by EFSA. It provides a service on EFSA's website whereby users can access information about applications and submit specific questions. During 2012, the unit received 279 written requests for information from the public. Four information sessions on applications were organised: pesticides (September), food additives (September), GMOs (October) and flavourings (November) in order to enhance interaction and communication with stakeholders. The Applications Helpdesk on EFSA's website has been updated with an overview table, providing structured access to the key documents for the preparation of an application per scientific area as well as a video describing the role of EFSA and the APDESK unit. The unit is working to harmonise, where possible, administrative procedures and workflows in relation to applications for regulated products.

#### *Food additives and nutrient sources*

In addition to the re-evaluation of aspartame, on which a draft opinion will be submitted for public consultation in early 2013, the ANS Panel adopted 17 scientific opinions. Seven opinions were related to the re-evaluation programme on food additives (beta-carotene use in heavy smokers, beta-carotene and mixed carotenes, patent blue V, vegetable carbon, butylated hydroxitoluene, carnauba wax and candelilla wax). Three opinions were adopted in relation to exposure assessments of food additives (butylated hydroxyanisole, sucrose ester of fatty acids and lutein), two opinions were related to applications as nutrient sources (chromoPrecise cellular bound chromium yeast and chromium (III) lactate trihydrate as a source of chromium (III)) and two were on food additives (stigmasterol-rich plant sterols and medium viscosity mineral oils class). In addition, the ANS Panel adopted a guidance document for the submission for food additive evaluations including a new Food Additive Intake Model (FAIM) tool for exposure assessment. The FIP unit issued two EFSA statements on the revised exposure assessment for ethyl lauroyl arginate and caramel colours.

#### *Food contact materials, enzymes, flavourings and processing aids*

The CEF Panel adopted 50 scientific opinions concerning applications, 21 of which covered the evaluation of new flavouring substances, as well as additional data provided for the re-evaluation of substances of the Flavourings Evaluation Programme. A total of 25 opinions covered substances used to manufacture materials in contact with foodstuffs (FCMs), nine of which are related to recycling processes. In addition, the Panel adopted three opinions related to smoke flavourings and thus has finalised this area of work. The Panel adopted an opinion with the BIOHAZ Panel on a processing aid to decontaminate raw poultry products. The self-task on the risk assessment of bisphenol A will be finalised during 2013.

## **mb 14 03 13 item 4 doc 3 - Draft Annual Activity Report 2012**

### *Additives and products or substances used in animal feed*

The FEEDAP Panel adopted 87 scientific opinions under Regulation (EC) No 1831/2003, and two opinions evaluating the supplementary information submitted after inconclusive opinions. The main activity of the Panel was related to the re-evaluation of feed additives currently on the market, where a total of 60 opinions were adopted in 2012. During the re-evaluation, the FEEDAP Panel concluded positively in many cases, while in some others, the Panel recommended: a reduction in the maximum content levels in feed due to safety concerns; restrictions on use in specific animal species; or a revision of the established safety level. It was not possible to favourably conclude when the efficacy of some technological additives or the safety for the target animals of a feed colourant could not be demonstrated. For two microorganism-based additives, unfavourable opinions were delivered with regard to both safety and efficacy. In order to continue assisting applicants, the FEEDAP Panel adopted two new guidance documents following a wide public consultation. A guidance document on the safety assessment of *Enterococcus faecium* in animal nutrition and an update of the guidance on the assessment of bacterial susceptibility to antibiotics of human and veterinary importance were published. Currently, the total number of guidance documents available to applicants is 18.

### *Genetically modified organisms*

The GMO Panel adopted 25 scientific opinions and statements in 2012. Eight opinions related to GM plant applications under Regulation (EC) No 1829/2003 covering nine application dossiers for: one soybean cultivar for cultivation, three maize cultivars, one oilseed rape cultivar, two soybean cultivars and one cotton cultivar for import and processing and its renewal application. A further three opinions supported the European Commission in relation to post-market environmental monitoring (PMEM) of GM plants grown in the EU. In 2012 the opinions on PMEM reports adopted by the GMO Panel concerned maize MON810 for season 2010 and potato Amflora for seasons 2010 and 2011. The GMO Panel provided support to the FEEDAP Panel for two applications in the area of feed additives from GM microorganisms. Thirteen opinions and one statement were adopted in relation to previously assessed applications, including: seven safeguard clauses (one on maize GT73, one on oilseed rape Ms8, Rf3 and Ms8 x Rf3, three on potato Amflora, and two on maize MON810); five other opinions on maize MON810, 1507 and Bt11; two opinions of the mandate of the European Commission on new techniques, one on zinc finger nuclease 3 (ZFN-3); and another on cisgenesis. Other outputs included two technical reports of EFSA following requests from the European Commission on the safety of pollen produced by oilseed rape Ms8 x Rf3 and GT73 and one technical report on the public consultation of the guidance document related to the risk assessment of food and feed from genetically modified animals. Nine technical reports connected to applications submitted under Regulation (EC) No 1829/2003 ("overall opinions") were published, each containing the scientific opinion of the GMO Panel, Member State comments and responses to these, PMEM plans, and other annexes.

### *Dietetic products, nutrition and allergies*

In 2012, the NDA Panel completed the re-assessments for a number of 'general function claims', which were eligible for further assessment. These included 74 claims related to microorganisms which were considered initially by the Panel to be insufficiently characterised and 17 claims for which the Panel initially concluded that the evidence provided was not sufficient to establish a cause and effect relationship; these assessments were published in 24 scientific opinions. In relation to health claim applications, the Panel adopted three opinions covering four applications on disease risk reduction claims, 33 opinions covering 34 applications on claims based on newly developed science and/or proprietary data, and one opinion on a change in authorised conditions of use. To better support applicants and based on the experience gained with the evaluation of health claims, EFSA has placed considerable focus on developing guidance on the scientific requirements for the substantiation of health claims in specific areas. Following public consultations, the NDA Panel adopted four guidance documents, accompanied by summary reports of the outcome of the preceding public consultations, related to: appetite ratings, weight management and blood glucose concentrations; bone, joints, skin and oral health; nervous system, including psychological functions; and physical performance. Regarding the safety assessment of novel foods, the NDA Panel adopted three opinions and one statement. The Panel adopted a statement on the safety of conjugated linoleic acid (CLA)-

## **mb 14 03 13 item 4 doc 3 - Draft Annual Activity Report 2012**

rich oils as novel food ingredients, following a request from the Commission to update the existing opinion and, in addition, issued an opinion on the suitability of goat milk protein as a source of protein in infant formulae and follow-on formulae.

### *Pesticides*

The PPR Panel adopted 4 scientific opinions and two guidance documents. The adopted opinions address the prediction of environmental concentrations of pesticides in soil, the emission of pesticides from protected crop to the environment, the toxicological relevance of metabolites of pesticides in food and the state of the science regarding the risk assessment of pesticides for bees. The guidance documents cover the dermal adsorption of pesticides and the use of probabilistic methodologies for modelling the dietary exposure to pesticide residues. The Pesticides unit issued 57 conclusions on the pesticide peer review of new active substances, approved substances for which EFSA conclusions were due to be delivered by 31 December 2012 (the so-called “green track” of stage 4 of the review programme of existing active substances), and substances for which data were submitted after approval. In addition, the unit issued two statements and three specific conclusions in response to requests from the European Commission for advice regarding the risks to bees associated with the use of particular neonicotinoid active substances.

### *Biological hazards*

The BIOHAZ Panel adopted five opinions and a statement. Two opinions were on food hygiene: evaluation of the efficacy of the substance Cecure for the removal of microbial surface contamination of raw poultry products; and the evaluation of the safety and efficacy of LISTEX P100 for the removal of *Listeria monocytogenes* surface contamination on raw fish. Two opinions were on requests for approval of new methods of disposal of category 2 animal by-products: one was on composting and incineration of dead-on-farm pigs and the other was on the “biomation” process. One opinion was adopted on the evaluation of new TSE rapid tests. A statement on the GM potato EH92-527-1 for cultivation was adopted by the BIOHAZ and GMO Panels.

### *Dietary and chemical monitoring*

In addition to the provision of food consumption and energy intake data, the DCM unit provided estimations of dietary exposure using EFSA’s Comprehensive Food Consumption database. The unit contributed to a scientific opinion adopted by the ANS Panel on guidance on submission for food additives evaluations, a draft scientific opinion on the re-evaluation of aspartame as a food additive and two EFSA statements: refined exposure assessment for caramel colours, and revised exposure assessment of ethyl lauroyl arginate as a food additive. Support was also provided for the development of the Food Additive Intake Model (FAIM) template to support food additive applications. Other contributions included the scientific opinions adopted by the NDA Panel on dietary reference values for energy and a scientific opinion adopted by the FEEDAP Panel on the re-evaluation of copper as a feed additive. Support was provided to the GMO Panel through the publication of food consumption summary statistics relevant to applications for GMOs, and to the PRAS unit through pesticide residue data collection and the DCM contribution to the annual EFSA scientific report on pesticide residues.

### *Scientific assessment support*

One of the main tasks of the SAS unit was the appraisal of clinical trials and experimental studies related to dossiers delivered to EFSA. In recent years, SAS has developed harmonised and standardised approaches and templates to carry out these appraisals and provided hands-on support when required. The outcomes of these appraisals are reported to the respective Working Groups and Panels. Together with the GMO and PRAS Units, two statements were issued in response to an urgent request from the European Commission to evaluate a publication by Séralini *et al.* (2012) entitled “Long term toxicity study of a Roundup herbicide and a Roundup-tolerant genetically modified maize”.

**Table 2: Resource summary Activity 2**

Staff number	Staff costs	Infrastructure costs	Operational Budget (incl. grants & procurements)	Execution Grants / Procurement 2012	Total Budget 2012	Budget Execution 2012
138	10,713	2,607	6,787	1,411	20,107	20,027

## V DATA COLLECTION, SCIENTIFIC COOPERATION AND NETWORKING

### V.1 Overview

The renewal of eight of EFSA's Scientific Panels and Scientific Committee was one of the organisation's key achievements in 2012 and all the renewed bodies began to operate from July. The renewal exercise confirmed the continuing appeal of the organisation for experts but in some cases such as the GMO Panel it did raise some questions in relation to the sustainability of the panel system in some areas involved in the evaluation of regulated products. In practice, it meant the establishment and maintenance of a register of food safety organisation i.e. scientific institutions across Europe that have a public health protection remit and who are in large part publicly funded. The implementing rules of EFSA's Policy on Independence and Scientific Decision Making were finalised and published in March and were applied to the Panel renewal exercise. The new rules were launched with an information session for stakeholders in Brussels during which the practical implementation was explained in detail and EFSA staff members were available to answer questions. One of the initiatives introduced on the back of the new policy and rules was the participation of observers at selected EFSA scientific meetings. After the terms of reference were established in early 2012, a pilot programme was launched with the first plenary meeting hosting observers in March. This pilot is due to run until mid-2013 when it will be evaluated and decisions taken on how or whether to expand the programme. A number of key issues have already been identified by stakeholders such as providing advance notice of meetings that allow observers, publication of agendas etc. and all of these will feed into the review.

The availability of high-quality risk assessment expertise is an important consideration at both the national and European levels. With constant developments in science and technology, it is crucial that our ability to assess and mitigate risks keeps pace. This is identified as a priority in EFSA's Science Strategy and the Authority continued to contribute to strengthening European risk assessment capacity in 2012 with the development of a continuing professional development programme for both external experts and EFSA staff and collaboration with the Commission on basic training in risk assessment through the Better Training for Safer Food programme. These initiatives were welcomed by the scientists who attended the scientific conference organised by EFSA in November to mark its tenth anniversary. The two-day event provided an effective platform for scientists from across the range of disciplines relevant to risk assessment pertaining to the food chain to discuss common issues and to address the future challenges that risk assessors face. The conference was a useful addition to the science of risk assessment and EFSA is considering making it a regular event as part of its remit in developing European risk assessment.

EFSA has continued to develop the capability to proactively identify and assess emerging issues. In 2012, a standing working group of the Scientific Committee dedicated to implementing the process of emerging risk identification was developed and its activities are complemented by the Stakeholder Consultative Platform Working Group on Emerging Risks and the Member State network on emerging risks. Of the sixteen issues discussed with the Member State network, two are currently being pursued: the use of data coming from the REACH programme for the identification of priority emerging chemical risks in the food chain; and a recommendation for carrying out research in the area of emerging indigenous ciguatera toxin production in European waters which was sent to DG Research and Innovation. EFSA's EMRISK unit is coordinating a Task Force that in 2012 summarised EFSA's activities to date in the area of bee health and is also coordinating an activity to provide supporting information to the Scientific Committee with a view to

## **mb 14 03 13 item 4 doc 3 - Draft Annual Activity Report 2012**

developing an EFSA strategy for addressing exposure to multiple chemical residues (chemical mixtures). The unit also coordinated EFSA's response to urgent requests in 2012 including Schmallenberg virus and on the study by Séralini et al. on GM maize MK 603 and glyphosate.

The evolution of EFSA's scientific cooperation strategy towards multiannual framework contracts was implemented in 2012 with EFSA's reinforced Planning & Monitoring capacity playing a key role in enabling the organisation to reach 100% of its commitment goals. The mandate and membership of EFSA's Stakeholder Consultative Platform were renewed in 2012 and dialogue has been strengthened with groups representing sectoral organisations engaged in the Authority's areas of work, including industry and non-governmental organisations. EFSA sought the views of the Platform on key corporate documents and organised a series of technical meetings and information sessions including the session dedicated to the implementing rules of the *Policy on Independence and Scientific Decision-Making Processes*.

The Advisory Forum met on four occasions in 2012 to address key strategic issues for European food safety. The Focal Point network held three meetings one of which addressed national risk communication activities. The Information Exchange Platform (IEP) continued to develop as a key food safety data and information exchange mechanism with 254 documents from 22 different countries uploaded in 2012, a 20% increase over 2011. EFSA's Expert Database grew to more than 3000 registrants and its functionality was enhanced. A series of training courses on risk assessment kicked off for scientists from national public institutions, through the Better Training for Safer Food programme. EFSA's engagement in the Pre-Accession Programme focused on providing information to the beneficiary countries on EU food safety through training seminars, a study tour and conferences; experts from the countries participated in 27 EFSA and network meetings as observers. The EFSA Journal continues to establish itself as the dedicated medium for the communication of EFSA's scientific advice and an important open-access resource for the risk assessment community worldwide. Developments in 2012 included the addition of a new section for Special Issues, the first of which provided a comprehensive overview of EFSA's scientific achievements over the past decade, as well as the renewal of the Editorial Board and the appointment of a new Editor-in-Chief.

### **V.2 Scientific Committee**

The second version of the compendium of botanicals was published, replacing the previous 2009 version. Work on the third version of the compendium was initiated and will be completed in 2014. The Scientific Committee organised meetings of the Scientific Network for Nanotechnologies in Food and Feed Safety (Nano Network) and the Network on Harmonisation of Risk Assessment Methodologies in 2012. Information sharing and cooperation within the networks is being actively pursued. The Nano Network reports for 2011 and 2012 were finalised and published.

### **V.3 Scientific Units**

#### *Advisory Forum and scientific cooperation*

At its four meetings held in 2012 the Advisory Forum continued to address key strategic issues. The Forum emphasised its support for EFSA's contribution to the progress of EU food safety over the past decade in a statement of support published by Member States. Scientific cooperation with Member States, EEA/EFTA and candidate countries continued to be promoted by the Focal Points. One of the three Focal Point meetings was organised back-to-back with a joint meeting with the Advisory Forum Communications Working Group which aimed at optimising risk communication activities at national level. During 2012, the documents uploaded to the Information Exchange Platform increased by almost 20% compared to 2011. A total of 254 documents from 22 different countries were uploaded. EFSA's engagement in the Pre-Accession Programme focused on providing information to the beneficiary countries on EU food safety through training seminars, a study tour and conferences; experts from the countries participated in 27 EFSA and network meetings as observers. In 2012, a comprehensive review of the Article 36 was launched for organisations to update their profiles and for Member States to (re-)assess their nominated organisations in the light of new guidelines. EFSA's Expert Database grew to more than 3000 registrants with important improvements in its functionality. A series of training courses on risk assessment kicked off for scientists from national public

## **mb 14 03 13 item 4 doc 3 - Draft Annual Activity Report 2012**

institutions, through the Better Training for Safer Food programme. At a Scientific Colloquium, ca. 100 experts debated the possible health effects of low levels of certain chemicals (the “low-dose hypothesis”) and the current and future challenges these pose for food and feed risk assessment. A Scientific Conference with 600 experts was organised by EFSA in November in Parma to mark its tenth anniversary (“Challenging boundaries in risk assessment – sharing experiences”). The *EFSA Journal* was further developed by implementing new features and creating a new section for Special Issues. The first Special Issue provided a comprehensive overview of EFSA’s scientific achievements in the past decade. The Editorial Board was renewed and a new Editor-in-Chief has been appointed.

### *Emerging risks*

As outlined in Management Plan 2012, EMRISK, with support from the Scientific Committee has continued to develop the capability to proactively identify and assess emerging issues. Sixteen separate issues were discussed in detail with the Member State network on emerging risks, and a selection of these was also discussed with the dedicated stakeholder group. Of these issues, two are already being followed up on. Firstly, the use of data coming from the REACH programme for the identification of priority emerging chemical risks in the food chain, and secondly, a recommendation for carrying out research in the area of emerging indigenous ciguatera toxin production in European waters was sent to DG Research and Innovation. This year has seen the establishment of a standing working group of the Scientific Committee, dedicated to implementing the process of emerging risk identification that has been developed, and from this experience, contributing to the further development of this approach. The role of the Member State network and Stakeholder group supporting this activity has been expanded to encourage bringing forward new issues, as well as providing supporting data. The unit is coordinating a Task Force that in 2012 summarised EFSA’s activities to date in the area of bee health, with a view to identifying in 2013 gaps in data, research and risk assessment in this topic, exploring the need for a holistic approach, uniting the different areas of risk assessment. Similarly, EMRISK is coordinating an activity to provide supporting information to the Scientific Committee with a view to developing an EFSA strategy for addressing exposure to multiple chemical residues (chemical mixtures), and on coordinating a document summarising risk assessment data requirements outlined in both the legislation and EFSA guidance documents. The role of EMRISK in supporting the coordination of EFSA’s response to urgent requests continues, both through coordinating a multi-annual training plan, with representatives from the Member States and Commission participating in a workshop, and through support given to responding to two urgent requests; on Schmallenberg virus and on the Séralini et al. study on GM maize NK603 and glyphosate. Other preparative work ongoing in 2012 included the preparation of reports on the potential use of “omics” data in risk assessment, and gathering consumption data for “energy” drinks. Work on the chemical hazards database continues on schedule, with a view to having a first version available within EFSA in 2013. During 2012, EMRISK finalised more scientific outputs than planned, partly due to the support provided to other units through internal reports, including the extraction of data on trade statistics and from the RASFF.

### *Additives and products or substances used in animal feed*

The FEED unit prepared four procurement procedures, related to literature searches and reviews. A systematic review on antimicrobial resistance and copper was finalised and used in the copper opinion adopted in 2012. Other calls for tender covered substances with direct beneficial effects on the environment, the bioavailability of selected trace elements in animal nutrition, and applications in the field of nanotechnology jointly prepared with other EFSA units. Two technical reports were published summarising the outcome of the public consultations related to the first guidance on the safety assessment of *Enterococcus faecium* in animal nutrition and an update of the guidance on the assessment of bacterial susceptibility to antibiotics of human and veterinary importance.

### *Genetically modified organisms*

Two calls for tender were completed, one on a literature review of allergenicity related studies focusing on non-IgE mediated food allergy and in vitro digestibility tests and the other on the criteria for a comprehensive food and feed safety and nutritional assessment of GM plants. The GMO Unit also implemented a framework

## **mb 14 03 13 item 4 doc 3 - Draft Annual Activity Report 2012**

contract for statistical support for the assessment of GMO field trials. A negotiated procedure was finalised on the establishment of a database of bio-ecological information on non-target arthropod species to support the environmental risk assessment of genetically modified crops and its outcome was published as an external scientific report. The unit published three event reports in relation to: the EFSA-OECD workshop on key allergens and compositional analysis in the allergenicity assessment of genetically modified plants; the 3<sup>rd</sup> meeting of the EFSA GMO scientific network; and the outcome of a bilateral meeting with Austria on the invoked safeguard clause on Amflora potato.

### *Dietetic products, nutrition and allergies*

In the area of dietary reference values, five calls for tender were completed, which comprised literature searches and reviews related to specific preparatory work in the establishment of dietary reference values for: vitamins A, C, E and K; chromium, manganese, molybdenum; magnesium, potassium, fluoride; copper; niacin, biotin and vitamin B6. Another call for tender was also completed related to the collection and analysis of data regarding the reference heights and weights of children and adolescents in the EU. A negotiated procedure was finalised on the characterisation of certain micro-organisms in the framework of the reassessment of certain Art. 13 health claims. Eight technical reports were issued which addressed scientific comments from the public after the publication of opinions on health claim applications. The comments were forwarded by the European Commission to EFSA to enable full consideration of all scientific comments made before proceeding with the authorisation or rejection of health claims. Six technical reports were issued which summarised the outcome of four public consultations related to the scientific requirements for health claims in specific areas, and two public consultations related to dietary reference values.

### *Pesticides*

EFSA issued 73 reasoned opinions regarding routine maximum residue level (MRL) applications for more than 400 MRLs in response to 89 MRL applications. In addition, EFSA provided four reasoned opinions on urgent requests and one scientific report providing advice on the EU position to be taken in the Codex Committee on Pesticide Residues (CCPR Meeting). The reasoned opinions issued by EFSA were the basis for revising MRLs in Annex II or III of Regulation (EC) No 396/2005 whereby the European Commission has adopted eleven new MRL Regulations on Pesticide Residues in the Standing Committee. Regarding the review programme under Article 12 of Regulation (EC) No 396/2005, 50 reasoned opinions assessing more than 1100 MRLs were finalised in 2012. In addition, EFSA drafted the fourth *Annual Report on Pesticide Residues* for the reference period 2010. The report (which will be published in 2013) summarises the results of more than 77,000 samples of approximately 300 different types of food which were analysed in the 27 Member States and two EFTA countries (Norway and Iceland). Based on the results submitted, EFSA calculated the actual consumer exposure to pesticide residues via food and identified potential risks related to certain pesticide/crop combination containing critical concentrations of residues. In addition to the acute and chronic risk assessment for the individual pesticides, for the first time in the Annual Report series EFSA reported on the outcome of a cumulative risk assessment for a group of ca. 40 pesticides which share a common toxicological effect. In the area of scientific cooperation, 12 external scientific reports were published by EFSA, supporting current or future activities of the PPR Panel. These reports focused on human dietary and non dietary cumulative exposure to pesticides and on various aspects of environmental risk assessment (sediment-dwelling organisms, population of vulnerable species, bees, amphibians, multiple stresses on aquatic organisms, non target arthropod communities, microbial organisms and marine and estuarine organisms).

### *Animal health and welfare*

Several meetings of the Scientific Network on Risk Assessment in the field of Animal Health & Welfare were held in 2012 addressing issues such as testing for bovine tuberculosis, Schmallenberg virus as an emerging disease, and surveillance options for *Ecchinococcus multilocularis*. A technical meeting of the network was also held on collaboration on non-foodborne zoonotic and potential zoonotic diseases, with participation of ECDC and EC representatives. The meeting participants concluded that EFSA and ECDC should proceed with establishing a joint animal health/human health network on non-foodborne zoonotic and potentially

## **mb 14 03 13 item 4 doc 3 - Draft Annual Activity Report 2012**

zoonotic diseases that should be flanked with an IT information exchange platform. A technical meeting with stakeholders on the use of animal-based measures for the welfare of dairy cows, pigs and broilers was held in July; participants included the leading international animal scientist Temple Grandin.

### *Biological monitoring*

In 2012 the unit issued two European Union Summary Reports from the results of the annual reporting by the EU Member States prepared in collaboration with the ECDC. The Summary Report on zoonoses and food-borne outbreaks demonstrated that campylobacteriosis continued to be the most often reported zoonotic disease in EU with increasing numbers of cases. The *EU Summary Report on Antimicrobial Resistance* showed on its part that resistance to several antimicrobials was commonly detected in zoonotic bacteria such as Salmonella and Campylobacter. The unit continued to develop its annual data reporting, particularly by issuing three reports aiming at harmonisation of the monitoring and reporting of data on antimicrobial resistance in animals and food. A major step forward was the implementation of the automatic reporting tools, such as XML and Excel transmissions, for most of the annual reporting, and indeed half of the reporting countries already used this opportunity successfully in 2012 at least for some datasets.

### *Dietary and chemical monitoring*

The unit published five scientific reports using chemical occurrence data collected within the framework of the unit's annual chemical occurrence data collection activity: update on acrylamide monitoring, update of the monitoring of levels of dioxins and polychlorinated biphenyls in food and feed, lead dietary exposure, occurrence and exposure to perfluoroalkylated substances in food, and cadmium dietary exposure. In addition, three technical reports were published: an overview of 2011 European data collection of chemical occurrence in food and feed, report for 2010 on the results from the monitoring of veterinary medicinal product residues and other substances in live animals and animal products, and dietary exposure to aflatoxins in dried figs. The latter report contributed to the publication in November 2012 of Commission Regulation No. 1058/2012 amending Regulation No. 1991/2006 as regards maximum levels for aflatoxins in dried figs. Six external reports were published relating to projects supporting Member States regarding implementation of electronic transmission of chemical occurrence data. In addition, support was granted to two new Member States in 2012. Cooperation with Member States is ongoing regarding extension of the Standard Sample Description (SSD), a model harmonising the collection of a wide range of analytical results in several domains of EFSA's activity. Within the framework of the EU Menu programme, an external report was published regarding a pilot project on the assessment of food consumption among children in Europe. Two pilot studies in adolescents and adults are ongoing. Support was granted to five Member States to collect food consumption data in accordance with the EU Menu programme. Support was also granted to two Member States regarding an update on the Comprehensive European Food Consumption database. Three external reports were published relating to methodological considerations relating to exposure assessments. Work is ongoing on the development of a European food conversion model to convert food as consumed into raw agricultural commodities, to support pesticide residue exposure assessments, and support was granted for a pilot study on post-market monitoring of food additives.

### *Plant health*

In 2012, the PLH Unit organised 2 meetings of the scientific network for risk assessment in plant health; the second meeting was organised back-to-back with a scientific conference on pest risk assessment as part of EFSA's tenth anniversary. A number of questionnaires were sent to Member States to collect data on the status of certain harmful organisms as part of the PLH Panel's risk assessment activities. A public consultation was conducted on the guidance document for the assessment of risk reduction options and the resulting report was published on the EFSA website.

### *Scientific assessment support*

The SAS unit continued to provide access to bibliographic information sources to support EFSA's scientific work. In 2012, more than 250, 000 papers were downloaded through the online electronic library resources and around 3000 papers delivered through other contracted providers. To further optimize SAS started a

three-year project in order to create a Virtual Library. Through the Virtual Library access, searches, retrieval, storage and appraisal of peer reviewed and grey literature will be centralised, transparent, accessible and linked to a specific mandate. In line with the guidance document on systematic reviews, the SAS unit will continue to allocate a significant amount of resource to the provision of methodological and practical support for systematic literature reviews including training for experts and staff. The outcome of procurement on the implementation of systematic reviews in EFSA's scientific outputs workflow was published and a framework contract was set up in order to provide the systematic review services (including training) needed for EFSA in the coming 5 years. If no empirical evidence or raw data is available for a risk assessment, the use of subjective information 'expert knowledge' is appropriate. To provide a framework for the elicitation of this subjective information, the SAS unit started the work on providing guidance for the development of a framework. In relation to the post-market environmental monitoring of GMOs, two procurements were successfully launched with the final deliverables due by the end of 2013.

#### *Other activities*

Meetings of the Scientific Networks on Microbiological Risk Assessment (MRA) and BSE-TSE were held in March and October, respectively. Four event reports were issued following technical hearings on issues related to current meat inspection of bovines, sheep and goats, farmed game and solipeds. In May, a call for tender was launched on "EFSA's stakeholders' needs" aiming to put EFSA and its APDESK Unit in a position to better tailor future initiatives to stakeholder needs. Several contracts/order forms were awarded in the fields of literature review on Bisphenol A, Aspartame, Flavourings, Food Contact Materials and Food Additives as well as for Screening of European Commission Scientific Committee Archives to support the preparatory work of the ANS and CEF Panel.

#### **V.4 International relations**

In line with EFSA's *Strategic Approach to International Activities*, scientific support was provided to the European Commission (DG SANCO) in its Codex Alimentarius commitments including the 6<sup>th</sup> session of the ad hoc Task Force on animal feeding in Switzerland, the 44<sup>th</sup> session of the Codex Committee on food additives and the Codex Committee on Pesticide Residues in China, as well as the 44<sup>th</sup> Session of the Codex Committee on food hygiene in the USA. A video conference meeting with Health Canada was organised to update on current collaboration and to discuss options of work sharing, in particular in the area of health claims and the assessment of supplemented foods/functional foods. As an outcome of the Trans Atlantic Consumer Dialogue (TACD) 13<sup>th</sup> annual meeting in Washington, EFSA will sign cooperation agreements with the US Department of Agriculture (USDA) and share multiannual work programmes to identify possible overlapping areas and efficient collaboration. Furthermore, it was agreed to meet at a regular basis with the US Environmental Protection Agency in order to share multiannual programmes and establish communication platforms for guidance documents, new compounds or re-evaluations. Discussions with the US Food and Drug Administration (FDA) comprised US/EU networks on data collection and the exploration of collaboration in areas commonly engaged at the Codex scientific committees developing methodologies on quantitative-qualitative methods for risk assessment and to avoid duplication between JECFA, FDA and EFSA. In May, EFSA welcomed the Working Group on the revision of the Codex Alimentarius principles for the establishment and application of microbiological criteria for food. Cooperation activities with EU agencies were intensified, signing a cooperation agreement with the European Medicines Agency and exchanging views and data at physical and video conference meetings with the European Chemicals Agency and the European Centre for Disease Prevention and Control. International delegations received in EFSA included the Republic of Korea, China, Thailand, Canada and Chile. On the occasion of a visit of the National Toxicology Program/National Institute of Environmental Health Sciences EFSA discussed cross-cutting issues, such as new concepts in risk assessment, risk assessment of chemical mixtures and exchanged experience in the area of systematic literature review. An EFSA mission to Japan and South Korea laid the groundwork for future collaboration with the Food Safety Commission of Japan and the Korean Food and Drug Administration.

### V.5 Stakeholder activities

With the renewal of the Platform membership in June 2012, EFSA strengthened its dialogue with groups directly representing interests in the food chain. Throughout the year, EFSA provided Platform members with information on its activities and increased the interaction with stakeholders to reinforce their scientific engagement. EFSA sought the views of the Platform on corporate documents such as EFSA's 2013 work programme and the second external evaluation of the organisation. The Platform's Consultative Group on Emerging Risks made an important contribution to EFSA's activities in this area, particularly in relation to the annual report on emerging risk identification published in July 2012. The Platform is not the only way EFSA engaged with stakeholders; in March 2012 EFSA organised an information session for stakeholders on the implementing rules of its independence policy to provide a detailed description and practical illustrations of the factors EFSA considers when screening declarations of interest. A number of technical meetings were organised on specific scientific issues including the annual meeting with NGOs on methodologies and procedures applied in the field of GMOs and environmental risk assessment. EFSA also commenced dialogue with a wider group of stakeholders other than Platform members to discuss broader topics related to the Authority's work in 2013. Comments received during public consultations were published as technical reports for several opinions including those on the threshold of toxicological concern, guidance on default values in the absence of actual measured data, and EFSA's *Science Strategy 2012-2016*.

**Table 3: Resource summary Activity 3**

Staff number	Staff costs	Infrastructure costs	Operational Budget (incl. grants & procurements)	Execution Grants / Procurement 2012	Total Budget 2012	Budget Execution 2012
127	8,624	2,101	13,940	5,172	24,664	24,263

**Table 4: Key performance indicators for EFSA scientific activities (Activities 1, 2, 3)**

Objective	Indicator	Target 2012	Achieved 2012
Timeliness of scientific advice	Proportion of scientific outputs adopted within deadline	90%	81%
	Proportion of scientific outputs finalised and published in the <i>EFSA Journal</i> within 15 working days of adoption*	90%	84%
Independence of experts	(i) Proportion of experts with approved annual DoI before invitation to first meeting of new working group	100%	99.6%
	(ii) Proportion of experts with approved specific DoI prior to meeting	100%	99.8%
Quality of scientific outputs	Number of errata**	-	3

\*Excludes outputs released in batches or with additional communications activities (e.g. press releases, web news items).

\*\*Errors of a scientific nature that require amendment of the output.

**Table 5: Scientific outputs and supporting publications 2012**

	APDESK	FEED	FIP	GMO	NUTRI	PRAS	AHAW	BIOHAZ	BIOMO	CONTAM	DCM	PLH	SAS	AFSCO	EMRISK	SCOM	Total
<b>Activity 1 Provision of scientific opinions and advice &amp; risk assessment approaches</b>																	
Guidance of the Scientific Committee / Scientific Panel		2										1				1	4
Opinion of the Scientific Committee / Scientific Panel					5		10	9		10		10				2	46
Scientific Report of EFSA							1	3	2				3			1	10
Statement of Panel/SC							1					2					3
Statement of EFSA										1						1	2
<b>Total Activity 1</b>		<b>2</b>			<b>5</b>		<b>12</b>	<b>12</b>	<b>2</b>	<b>11</b>		<b>13</b>	<b>3</b>			<b>5</b>	<b>65</b>
<b>Activity 2 Evaluation of products, substances and claims subject to authorisation</b>																	
Conclusion on Pesticide Peer Review							60										60
Guidance of the Scientific Committee / Scientific Panel			1		4	2											7
Opinion of the Scientific Committee / Scientific Panel		87	54	25	66	4		5									241
Statement of Panel/SC			5	1	1												7
Statement of EFSA			2			2											4
Scientific Report of EFSA			1														1
<b>Total Activity 2</b>		<b>87</b>	<b>63</b>	<b>26</b>	<b>71</b>	<b>68</b>		<b>5</b>									<b>320</b>

**Table 5: Scientific outputs and supporting publications 2012 (continued)**

	APDESK	FEED	FIP	GMO	NUTRI	PRAS	AHAW	BIOHAZ	BIOMO	CONTAM	DCM	PLH	SAS	AFSCO	EMRISK	SCOM	Total
<b>Activity 3. Data Collection, scientific cooperation and networking</b>																	
Guidance of EFSA						1											1
Reasoned Opinion						114											114
Scientific Report of EFSA						1			5		5					1	12
Statement of EFSA						2							2				4
<b>Total Activity 3</b>						<b>118</b>			<b>5</b>		<b>5</b>		<b>2</b>			<b>1</b>	<b>131</b>
<b>Other publications</b>																	
Event report				2			1	4							4		11
External Scientific Report				1	6	11	14	4	5	4	19	5	3		1		73
Internal Report	3	1	6	1	1		1	1	5		14		24	17	11		85
Technical report		2	1	13	14	6	6	3	7		3	1	2	7	8	5	78
<b>Total other publications</b>	<b>3</b>	<b>3</b>	<b>7</b>	<b>17</b>	<b>21</b>	<b>17</b>	<b>22</b>	<b>12</b>	<b>17</b>	<b>4</b>	<b>36</b>	<b>6</b>	<b>29</b>	<b>28</b>	<b>20</b>	<b>5</b>	<b>247</b>
<b>Total outputs</b>	<b>3</b>	<b>92</b>	<b>70</b>	<b>43</b>	<b>97</b>	<b>203</b>	<b>34</b>	<b>29</b>	<b>24</b>	<b>15</b>	<b>41</b>	<b>19</b>	<b>34</b>	<b>28</b>	<b>20</b>	<b>11</b>	<b>763</b>
<b>Targets</b>	<b>5</b>	<b>77</b>	<b>115</b>	<b>33</b>	<b>79</b>	<b>264</b>	<b>21</b>	<b>27</b>	<b>23</b>	<b>14</b>	<b>22</b>	<b>16</b>	<b>38</b>	<b>25</b>	<b>4</b>	<b>4</b>	<b>767</b>

## VI Communication and dialogue

### VI.1 Overview

A number of factors made 2012 a significant year in terms of communication, including the 10-year anniversary activities and the roll-out of Communications Strategy 2010-2013 underpinned by the development of a new range of impactful multimedia tools. One of the main achievements in 2012 was the full implementation of EFSA's thematic approach to communications. This resulted in a positive impact among key target audiences who gained greater understanding of the Authority's work through an increased emphasis on simplification and context. In particular, significant progress was made in the areas of zoonotic diseases, chemicals in food, GMOs and independence. Cooperation with Member States continued to be crucial, ensuring message coherence across the EU in food safety-related issues. This fact was noted in the findings of the Authority's External Evaluation and the work of EFSA's Advisory Forum Communications Working Group (AFCWG) continued to be imperative to fulfilling this remit. The highlight of the group's ambitious 2012 work programme was the launch of its Risk Communications Guidelines which has been translated into 17 EU languages. The AFCWG has committed to revising the guidelines annually, adding best practice case studies when appropriate. In support of these efforts, a dedicated mailbox has been established to respond to all questions about EFSA's risk communications mandate [riskcommunications@efsa.europa.eu](mailto:riskcommunications@efsa.europa.eu). A natural extension of the guideline initiative is the development of a shared glossary of food safety terminology. The framing of this work was initiated in 2012 and will continue in 2013. Recognising the need to better align the activities of the Focal Points and the AFCWG, the first joint meeting of these two networks took place in 2012. The Communications Directorate had responsibility for internal communications for the first time in 2012. In this initial phase, processes were established and additional communications tools were developed across the Authority's new seat.

The creation of 'In focus' campaigns on EFSA's homepage in support of the thematic approach generated additional traffic to the featured content on the website (topics, recent opinions, FAQs). The impact of this added value could be measured through the increased longevity of website visitor sessions. In support these online feature campaigns, the Understanding Science video series was launched in 2012. This series of scientific white board videos, in which EFSA staff explain scientific concepts in an accessible manner proved popular; necessitating the creation of a dedicated EFSA Channel on YouTube to maximise outreach; the 25 videos were viewed more than 40,000 times in 2012. The Media Relations team focused on improving impactful key messages in interview briefings prepared for EFSA scientific staff and Panel experts. The necessity to proactively explain the Authority's work in the area of independence was a significant aspect of the 2012 work programme. Key activities centred on a dedicated stakeholder meeting that took place in Brussels to explain the Authority's implementing rules of its *Policy on Independence and Scientific Decision-Making Processes*, the external evaluation of EFSA and the special report of the European Court of Auditors on the management of conflicts in certain EU agencies (<http://eca.europa.eu/portal/pls/portal/docs/1/17190743.PDF>).

To mark the occasion of its tenth anniversary, EFSA organised a number of key activities in 2012; a scientific conference (591 participants mainly drawn from the scientific community), a high-level joint conference with the European Commission's Directorate General for Health and Consumers (119 participants from partner institutions and stakeholder bodies), and officially inaugurated its premises. EFSA also organised different events for key partners and stakeholders as well as together with EU Member States. These events were promoted externally through different communication activities, including web announcements, press releases, media visits, tweets, and inclusion in the weekly EFSA Highlights. The EFSA-DG SANCO conference was webcast (live and on-demand).

Overall, EFSA-related media coverage in 2012 was 9,194 articles compared with 9,397 articles in 2011. The Media Relations team organised 111 interviews in 2012 (126 in 2011) and responded to 893 media enquiries (1,076 in 2011). In terms of favourability, positive articles increased from 2% to 7.77% in 2012 whereas the neutral/factual favourability target decreased from 94% to 86% representing an 8.5% decrease. Negative articles increased to 7.68% (from 4% in 2011); this increase was due mostly to independence-related issues, the European Parliament's budgetary discharge debate and the assessment of GMOs. In 2012, media reporting in five Member States represented 46% of EFSA-related coverage; these were France, Germany, Spain, UK, and Italy. Pan-

European media represented 16%, USA 10%, other non-EU media 9%, and the remaining 19% came from other Member States. The analysis of media message penetration is feeding into the work of the Media and Editorial teams as a means of gauging the types of messages that are picked up and where further simplification is required. A relevant increase in key message penetration was observed during 2012 compared to 2011. Both targets (one message pick-up and two messages pick-up) exceeded target levels.

The number of press releases and web stories rose from 80 in 2011 to 85 in 2012, meaning that 9.5% of EFSA's outputs (14% of EFSA's scientific opinions) were accompanied by proactive communications. This increase was accompanied by the publication of 15 feature stories, a new format designed for short, contextual background pieces that are powerful tools for developing EFSA's thematic-based communications. This type of story proved versatile in 2012, being used both on the website and in ad hoc publications in support of EFSA's tenth anniversary as well as the Authority's presence at key scientific events. The importance of EFSA's website continued to increase in 2012, with visits increasing by more than 27% compared to 2011. Improvements to the website's search engine aiding the recall and precision of results as well as some information architecture changes, in light of user feedback, were amongst the technical developments in 2012.

On the content side a dedicated section was developed to assist the work of the Applications Help Desk Unit, while many efforts focussed on the provision of dedicated subscriber services; subscriptions to EFSA's online products increased by 8% in 2012. Email alerts were launched, allowing interested parties to tailor EFSA's web content to their needs, and the weekly "EFSA Highlights" newsletter was launched replacing the printed "EFSA News" and "EFSA In Focus" newsletters; this e-newsletter has been developed so that it can be received on mobile platforms. The Communications Directorate produced more than 80 publications including EFSA's Work Plan and Annual Report, corporate brochure, dedicated event publications, factsheets as well as scientific posters. To optimise budget use, the Authority offers print-on-demand services through the EU's centralised Publications Office. The social media micro blog "Twitter" was launched on January 2012. Throughout the course of the year, EFSA tweeted 169 tweets which were re-tweeted 779 times. At the end of 2012, the EFSA account had 2,130 followers. EFSA's twitter account is promoted on EFSA's website and in the signature of e-mails. 2012 also saw the creation of a new corporate brochure and video for the Authority. Both products provide a concise overview of the Authority's role in the EU food safety system and its contribution to protecting consumers, animals and the environment from risks associated with the food chain. They explain how Europe's food chain is continually evolving and how in turn, EFSA's remit has evolved to cover an increasingly complex number of areas related to the safety of the food chain.

Efficiency was enhanced by the introduction of a Planning & Monitoring Team which supports the long-term planning processes, reporting and budgetary and financial issues, enabling the communication officers to concentrate on the fulfilment of EFSA's risk communication remit.

## **VI.2 Relations with European institutions and agencies**

EFSA continued to ensure effective working relations with the European Commission, the European Parliament and the Council of EU Ministers. A delegation from the European Parliament's Environment, Public Health and Food Safety (ENVI) Committee led by its Chair Matthias Groote and liaison MEP for EFSA Pilar Ayuso, visited EFSA in May. Topics for discussion included working practices as well as EFSA's extensive scientific work programme with a focus on nutrition, new technologies, GMOs, pesticides as well as animal health and welfare. Support was provided to the European Parliament and build awareness of EFSA's role and ongoing work in the EU food safety system. EFSA's Executive Director had regular bilateral meetings with MEPs and welcomed Monica Macovei (Budgetary Control Committee) to Parma in February. The annual hearing of EFSA's Executive Director Catherine Geslain-Lanéelle before the ENVI Committee in the European Parliament took place in September and a significant number of MEPs attended the high-level conference organised by EFSA in Parma to mark its 10-year anniversary. During 2012, EFSA visited its counterparts in Member States and participated in a variety of forums to discuss key food safety issues. EFSA received delegations from Republic of Korea, China, Thailand, Canada and Chile and EFSA delegation visited Japan and South Korea to lay the groundwork for future collaboration. EFSA

liaised closely with the two rotating six-month EU Presidencies of Cyprus and Denmark in 2012 and held meetings of its Advisory Forum in Paphos and Copenhagen. EFSA met both Presidencies on a number of occasions and held discussions with its counterparts and related organisations in the USA and international organisations such as the OECD, the latter in relation to governance issues. In addition, the Executive Director addressed a number of high-level food safety events during the course of 2012.

### VI.3 Relations with the Italian authorities

To mark the annual Festa dell'Europa, a number of events were organised in cooperation with external partners (mainly non-profit and local organizations), and institutions and EFSA opened the doors of its new premises to present its work to the local community. The main partners included the Representation of the European Commission to Italy (Milan office), the Province of Parma, the University of Parma, Europass and the Municipality of Parma. The events addressed topics linked to European awareness and culture, food safety, biodiversity, exchange programmes, sustainability, and the environment. Collaboration with Europass (the independent body set up through a special agreement between Emilia-Romagna Region and Parma to foster relations among EFSA, the local authorities and stakeholders) continued and local officials and dignitaries played a prominent role in the events organised to mark EFSA's tenth anniversary.

**Table 6: Performance Indicators for Communications and Dialogue**

Objective	Performance Indicator	Target 2012	Achieved 2012
Effective use of financial resources*	Budget execution	99%	99%
Effective delivery of communication outputs	Understanding Science video series	35	26
Timeliness	Proportion of press releases/web news items accompanying scientific outputs delivered within 20 working days of adoption	60%	73%
Visibility/outreach	Web visits	3.4 m	4.4 m
	Bibliographic databases indexing the <i>EFSA Journal</i>	5	8
	Newsletter subscriptions	29,000	30,309
Transparency	Number of public consultations	100	39
Effectiveness of communication	Message penetration and tracking:		
	1. One key message taken up by media	90%	95%
	2. Two key messages taken up by media	60%	67%
	<i>Based on the following outputs</i>		
	Number of press releases and web stories	80	85

\*Operational costs only

Table 7: Resource summary Activity 4

Staff number	Staff costs	Infrastructure costs	Operational Budget	Total Budget 2012	Budget Execution 2012
40	2,808	715	2,329	5,852	5,811

## VII Governance and support

### VII.1 Overview

A number of notable milestones were reached in particular associated with the move of EFSA staff to its new premises in January 2012 with no loss of business continuity. The EFSA-owned premises have been occupied from the date of purchase and the previous rented premises were released simultaneously. This move to the new building has generated by comparison to 2011 a saving of €3.94 m mainly originating from building, furniture and IT infrastructure expenditure as well as from governance expenditure and as well as the obvious efficiencies generated by having all staff in the same building, it has also enabled EFSA to host all the meetings of its Management Board at its new premises. In terms of budget utilisation, 2012 represented the strongest performance to date for EFSA, with a carry forward of €8.8 m (€12.7 m in 2011) and commitment credit of €77.7 m (€76.1 m in 2011). Furthermore, beyond the reduction of the carry forward by 30%, EFSA's financial control demonstrated improved respect of the annuality principle with 96.7% of the carry forward effectively utilised compared to 94.3% in 2011.

The Executive Office continued to develop the range of support activities it provides to the organisation particularly in relation to planning and monitoring. A Balanced Scorecard was implemented in early 2012 and monthly performance statistics were provided to EFSA's Management Team. In addition, a quarterly report of EFSA's progress was presented to the Management Board along with key performance indicators. EFSA's aim of putting in place an ISO9001 accredited quality management system was progressed with a number of key milestones being met including the renewal and strengthening of the External Review Working Group (independent scientists who assess EFSA's compliance with its rules and operating procedures), and the assessment by an internationally recognised certification body of the organisation's progress towards developing an ISO 9001 compliant system for its scientific activities.

There were several noteworthy advances in the human resource area including the launch of revamped performance appraisal and competence development approaches. In relation to organisational efficiency, the process gains of 2011 were progressed further with the centralisation of meeting logistics (including both financial and operational support) which reduced the number of posts required for administration processes by 4%. The development of scientific competences was prioritised in 2012 as indicated by the increase in the proportion of days spent on scientific training courses from 1.33% in 2011 to 10% in 2012. The occupancy of EFSA posts also improved significantly in 2012 from 92% in 2011 to 96.3% in 2012.

One of the key developments in the legal and regulatory context for EFSA in 2012 was the establishment of implementing rules for the *Policy on Independence and Scientific Decision Making Processes* adopted in late 2011. Following the entry into force of the rules, the legal function ensured a coherent application and development of the concepts and principles enshrined therein, first to the renewal of members of eight of EFSA's Scientific Panels and Scientific Committee and subsequently to the ongoing operations of the Authority. The provision of ethics advice for EFSA staff in relation to Staff Regulations and good governance principles also featured strongly in this area in 2012.

The strategic importance of information technology (IT) to EFSA is recognised and in 2012 an investment plan was put in place to identify and prioritise resources for the core activities. These enabled the organisation to deliver a number of key projects in 2012 as defined in the Investment Plan. These included an electronic tool for the

management of declarations of interest, a number of improvements in functionality for the EFSA Journal and the corporate website and a number of other strategically important projects such as the development of electronic workflows for applications, the automation of expert reimbursement, and the extension of the contracts database. Two of the key challenges for Corporate Services in 2012 related to the settlement of EFSA staff in the new premises and the ongoing centralisation of meeting logistics in order to enhance efficiency. In relation to the latter, a successful pilot project was carried out in the second half of 2012 and a number of efficiencies identified which will be built on.

## **VII.2 Human resources**

Following the establishment of the Human Capital and Knowledge Management Unit, 2012 marked the start of the implementation of a strategic vision for the deployment of EFSA's human capital focusing in particular on a 'bottom-up' approach. In this context, and as part of the efficiency programme, a staffing and resource planning model which relies more on internal competencies and, where possible, less on external recruitment has been initiated. This has resulted in several internal mobility procedures as well as career projects in order to grant career opportunities to EFSA's most committed and talented staff, as well as to centralise and rationalise some of the support activities (e.g. meeting organisation) to enhance efficiency. In addition, a career development model was designed aimed at enhancing internal mobility and career opportunities. The concept of talent management was introduced and an analysis of the key accountabilities for a lead expert role was undertaken. Moreover, the identification of key scientific competences and the definition of a harmonised and consistent set of job titles (down from 400 to 60 clusters) for all staff has contributed to enhanced clarity on roles, responsibility and competences within the organisation. The career development model also integrates the revision of the former career development and appraisal dialogue into a simplified performance dialogue process, which has shifted the annual exercise more towards a reflection on career plans. To reinforce the link between EFSA strategies and learning activities and methods, an assessment of knowledge management and development was performed in consultation with directors and operational managers. This has led to the drafting of an analysis for a Learning Strategy 2013-2015. In addition, a pilot of a new scientific training programme on the foundations of risk assessment was deployed towards the end of 2012. The execution of the establishment plan stood at 96.3% at year-end and the average duration from publication of vacancy to offer was 3.89 months.

## **VII.3 Finance and accounts**

### *Budget management and activity-based budgeting (ABB)*

Budget execution was reported to the Management Team on a monthly basis with deviations from budget execution targets by activity, by Unit or in relation to specific actions such as the scientific cooperation programme. This allows for corrective actions where needed in order to optimise the utilisation of the financial resources available. Comprehensive budget and activity reports were made available online to the organisation. The allocation of the human and financial resources was monitored during the year and re-allocations implemented where required. The €78.28 m budget was committed to 99.3% and paid to 88.0%; detailed figures and analysis are presented in Annex 1.

### *Financial management*

The second phase of the centralisation of the financial administration of meetings at EFSA, which represents a budget of €8.5 m, was implemented. Whereas the centralisation of commitments was done in 2011, the centralisation of the payments related to meetings (8000 payments a year) was initiated in September with a limited number of units and successfully concluded. In January 2013, the centralisation will be fully effective with implementation of an automated and leaner payment processing.

### *Procurement and grants*

In 2012, 554 contracts including framework contracts were finalised in the Communication and Resources & Support Directorates for an amount of €40.1 m of which €13.6 m were committed. In addition, 147 procurement contracts including framework contracts and 12 grant agreements were finalised as part of the scientific cooperation programme for an amount of €15.2 m of which €8.0 m and €1.4 m were respectively committed. The

commitment level represents 102% of the initial 2012 budget for the scientific cooperation programme. Guidance manuals, templates and training were provided to all Units. The Scientific Governance Board supervising the implementation of the programme held monthly meetings to monitor contracts and grants in the Risk Assessment and Scientific Cooperation & Assistance Directorates.

#### *Control environment*

The control environment evolved towards the further empowerment of Authorising officers and their deputies through a cascade delegation mechanism while at the same time enlarging the scope of registration of exceptions and non-compliance events in order to provide better reference for management supervision. Risk management was given special attention, with the Management workshop on the subject matter leading to the identification and assessment of the critical and significant risks to be addressed beyond the setting up of a comprehensive risk register. The action plan addressing these risks as well as an in-depth review of internal control effectiveness will be conducted in 2013.

#### *Accounting*

The number of payments executed in the year surpassed 13,000 (12,800 in 2011) representing in terms of value an increase of 8.6% compared to 2011, mirroring the introduction of batch payments and the reduction of the number of payments to be processed. There are no comments in the Court of Auditors report on EFSA's annual accounts for 2011 and in the Court's opinion, the transactions underlying the annual accounts are in all material respects legal and regular.

#### *Management tools*

Further progress was made in developing management tools. The ABB application for budget allocation and monitoring now integrates the relevant resources and performance indicators for the five core activities and is therefore fully integrated in EFSA's Management Plan and objective setting. This allows the establishment of a zero-based budgeting approach whereby resources will progressively be allocated as a function of the standard costs of the outputs generated by each activity. The Procurement and Grants management tool is fully operational for all procurement procedures since June 2012. The Meeting Organisation System was further developed to integrate the functionalities allowing centralisation and increased automation of the payments related to meetings.

### **VII.4 Legal and regulatory**

The legal function at EFSA pursued its objective of analysing legal risks for EFSA and advising in a coherent manner on risk proportionate measures to manage identified legal risks. Horizontal legal support was provided for all EFSA's operations, ensuring coherence and reducing the risks of regulatory and legal challenges. In relation to organisational governance, support was provided for the drafting and review of decisions and rules and the establishment of a repository of governance rules was initiated. The regularity of EFSA regarding its obligations linked to formal administrative procedures was ensured by the centralised management of pre-litigation processes, Ombudsman requests, data protection processes and public access to documents applications; the latter were particularly intense in 2012 due to stakeholder focus on EFSA's transparency obligations. Another growing demand in 2012 was the provision of internal ethics advice, advising EFSA staff on the interpretation of the Staff Regulations and good governance principles. In the first quarter of 2012, the legal function finalised the Implementing Rules on Declarations of Interest which represent one of the main pillars of the *Policy on Independence and Scientific Decision Making Processes*. The rules provide a detailed regulatory framework for all persons who are obliged to submit declarations of interest and they define and describe the consequences of potential conflicts of interest. Following the entry into force of the rules, the legal function ensured a coherent application and development of the concepts and principles enshrined in these rules, first to the selection of members of EFSA's Scientific Committee and Scientific Panels, and subsequently to the daily operations of the Authority. With regard to specific Court cases, in 2012, EFSA submitted its Rejoinder and answered questions from the Court in case T-214/11, ClientEarth and PAN Europe v EFSA, in which the applicant challenged a partial refusal to provide access to certain documents. In Case T-457/07, European Dynamics v EFSA, the judgement of the General Court was pronounced on 12 December 2012 ruling in favour of the Applicant and annulling the

contested EFSA decision, concerning the award of a procurement procedure. In joined cases T-339/10 and T-532/10, Cosepuri v. EFSA, regarding procurement and access to documents, the General Court upheld EFSA's defence and ordered the applicant to pay the costs of the proceedings. EFSA lodged its Defence in case T-334/12, Plantavis & NEM v Commission & EFSA, concerning an action for annulment of Regulation (EC) No 1924/2006 in conjunction with Regulation (EC) No 432/2012 and the Union Register of nutrition and health claims made on foods.

### **VII.5 Information technology (IT)**

The main challenges faced by the Information Technology Unit in 2012 were related to the implementation of the initial part of the IT Investment Plan 2012–2014. A number of key projects were delivered to support EFSA's core activities, as defined in the Investment Plan. These included an electronic tool for the management of declarations of interest as part of the implementation of the new *Policy on Independence and Scientific Decision Making Processes*, the management of special issues of the EFSA Journal, an electronic workflow supporting applications in the FIP unit, electronic tracking of meetings with applicants, introduction of local budget lines in financial tools, new search functionalities on the EFSA corporate website, automation of expert reimbursement, extension of the contracts database to non-science contracts, and the introduction of an electronic workflow for non-compliance events and non-financial exceptions. The IT budget increased 106% during 2012 to meet the resources required for the activities mentioned above and other commitments such as increasing the capacity of EFSA's Data Warehouse.

### **VII.6 Executive Office**

The Executive Office supports EFSA's Executive Director in four areas: strategic planning and monitoring; institutional relations; the secretariat of EFSA's Management Board; and quality management. In line with the need for strengthened centralised planning and monitoring identified in the efficiency programme, EFSA's Executive Office began to implement the Balanced Score Card system as part of its enhanced role in organisational performance monitoring and regular reporting. The management of institutional relations were particularly challenging in 2012 as a result of the lengthy budget 2010 discharge process and other demands such as the high-level conference in November. The Executive Office organised and supported four meetings of the Management Board in 2011 including the timely provision of meeting documentation and minutes. The organisation of all Management Board meetings at EFSA's new premises and the provision of on-demand audio rather than live webcasting resulted in significant cost savings and efficiency gains. Further progress was made on implementing a fully integrated Quality Management system for EFSA based on ISO 9001:2008 covering the scientific activities implemented by the end of 2013 and covering all activities by the end of 2016. The key achievements in 2012 included: renewal of the mandate of the External Review Working Group (ERWG) and strengthening of its membership; completion of the scientific process mapping exercise which provided the basis for the revision and re-launch of the standard operating procedures; the development of a mechanism for collating and managing documents relating to organisational governance; and the completion of an exercise by an internationally recognised certification body to assess the organisation's progress towards its stated aim of developing an ISO 9001 compliant QMS for its scientific activities by the end of 2014. During 2012, the Strategy and Prospective function within EFSA provided regular insights for all staff into strategic and prospective issues with a direct or indirect impact on the Authority. A progress report on impact indicators for the organisation was presented to EFSA's Management Board in December and the development of a multiannual work programme continued with a view to submitting a draft to the Board in March 2013.

### **VII.7 Audit**

EFSA performs an annual audit risk assessment that is endorsed by the Audit Committee at the December meeting of the Management Board. The outcome of this audit risk assessment provides the basis for the annual audit work plan that is endorsed by the Audit Committee at the March meeting of the Management Board. A total of 59% of the initial audit work-plan assurance area was reviewed by the Audit Committee during 2012. The 41% deviation is due to re-prioritization following increased support provided to the completion of the European Court of Auditors' special report on management of conflict of interest and the delivery of one special audit report. All

information conveyed to the Internal Audit Services of the European Commission, Court of Auditors and the European Parliament in 2012 was provided within the legal deadlines. The internal audit was also responsible for the coordination of the second independent evaluation on the functioning of the agency carried out every six years after the initial evaluation of 2005 as stipulated in EFSA's founding legislation (Article 61 of Regulation (EC) No 178/2002). The second evaluation was completed in August 2012 and its report submitted to the Management Board in October 2012.

### VII.8 Corporate services

The centralisation of logistical support to meetings organisation progressed with the implementation of the pilot phase started in September until December. The main advantages experienced during this phase were: enhanced budget monitoring and better allocation of financial resources; more structured and standardised communication with experts; specialisation of staff with a harmonised approach to guidelines and procedures oriented towards a full customer satisfaction. The gradual extension of the full implementation (as from February 2013) led to the centralisation of more than 35% of the volume of logistic activities related to EFSA meetings. Moreover, Corporate Services were fully involved in the organisation of EFSA's Tenth Anniversary conferences which were successfully achieved. The survey organised on both occasions showed a satisfaction level of 90% for the logistical aspects of the events. In relation to EFSA's move to its new premises, operations at the new building commenced on 5 January 2012 without any disruption to EFSA's work. Staff members were fully operational from the first day and meetings with scientific experts resumed in the first week of activities without interruption. Almost one year after the move, the adequacy of the building has been demonstrated even if some minor adjustments are still necessary. The successful achievement of all tests (structural and systems) triggered the release of the *Certificato di collaudo* (Certificate of compliance, signed on 7 December 2012), attesting that the building is compliant with Italian law and the project specifications. The release of the *Certificato Prevenzione Incendi* (Fire Prevention Certificate) required by the Italian legislation and to be granted by the fire services of Parma was postponed as the final inspection was delayed in 2013 due to the extra work generated by the earthquakes in the region. As foreseen in the *Contratto di compravendita* (purchase contract), *Società di Trasformazione Urbana* (STU), the company created by the Municipality of Parma to manage the implementation of Parma's urban development and the settlement of EFSA in the town, submitted all costs occurred within the legal deadline of 19 December 2012. In particular: the STU presented a total of €38.77 m of which €38.14 m was eligible and €0.155 m rejected. A total of €0.5 m was questioned and therefore is still to be cleared by EFSA. However, the EFSA auditing process on the costs claimed by STU will ensure that the ceiling of €38.6 m is respected, corresponding to the maximum amount cleared by the EU Budgetary Authority, payable by EFSA for the new building.

### VII.9 Implementation of Independence Policy and Implementing Rules

EFSA's *Policy on Independence and Scientific Decision-Making Processes* was adopted by its Management Board in December 2011 and its implementing rules were launched in March 2012 after an information session for stakeholders in Brussels. The new rules entered into force on the day of their signature (21 February 2012) for the selection and appointment procedures of the members of EFSA's Scientific Committee and eight Scientific Panels; for all other individuals and processes concerned, the new rules entered into force as of 1 July 2012. As a result of a European Parliament request emanating from the Budget 2010 discharge process, EFSA committed to providing regular reporting on the implementation of the new policy and as a first step presented a comprehensive report including the historical context to the Parliament in June 2012. This annex provides updated statistics on the implementation of EFSA's independence procedures for the whole of 2012 including the panel renewal exercise. In addition, it describes briefly the approach EFSA will employ in the compliance checking introduced by the new policy that will begin to be implemented in the first quarter of 2013.

#### (a) Scientific Panel & Scientific Committee renewal

In March 2012, EFSA's Executive Director submitted to the Management Board the list of candidates proposed for appointment as members of the Scientific Committee and eight Scientific Panels and for the Reserve List. The final selection of the candidates Proposed for Nomination to the Scientific Committee or a Scientific Panel, took into consideration the overall competence score High-Level (candidates), the expertise required for the relevant Scientific Panel or Scientific Committee, a thorough knowledge of the English language, as well their nationality

and gender. As described in the Executive Director Decision on the selection of members of the Scientific Committee and Scientific Panels, another requirement for the inclusion of experts in the above lists is an approved Annual Declaration of Interest (ADoI). The first screening of the ADoIs of the High-Level candidates was performed by the EFSA Evaluation Team (EET) according to the previous EFSA Policy on Declaration of Interest between July 2011 and February 2012; subsequently, a second assessment was carried out to ascertain compliance with the new *Policy on Independence and Scientific Decision Making Processes* and its Implementing Rules.

The Management Board adopted a list of experts to participate in eight EFSA Scientific Panels and the Scientific Committee at its 14 March 2012 meeting. Subsequently, the experts nominated to the Scientific Committee or Panels were requested to submit an updated ADoI, so as to check the ADoI once more according to the new Policy and against the most recent information available. Following this screening, the Management Board was asked to adopt an updated list of candidates at its 13 June 2012 meeting.

(b) Other independence related activities in 2012

In addition to the Panel renewal exercise and the ongoing screening of declarations of interest (Dols), EFSA renewed 27 Standing Working Groups by November 2012 which included an assessment of Dols under the new implementing rules. EFSA also evaluated the Dols of ANS and CEF Panel members and their working groups and initiated a review of ad hoc working groups. The concept of Food Safety Organisations was introduced in the new rules and a programme to classify all organisations listed in Dols was initiated in May 2012.

(c) Independence-related statistics for 2012

The following statistics provide an overview of key independence related outcomes for 2012 for EFSA experts, staff and governance bodies.

Year	Dols Screened	Meeting agenda items scrutinised	Potential conflicts prevented	Breach of trust procedures	Staff members leaving EFSA	Restrictions on members of other EFSA bodies
2012	6869	36,609	272	1*	Total: 28 Private sector: 4** Restrictions: 0	2

\* *The breach of trust procedure in 2012 involved an expert for whom EFSA became aware of a potential conflict of interest. On investigation, the expert confirmed an omission in the declaration of interest and EFSA has opened a breach of trust procedure which will conclude in early 2013. If the breach is confirmed, an audit of the scientific outputs to which the expert in question contributed will be undertaken. The expert was not considered in the Panel renewal exercise in 2012.*

\*\* *Two to the chemical/pharmaceutical sector, one to a humanitarian non-profit organisation, and one self-employed in the mechanical components sector.*

(d) Activities in 2013

In the new policy and implementing rules on independence, EFSA introduced the concept of compliance checking of a sample of the submitted Dols. Veracity checks on the information provided will also be performed. The compliance and veracity checks will begin in the first quarter of 2013 and will involve the screening of the Dols of 15 randomly selected experts evaluated in the same quarter against (a) the implementing rules on independence for compliance and (b) against the biographies and other publicly available information for veracity. The outcomes will be reported in four quarterly internal reports available on request and one annual report which will be published in February 2014.

**Table 8: Performance indicators governance & support**

Objective	Indicator	Target 2012	Achieved 2012
Effective use of governance & support financial resources*	Proportion of original budget committed/paid at year end	100%/85%	99.7% / 84.4%
Effective use of EFSA financial resources	Execution of overall EFSA budget:		
	Commitments	99.0%	99.3%
	Payment credits requested from DG SANCO	99.0%	100%
	Carry forward of payments to following year	16.0%	12%
Enhanced skill profile of staff	Ratio of knowledge workers** /support workers	0.620	0.618
Efficient use of IT resources	Projects delivered within budget and deadline	92.5%	93%
Development of an integrated performance management system (IPM)	Milestones of implementation reached within deadline	Achieved	Achieved

**Table 9: Resource summary governance & support**

Staff number	Staff costs	Infrastructure costs	Operational Budget	Total Budget 2012	Budget Execution 2012
97	10,524	4,147	5	14,676	14,640

Submitted for adoption in Parma, Italy  
on 14 March 2013

For EFSA's Management Board

Sue Davies  
Chair of the Management Board

# ANNEXES

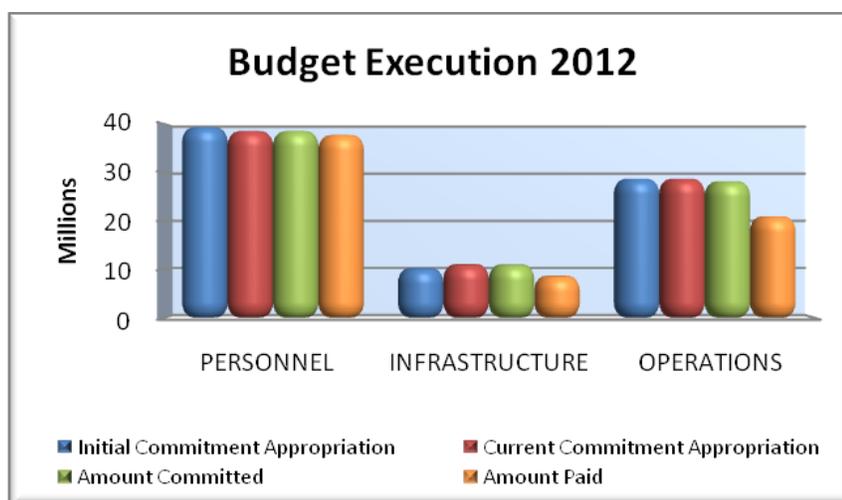
## Annex 1: Budget Execution

### 1. Budget execution

As of 31 December 2012,

- €77.69 m or **99.3%** of the €78.28 m budget was committed. This commitment level stands only 0.75% below the 100% target set for the year. The difference is mainly due to under-spending under Title III utilised at 98.1%. Transfers at year end amounting to €0.5 m to infrastructure and €0.8 m to IT support allowed optimising the budget execution. The infrastructure transfer relates to the non-decision by the Council on salary indexation leaving funds unutilised. The IT support transfer allowed anticipating foreseen investments in operational support.
- €67.28 m or **88.0%** of the €76.48 payment appropriations were paid. This global payment level stands however 7% below the €72.61 m payment target. This global target integrates two distinct targets for non-differentiated and differentiated payment credits:
  - For non-differentiated payment credits, €59.45 m was paid out of the initial €69.08 m appropriation available. This payment level represents 91% of the €65.20 m target for non-differentiated payment credits.
  - For differentiated payment credits (SC coop), €7.83 m was paid out of the €7.41 m appropriation available including the €1.1 m global transfer. This payment level represents 106% of the €7.41 m target for differentiated payment credits.

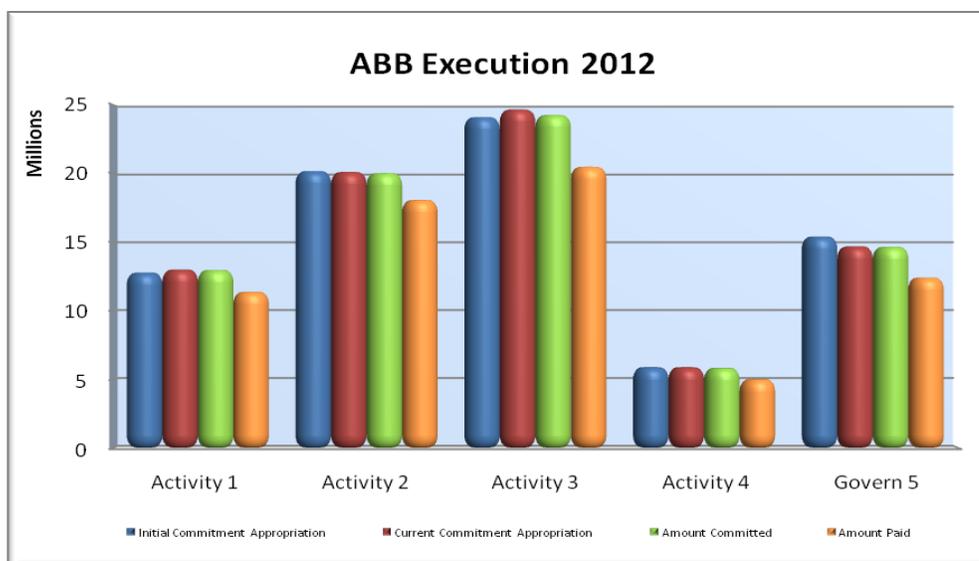
Title	Initial Commitment Appropriation	Current Commitment Appropriation	Δ	Amount Committed	%	Payment Appropriation	Amount Paid	%
PERSONNEL	39.359.000	38.573.067	-2,0%	38.563.788	100,0%	38.573.067	37.754.147	97,9%
INFRASTRUCTURE	10.222.000	11.007.933	7,7%	10.966.034	99,6%	11.007.933	8.602.142	78,1%
OPERATIONS	28.698.000	28.698.000	0,0%	28.164.869	98,1%	26.905.090	20.922.308	77,8%
<b>Total:</b>	<b>78.279.000</b>	<b>78.279.000</b>	<b>0,0%</b>	<b>77.694.691</b>	<b>99,3%</b>	<b>76.486.090</b>	<b>67.278.597</b>	<b>88,0%</b>



The following table and chart report the budget appropriations and executions along with the four operational activities and governance & support (Activity Based Budgeting):

In EUR	Initial Commitment Appropriation	Current Commitment Appropriation	Δ	Amount Committed	%	Payment Appropriation	Amount Paid	%
Activity 1	12,762,762	12,979,554	1.70%	12,953,595	99.8%	13,049,966	11,354,948	87.0%
Activity 2	20,169,364	20,107,292	-0.31%	20,026,863	99.6%	20,155,422	18,062,624	89.6%
Activity 3	24,101,010	24,664,394	2.34%	24,263,404	98.4%	22,752,942	20,470,089	90.0%
Activity 4	5,854,240	5,852,267	-0.03%	5,811,301	99.3%	5,852,267	4,987,487	85.2%
Govern 5	15,391,434	14,675,493	-4.65%	14,639,719	99.8%	14,675,493	12,403,449	84.5%
<b>Total</b>	<b>78,278,810</b>	<b>78,279,000</b>	<b>0.00%</b>	<b>77,694,882</b>	<b>99.3%</b>	<b>76,486,090</b>	<b>67,278,597</b>	<b>88.0%</b>

The evolution observed during the year is a reduction of the resources allocated to the Governance & Administration and Communication activities with a correlative reinforcement of the resources available to the core scientific activities, mainly the scientific cooperation, evidencing the impact of the efficiency (e3) programme.



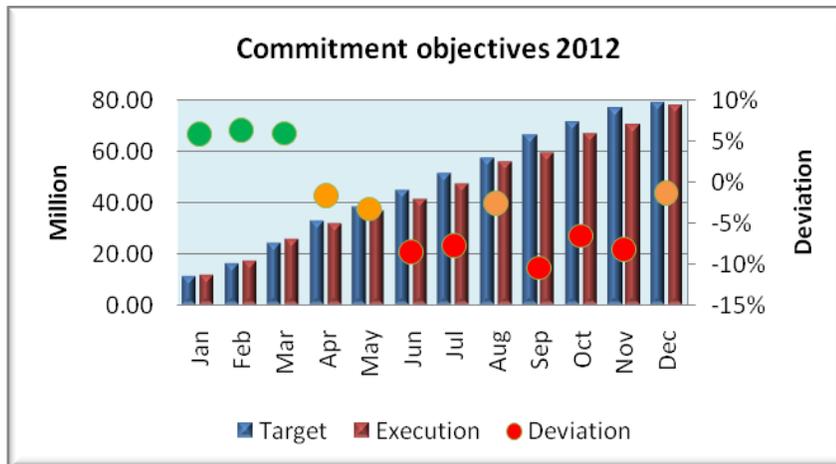
## 2. Year-on-year

Year-on-year, commitments increased by €1.56 m, a 2.1% increase. Payments substantially increased by €5.33 m or 8.6% compared to last year. For both commitments and payments, the increase is mainly due to operational improvements and in particular the close management of the scientific cooperation programme. The substantial decrease in commitments and payments under Title II (Infrastructure) can be explained by the finalisation last year of the new seat building project which required additional resources at that time.

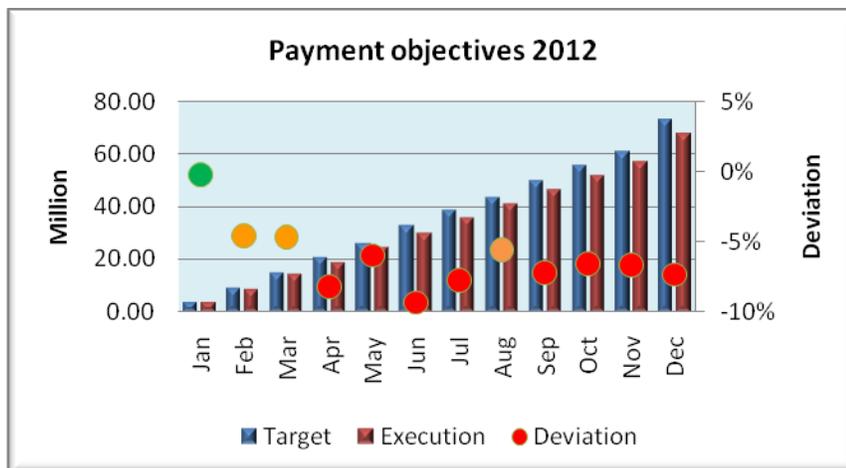
Title	Commitments 2012	Commitments 2011	Increase	Payments 2012	Payments 2011	Increase
PERSONNEL	38.563.788	37.097.113	3,9%	37.754.147	35.825.948	5,4%
INFRASTRUCTURE	10.966.034	14.286.533	-23,2%	8.602.142	9.122.558	-5,7%
OPERATIONS	28.164.869	24.747.012	13,8%	20.922.308	16.994.131	23,1%
<b>Total:</b>	<b>77.694.691</b>	<b>76.130.659</b>	<b>2,1%</b>	<b>67.278.597</b>	<b>61.942.637</b>	<b>8,6%</b>

### 3. Budget Execution versus Target

In 2012, commitments were less than 1% below the full execution objective as shown in the graph below. This is the strongest budget execution performance EFSA has ever achieved. The monthly deviation against target is measured on the right vertical axis and visualised by the (green / amber / red) dots.



Payments were 7% below the global target set for non-differentiated and differentiated payment appropriations. Including the €1.1 m payment appropriation added as a result of the global transfer procedure in December, the differentiated payments were 6% above target. The non-differentiated payments were however 9% below target due to the lag effect of transfers made at the end of 2011, carried forward and utilised in 2012.



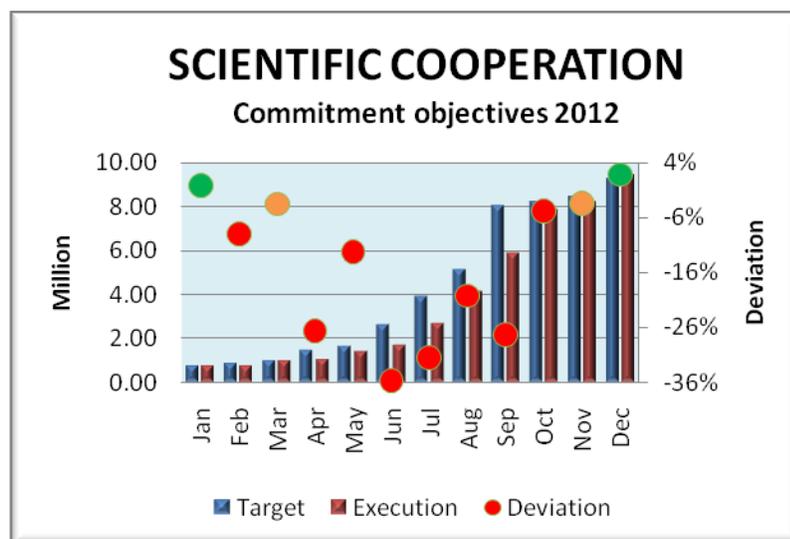
### 4. Transversal Actions

In 2012, the commitment appropriations for scientific meetings were reduced by 9% with a final 11% under-spend at year end. Commitment appropriations were increased for scientific cooperation (+4.5%) and the IT support tool (+6.1%) contributing to a high level of commitment rate versus the initial appropriations, 102% and 106% respectively. In scientific cooperation, the 105.6% payment rate is the result of the increase by €1.1 m of the payment appropriations during the year (global transfer) and the anticipation of a number of payments initially foreseen for 2013. The significant 55.5% reduction in commitment appropriations for the Advisory Forum to align with real needs should be noted. The operational budget for communication was reduced by 9.1%.

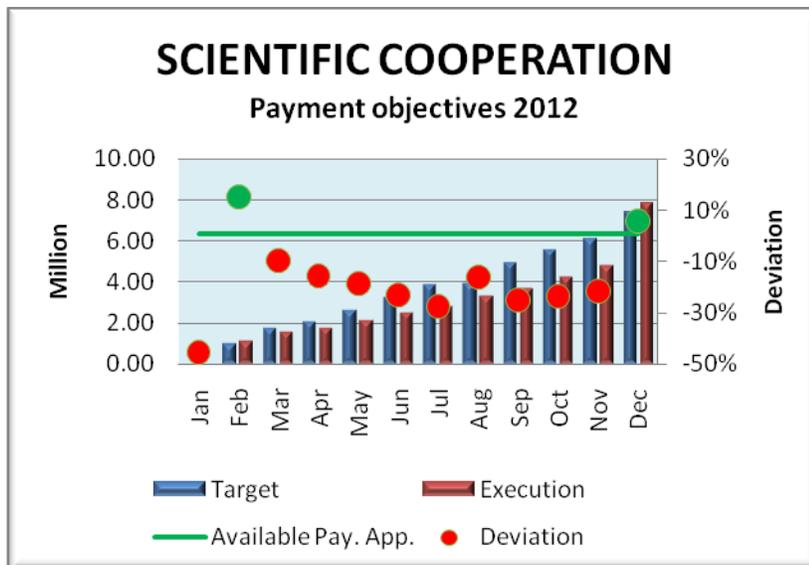
Description Action	Initial Commitment Appropriation	Current Commitment Appropriation	Δ	Amount Committed	%	Amount Paid	%
Science meetings	9.320.000	8.489.138	-8,9%	8.293.138	89,0%	7.832.800	84,0%
Scientific Cooperation	9.222.000	9.635.948	4,5%	9.428.607	102,2%	7.831.506	105,6%
IT Support Tools	7.775.000	8.247.199	6,1%	8.242.244	106,0%	2.790.738	35,9%
Communication	1.000.000	908.700	-9,1%	900.345	90,0%	609.517	61,0%
Conference & events	572.000	594.000	3,8%	570.530	99,7%	543.315	95,0%
Advisory Forum	497.000	221.373	-55,5%	209.110	42,1%	180.210	36,3%
<b>Total:</b>	<b>28.386.000</b>	<b>28.096.358</b>	<b>-1,0%</b>	<b>27.643.974</b>	<b>97,4%</b>	<b>19.788.086</b>	<b>77,6%</b>

### 5. Scientific Cooperation Programme

With €9.43 m committed in 2012, the scientific cooperation programme performed 2% above the initial target (€9.22 m initial budget). In view of the success of the calls launched this year, the programme was reinforced by €0.21 m and all available resources were utilised.



€7.83 m was paid against the €7.41 m appropriation. This stands 6% above the initial target after increase of the payment appropriations from €6.30 m to €7.41 m following approval by the Commission of the €1.1 m increase posted by EFSA in the framework of the global transfer. €3.01 m was paid in December representing nearly 40% of total payments under the programme.



## 6. By origin of funds

EFSA drew its resources (both commitment and payments) in 2012 from 3 sources: a 2012 EU subvention made for part of differentiated and non differentiated credits, 2011 credit carried forward to 2012 and credit provided by the European Commission as earmarked resources for the pre-accession activities.

More in detail:

2012 Non-differentiated Appropriations (€69.07 m)

- Non-differentiated Commitment Appropriations (€69.07 m at year start, €68.68 m at year end), used to cover all personnel, infrastructure and operational activities – with the exception of outsourced Scientific Cooperation activities - were consumed at 99.4%. The consumption for personnel and infrastructure expenditure reached 99.9% (Title I and II) and 98.3% for operational expenditures (Title III).
- Related Payment Appropriations were required at 100% from the European Commission and 86.5% was paid out during the year. (81.1% in 2011). The operational projects initiated at year end to support Scientific Cooperation activities explain the portion of the appropriation that could not be paid within the year. The payments that could not be made in 2012 are automatically carried over with the corresponding commitments to 2013.

2011 Differentiated Appropriations (€9.22 m)

- Since 2009 EFSA is given resources for scientific cooperation activities outsourced through Grants and Contracts as differentiated appropriations i.e. with a longer time span for execution and payment appropriations lower than the commitment appropriations. €9.22 m of differentiated commitment appropriations were foreseen at year start to be invested in Scientific Outsourcing through Grants and Contracts and €9.44 m were effectively utilised.
- EFSA utilised €7.83 m differentiated payment appropriations to cover new and previous scientific cooperation activities. This amount was increased from €6.33 m at year start following the €1.1 m additional request posted by EFSA and approved by the Commission. An amount of €0.4 m was transferred from non-differentiated credit to enable the anticipation of payments following earlier delivery and approval of scientific reports.

Pre-Accession programme (€0.48 m)

- In 2012, EFSA implemented the second part of the convention signed with the Commission in 2011 to cover the Pre-accession programme over two years. The final expiry date of the convention was extended to July 2014.

- In 2012, €0.48 m were added to EFSA budget and earmarked for that purpose. €0.24 m was committed leading to automatic carry forward of the balance in 2013.

Carry-over from 2011 (€12.68 m)

Automatic carry-forward from 2011 amounted to €12.38 m with 96.7% utilisation in 2012.

Title	Commitment Appropriation	Executed Payment	%
Title 1	1.271.165	1.206.459	94.9%
Title 2	5.163.975	5.107.431	98.9%
Title 3	6.247.230	5.954.258	95.3%
<b>Total:</b>	<b>12.682.370</b>	<b>12.268.148</b>	<b>96.7%</b>

The 5% under-execution rate under Title I is mainly due to carry-forward from 2011 related to translation, removal, medical and training services. With 99%, the carry-forward in Title II was almost fully utilised. Under Title III the 5% under-execution rate is mainly due to carry-forward for meetings: REPRO utilised only 66.9%, RASA 77.9% and SCISTRAT 81.5% of the carry-forward for meetings. At 96.7% utilisation overall, the utilisation of the carry-forward credits is however the highest recorded.

## 7. Transfers in EFSA Budget

The transfers in the budget aimed at covering the re-allocations of resources requested for staff purposes, infrastructure and scientific cooperation. Transfers from Title I to Title II amounted to €0.79 m or 2.0% of appropriations under Title I (6.2% in 2011). Overall, transfers from chapters to chapters and from Title I to Title II amount to €1.36 m or 2.75% of total budget (€5.31 m or 6.87% in 2011), a substantial reduction compared to 2011. The purpose of the transfers, details of which can be found in the tables below, was to:

- Under Title I, re-allocating €0.48 m to the Temporary Agent appropriations while at the same time reducing the budget line for contractual agents by €0.74 m. The reductions under the other articles under Title I allowed transferring an amount of €0.28 m to Title II in order to accommodate identified priorities. In addition, a transfer of €0.50 m linked to the absence of a decision related to the indexation of salary allowed anticipating payments to be made in 2013 under Title II.
- Under Title II, covering critical requests in Infrastructure services related to building energy (€0.47 m) and works required by the premises start-up phase (€0.25 m). These reinforcements were made possible by the above mentioned transfer from Title I and by the reduction of (i) the other administrative expenditure (- €0.16 m) and of (ii) the appropriations initially foreseen for the building acquisition due to the better financial conditions obtained at the time of purchase in late December 2011 (- €0.21 m)
- Under Title III,
  - Increasing by €0.22 m the commitment appropriations of the scientific cooperation programme from €9.22 m to €9.44 m allowing launch of additional projects.
  - Decreasing investment for scientific meetings by €0.83 m to €8.49 m.
  - Reallocating €0.09 m in commitment appropriations from the Communication budget to translation in order to publish documents in all 22 EU languages.
  - Reinforcing the IT horizontal support by €0.47 m commitment appropriations, anticipating investment initially programmed in 2013, mainly in the field of data collection developments to support scientific operations.
  - The €0.40 m transfer in differentiated payment credits from REPRO to RASA and SCISTRAT served to cover all payments needs under the scientific cooperation programme and anticipating payments initially foreseen in 2013 due to earlier approval of the scientific reports delivered. The request for and additional €1.10 m in payment credits sent to the Commission was approved made available end November.

mb 14 03 13 item 4 doc 3 - Draft Annual Activity Report 2012 – Annex I

Budget Line		Initial Commitment Appropriation	Current Commitment Appropriation	Executed Commitment	% Committed	Payment Appropriation	Executed Payment	% Paid
		(0)	(1)	(2)	(2)/(1)	(3)	(4)	(4)/(3)
1100	Basic salary	21,088,000	21,534,484	21,534,484	100.0%	21,534,484	21,534,484	100.0%
1101	Family allowance	2,465,000	2,505,293	2,505,293	100.0%	2,505,293	2,505,293	100.0%
1102	Transfer and expatriation allowance	2,675,000	2,561,169	2,561,169	100.0%	2,561,169	2,561,169	100.0%
1103	Secretarial allowance	10,000	11,285	11,285	100.0%	11,285	11,285	100.0%
1113	Traineeship	240,000	230,222	230,222	100.0%	230,222	230,222	100.0%
1115	Contract staff	5,086,000	4,342,886	4,342,886	100.0%	4,342,886	4,342,886	100.0%
1130	Insurance against sickness	745,000	739,655	739,655	100.0%	739,655	739,655	100.0%
1131	Insurance against accidents and occupational disease	155,000	109,477	109,477	100.0%	109,477	109,477	100.0%
1132	Unemployment insurance for temporary staff	272,000	270,858	270,858	100.0%	270,858	270,858	100.0%
1140	Birth and death allowance	5,000	3,420	3,420	100.0%	3,420	3,420	100.0%
1141	Annual leave travelling expenses	543,000	459,333	459,333	100.0%	459,333	459,333	100.0%
1147	Call on duties	30,000	28,090	28,090	100.0%	28,090	28,090	100.0%
1149	Other allowances and repayments	0	14,256	14,256	100.0%	14,256	14,256	100.0%
1171	Translation centre Luxembourg (administrative matters)	200,000	180,000	180,000	100.0%	180,000	135,286	75.2%
1172	Payment for administrative assistance from the Community institutions	248,000	235,961	235,961	100.0%	235,961	233,461	98.9%
1175	Interim services	975,000	1,123,337	1,123,337	100.0%	1,123,337	1,032,083	91.9%
1176	Consultancy	75,000	56,718	56,718	100.0%	56,718	9,781	17.2%
1177	Other services	295,000	163,616	163,616	100.0%	163,616	163,616	100.0%
1180	Miscellaneous expenditure on recruitment	155,000	111,315	111,315	100.0%	111,315	86,509	77.7%
1181	Travel expenses (including for members of the family)	25,000	10,020	10,020	100.0%	10,020	10,020	100.0%
1182	Installation, resettlement and transfer allowances	125,000	53,809	53,809	100.0%	53,809	53,809	100.0%
1183	Removal expenses	140,000	112,136	112,136	100.0%	112,136	81,927	73.1%
1184	Temporary daily subsistence allowance	70,000	83,717	83,717	100.0%	83,717	83,717	100.0%
1190	WEIGHTINGS	1,420,000	1,526,389	1,526,389	100.0%	1,526,389	1,526,389	100.0%
<b>Chapter 11</b>		<b>37,042,000</b>	<b>36,467,447</b>	<b>36,467,447</b>	<b>100.0%</b>	<b>36,467,447</b>	<b>36,227,026</b>	<b>99.3%</b>

mb 14 03 13 item 4 doc 3 - Draft Annual Activity Report 2012 – Annex I

Budget Line		Initial Commitment Appropriation	Current Commitment Appropriation	Executed Commitment	% Committed	Payment Appropriation	Executed Payment	% Paid
		(0)	(1)	(2)	(2)/(1)	(3)	(4)	(4)/(3)
1300	Mission and travel expenses	125,000	79,456	79,456	100.0%	79,456	65,817	82.8%
1301	Shuttles for missions and duty	38,000	43,000	43,000	100.0%	43,000	38,820	90.3%
<b>Chapter 13</b>		<b>163,000</b>	<b>122,456</b>	<b>122,456</b>	<b>100.0%</b>	<b>122,456</b>	<b>104,637</b>	<b>85.4%</b>
1400	Restaurants, meals and canteens	38,000	50,750	50,750	100.0%	50,750	49,390	97.3%
1410	Medical service	270,000	170,401	167,129	98.1%	170,401	149,905	88.0%
1420	Further training, language courses and retraining for staff	716,000	690,945	688,190	99.6%	690,945	214,847	31.1%
<b>Chapter 14</b>		<b>1,024,000</b>	<b>912,097</b>	<b>906,069</b>	<b>99.3%</b>	<b>912,097</b>	<b>414,142</b>	<b>45.4%</b>
1520	Visiting experts, National Experts on Detachment	885,000	889,624	886,372	99.6%	889,624	871,739	98.0%
1521	Authority officials temporarily assigned	50,000	51,000	51,000	100.0%	51,000	21,412	42.0%
<b>Chapter 15</b>		<b>935,000</b>	<b>940,624</b>	<b>937,372</b>	<b>99.7%</b>	<b>940,624</b>	<b>893,151</b>	<b>95.0%</b>
1610	Social contacts between staff	80,000	50,618	50,618	100.0%	50,618	47,885	94.6%
1630	Early childhood centres and other creches	65,000	75,201	75,201	100.0%	75,201	64,397	85.6%
1640	Complementary aid for the handicapped	10,000	0	0	0.0%	0	0	0.0%
<b>Chapter 16</b>		<b>155,000</b>	<b>125,819</b>	<b>125,819</b>	<b>100.0%</b>	<b>125,819</b>	<b>112,282</b>	<b>89.2%</b>
1700	Reception and entertainment expenses	40,000	4,624	4,624	100.0%	4,624	2,909	62.9%
<b>Chapter 17</b>		<b>40,000</b>	<b>4,624</b>	<b>4,624</b>	<b>100.0%</b>	<b>4,624</b>	<b>2,909</b>	<b>62.9%</b>
<b>Title 1</b>		<b>39,359,000</b>	<b>38,573,067</b>	<b>38,563,788</b>	<b>100.0%</b>	<b>38,573,067</b>	<b>37,754,147</b>	<b>97.9%</b>

mb 14 03 13 item 4 doc 3 - Draft Annual Activity Report 2012 – Annex I

Budget Line		Initial Commitment Appropriation (0)	Current Commitment Appropriation (1)	Executed Commitment (2)	% Committed (2)/(1)	Payment Appropriation (3)	Executed Payment (4)	% Paid (4)/(3)
2000	Rent	600,000	590,083	590,082	100.0%	590,083	590,049	100.0%
2001	Acquisition	2,420,000	2,715,000	2,714,827	100.0%	2,715,000	2,714,827	100.0%
2010	Insurance	41,000	39,550	39,550	100.0%	39,550	39,550	100.0%
2020	Water, gas, electricity and heating	510,000	1,003,134	1,003,134	100.0%	1,003,134	800,224	79.8%
2030	Maintenance	235,000	219,720	219,720	100.0%	219,720	183,191	83.4%
2031	Cleaning	300,000	300,000	300,000	100.0%	300,000	250,784	83.6%
2040	Refurbishment of premises/ Fitting out	144,000	252,345	250,480	99.3%	252,345	181,008	71.7%
2050	Security and surveillance of buildings	840,000	839,009	839,008	100.0%	839,009	720,586	85.9%
2080	Preliminary to construction, acquisition or rental of immovable property	60,000	98,590	98,590	100.0%	98,590	85,810	87.0%
2090	Other expenditure on buildings	435,000	543,602	543,602	100.0%	543,602	518,285	95.3%
<b>Chapter 20</b>		<b>5,585,000</b>	<b>6,601,033</b>	<b>6,598,994</b>	<b>100.0%</b>	<b>6,601,033</b>	<b>6,084,314</b>	<b>92.2%</b>
2100	Purchase/ Maintenance of equipment	350,000	480,000	479,897	100.0%	480,000	179,819	37.5%
2101	Purchase / maintenance of software	245,000	327,000	324,195	99.1%	327,000	257,164	78.6%
2103	Software development	2,017,000	1,771,803	1,771,744	100.0%	1,771,803	726,705	41.0%
2104	User Support	625,000	709,696	709,695	100.0%	709,696	672,805	94.8%
<b>Chapter 21</b>		<b>3,237,000</b>	<b>3,288,499</b>	<b>3,285,531</b>	<b>99.9%</b>	<b>3,288,499</b>	<b>1,836,493</b>	<b>55.8%</b>
2200	Technical equipment and installations	100,000	98,992	98,992	100.0%	98,992	4,744	4.8%
2201	Hire or leasing of technical equipment and installations	110,000	13,550	13,550	100.0%	13,550	13,300	98.2%
2202	Maintenance and repair of technical equipment and installations	25,000	0	0	0.0%	0	0	0.0%
2210	Purchase of furniture	40,000	37,186	37,185	100.0%	37,186	12,224	32.9%
2250	Library stocks, purchase and preservation of books	12,000	12,000	8,198	68.3%	12,000	7,928	66.1%
2251	Special library, documentation and reproduction equipment	18,000	18,000	15,890	88.3%	18,000	15,890	88.3%
2255	Subscriptions and purchase of information media	9,000	11,040	11,001	99.6%	11,040	4,603	41.7%
<b>Chapter 22</b>		<b>314,000</b>	<b>190,768</b>	<b>184,816</b>	<b>96.9%</b>	<b>190,768</b>	<b>58,689</b>	<b>30.8%</b>

mb 14 03 13 item 4 doc 3 - Draft Annual Activity Report 2012 – Annex I

Budget Line		Initial Commitment Appropriation (0)	Current Commitment Appropriation (1)	Executed Commitment (2)	% Committed (2)/(1)	Payment Appropriation (3)	Executed Payment (4)	% Paid (4)/(3)
2300	Stationery and office supplies	162,000	149,999	149,999	100.0%	149,999	124,030	82.7%
2320	Bank charges	2,000	1,000	522	52.2%	1,000	522	52.2%
2330	Legal expenses	100,000	6,478	6,478	100.0%	6,478	6,478	100.0%
2340	Damages	25,000	0	0	0.0%	0	0	0.0%
2350	Miscellaneous insurance	17,000	9,850	9,031	91.7%	9,850	6,930	70.4%
2353	Removals and associated handling	15,000	0	0	0.0%	0	0	0.0%
2390	Publications	15,000	2,289	2,288	100.0%	2,289	1,034	45.2%
<b>Chapter 23</b>		<b>336,000</b>	<b>169,616</b>	<b>168,319</b>	<b>99.2%</b>	<b>169,616</b>	<b>138,994</b>	<b>81.9%</b>
2400	Postal charges	49,000	49,000	49,000	100.0%	49,000	32,385	66.1%
2410	Telecommunications subscriptions and charges	300,000	272,016	271,016	99.6%	272,016	218,106	80.2%
2411	Purchase and installation of equipment	251,000	297,000	296,700	99.9%	297,000	148,530	50.0%
<b>Chapter 24</b>		<b>600,000</b>	<b>618,016</b>	<b>616,716</b>	<b>99.8%</b>	<b>618,016</b>	<b>399,021</b>	<b>64.6%</b>
2500	Management Board meetings	150,000	140,000	111,657	79.8%	140,000	84,631	60.5%
<b>Chapter 25</b>		<b>150,000</b>	<b>140,000</b>	<b>111,657</b>	<b>79.8%</b>	<b>140,000</b>	<b>84,631</b>	<b>60.5%</b>
<b>Title 2</b>		<b>10,222,000</b>	<b>11,007,933</b>	<b>10,966,034</b>	<b>99.6%</b>	<b>11,007,933</b>	<b>8,602,142</b>	<b>78.1%</b>

mb 14 03 13 item 4 doc 3 - Draft Annual Activity Report 2012 – Annex I

Budget Line		Initial Commitment Appropriation (0)	Current Commitment Appropriation (1)	Executed Commitment (2)	% Committed (2)/(1)	Payment Appropriation (3)	Executed Payment (4)	% Paid (4)/(3)
<b>REPRO</b>								
3001	APDESK: Grant & Procurement	170,000	118,113	118,113	100.0%	17,717	17,717	100.0%
3002	APDESK: Expert Meetings	90,000	0	0	0.0%	0	0	0.0%
3011	FIP: Grant & Procurement	690,000	738,968	738,968	100.0%	658,613	658,613	100.0%
3012	FIP: Expert Meetings	1,220,000	1,310,000	1,269,136	96.9%	1,310,000	1,160,690	88.6%
3021	FEED: Grant & Procurement	380,000	206,198	206,130	100.0%	41,753	41,753	100.0%
3022	FEED: Expert Meetings	885,000	1,108,000	1,092,243	98.6%	1,108,000	997,886	90.1%
3031	NUTRI: Grant & Procurement	225,000	165,775	165,775	100.0%	251,360	251,360	100.0%
3032	NUTRI: Expert Meetings	623,000	585,640	552,789	94.4%	585,640	536,436	91.6%
3041	PRAS: Grant & Procurement	937,000	1,054,655	974,654	92.4%	829,202	825,791	99.6%
3042	PRAS: Expert Meetings	991,000	761,000	748,955	98.4%	761,000	736,689	96.8%
3051	GMO: Grant & Procurement	345,000	181,809	179,880	98.9%	189,049	188,689	99.8%
3052	GMO: Expert Meetings	1,055,000	846,791	832,725	98.3%	846,791	781,222	92.3%
<b>TOTAL REPRO</b>		<b>7,611,000</b>	<b>7,076,949</b>	<b>6,879,368</b>	<b>97.2%</b>	<b>6,599,125</b>	<b>6,196,846</b>	<b>93.9%</b>

mb 14 03 13 item 4 doc 3 - Draft Annual Activity Report 2012 – Annex I

Budget Line		Initial Commitment Appropriation	Current Commitment Appropriation	Executed Commitment	% Committed	Payment Appropriation	Executed Payment	% Paid
		(0)	(1)	(2)	(2)/(1)	(3)	(4)	(4)/(3)
<b>RASA</b>								
3101	AHAW: Grant & Procurement	332,000	1,063,626	1,061,582	99.8%	1,000,955	999,352	99.8%
3102	AHAW: Expert Meetings	771,000	771,000	770,693	100.0%	771,000	756,584	98.1%
3111	DCM: Grant & Procurement	1,859,000	2,208,167	2,118,767	96.0%	1,635,575	1,635,363	100.0%
3112	DCM: Expert Meetings	177,000	135,262	120,349	89.0%	135,262	120,349	89.0%
3121	PLH: Grant & Procurement	493,000	521,205	520,341	99.8%	701,787	701,787	100.0%
3122	PLH: Expert Meetings	650,000	702,500	688,057	97.9%	702,500	660,729	94.1%
3131	SAS: Grant & Procurement	551,000	324,427	324,427	100.0%	335,035	335,035	100.0%
3132	SAS: Expert Meetings	112,000	62,697	58,451	93.2%	62,697	56,141	89.5%
3141	CONTAM: Grant & Procurement	493,000	440,832	440,691	100.0%	338,597	337,741	99.7%
3142	CONTAM: Expert Meetings	724,000	770,920	762,925	99.0%	770,920	714,163	92.6%
3151	BIOMO: Grant & Procurement	983,000	562,178	534,374	95.1%	594,401	594,400	100.0%
3152	BIOMO: Expert Meetings	349,000	239,080	232,846	97.4%	239,080	219,662	91.9%
3161	BIOHAZ: Grant & Procurement	361,000	434,355	434,355	100.0%	193,411	193,411	100.0%
3162	BIOHAZ: Expert Meetings	811,000	668,000	660,609	98.9%	668,000	654,221	97.9%
<b>TOTAL RASA</b>		<b>8,666,000</b>	<b>8,904,249</b>	<b>8,728,467</b>	<b>98.0%</b>	<b>8,149,221</b>	<b>7,978,938</b>	<b>97.9%</b>

mb 14 03 13 item 4 doc 3 - Draft Annual Activity Report 2012 – Annex I

Budget Line		Initial Commitment Appropriation	Current Commitment Appropriation	Executed Commitment	% Committed	Payment Appropriation	Executed Payment	% Paid
		(0)	(1)	(2)	(2)/(1)	(3)	(4)	(4)/(3)
<b>SCISTRAT</b>								
3200	Advisory Forum, Plenary & Working groups	270,000	162,500	151,047	93.0%	162,500	122,147	75.2%
3201	Focal Points Agreements	978,000	959,000	953,911	99.5%	814,850	809,761	99.4%
3202	Focal Points working groups	227,000	58,873	58,063	98.6%	58,873	58,063	98.6%
3220	Institutional Cooperation	17,000	5,000	4,564	91.3%	5,000	4,564	91.3%
3221	Stakeholder relationships	50,000	57,000	34,938	61.3%	57,000	34,338	60.2%
3222	International Cooperation	17,000	0	0	0.0%	0	0	0.0%
3232	SCOM: Expert Meetings	732,000	450,748	434,483	96.4%	450,748	380,916	84.5%
3241	EMRISK: Grant & Procurement	425,000	656,640	656,640	100.0%	240,732	240,732	100.0%
3242	EMRISK: Expert Meetings	130,000	77,500	68,876	88.9%	77,500	57,113	73.7%
3243	Crisis support	20,000	6,360	6,360	100.0%	6,360	1,360	21.4%
<b>TOTAL SCISTRAT</b>		<b>2,866,000</b>	<b>2,433,621</b>	<b>2,368,882</b>	<b>97.3%</b>	<b>1,873,563</b>	<b>1,708,994</b>	<b>91.2%</b>
<b>COMMS</b>								
3400	Audiovisual Materials and Web development	161,000	161,000	160,205	99.5%	161,000	117,531	73.0%
3410	Offline communications activities and materials	381,000	381,000	376,907	98.9%	381,000	283,089	74.3%
3420	Advisory Forum Working group, AGRC, Evaluation and media monitoring	458,000	366,700	363,234	99.1%	366,700	208,897	57.0%
<b>TOTAL COMMS</b>		<b>1,000,000</b>	<b>908,700</b>	<b>900,345</b>	<b>99.1%</b>	<b>908,700</b>	<b>609,517</b>	<b>67.1%</b>

mb 14 03 13 item 4 doc 3 - Draft Annual Activity Report 2012 – Annex I

Budget Line	Initial Commitment Appropriation (0)	Current Commitment Appropriation (1)	Executed Commitment (2)	% Committed (2)/(1)	Payment Appropriation (3)	Executed Payment (4)	% Paid (4)/(3)
<b>OPERATIONAL SUPPORT</b>							
3501 IT tools for Data Collection	1,904,000	2,386,000	2,385,405	100.0%	2,386,000	978,327	41.0%
3502 IT tools to support Networking of organization	328,000	328,000	327,370	99.8%	328,000	55,106	16.8%
3503 Dedicated IT development and systems to support the scientific operations	1,295,000	1,448,396	1,448,217	100.0%	1,448,396	265,213	18.3%
3504 Dedicated IT development and systems to support Applicants	1,528,000	1,528,000	1,527,397	100.0%	1,528,000	316,503	20.7%
3505 Dedicated IT development and systems to support web development, communications and outreach	458,000	458,000	457,916	100.0%	458,000	191,720	41.9%
3511 Quality management & strategy	85,000	5,000	4,900	98.0%	5,000	0	0.0%
3512 Library: access to data base documents	250,000	250,000	239,718	95.9%	250,000	233,856	93.5%
3513 Mission of staff related to operational duties	890,000	787,000	787,000	100.0%	787,000	698,602	88.8%
3514 Shuttles	790,000	900,000	865,000	96.1%	900,000	828,268	92.0%
3515 Archives and scanning	15,000	11,644	11,643	100.0%	11,644	4,393	37.7%
3516 Video/Tele conferencing	60,000	214,609	214,578	100.0%	214,609	33,874	15.8%
3521 Translation & Interpretation	185,000	276,300	274,478	99.3%	276,300	244,744	88.6%
3522 Linguistic Proofreading and Editing	15,000	7,532	1,440	19.1%	7,532	1,440	19.1%
3530 Conference & Events	572,000	594,000	570,530	96.0%	594,000	543,315	91.5%
3531 Web and Audio casting	180,000	180,000	172,216	95.7%	180,000	32,652	18.1%
<b>TOTAL OPERATIONAL SUPPORT</b>	<b>8,555,000</b>	<b>9,374,481</b>	<b>9,287,808</b>	<b>99.1%</b>	<b>9,374,481</b>	<b>4,428,014</b>	<b>47.2%</b>
<b>Title 3</b>	<b>28,698,000</b>	<b>28,698,000</b>	<b>28,164,869</b>	<b>98.1%</b>	<b>26,905,090</b>	<b>20,922,308</b>	<b>77.8%</b>
<b>GRAND TOTAL</b>	<b>78,279,000</b>	<b>78,279,000</b>	<b>77,694,691</b>	<b>99.3%</b>	<b>76,486,090</b>	<b>67,278,597</b>	<b>88.0%</b>

**Earmarked revenue**

The pre-accession programme is conducted by EFSA with earmarked revenue allocated by DG ENLARG under a two-year agreement running from September to September, signed in September 2011. The commitment appropriations available in 2012 relates to the 2012 part of first year of the above agreement and were at 71.76% committed as shown in the table below.

Budget Line	Initial Commitment Appropriation (0)	Current Commitment Appropriation (1)	Executed Commitment (2)	% Committed (2)/(1)	Payment Appropriation (3)	Executed Payment (4)	% Paid (4)/(3)
3223 Pre-accession programme	339,590	339,590	243,687	71.76%	339,590	211,293	62.22%

**Annex 2: Establishment Plan**

Category and grade	Establishment Plan 2012	
	Officials	Temporary Agents
AD 16	0	0
AD 15	0	1
AD 14	0	2
AD 13	0	0
AD 12	1	14
AD 11	0	11
AD 10	1	9
AD 9	1	33
AD 8	0	44
AD 7	1	58
AD 6	1	27
AD 5	0	21
<b>Total AD</b>	<b>5</b>	<b>220</b>
AST 11	0	0
AST 10	0	0
AST 9	0	0
AST 8	0	1
AST 7	0	5
AST 6	0	5
AST 5	0	22
AST 4	0	38
AST 3	0	24
AST 2	0	24
AST 1	0	11
<b>Total AST</b>	<b>0</b>	<b>130</b>
		<b>355</b>

**Annex 3: Declaration of assurance**

I, the undersigned,

Executive Director of EFSA

In my capacity as authorising officer,

- Declare that the information contained in this report gives a true and fair view.
- State that I have reasonable assurance that the resources assigned to the activities described in this report have been used for their intended purpose and in accordance with the principles of legality, regularity and sound financial management, and that the control procedures put in place give the necessary guarantees concerning the legality and regularity of the underlying transactions.

This reasonable assurance is based on my own judgement and on the information at my disposal, such as the results of the work of the internal audit capability, the observations of the Internal Audit Service and the lessons learnt from the reports of the Court of Auditors for the years prior to the year of this declaration.

- Confirm that I am not aware of anything not reported here which could harm the interests of the Authority.

Parma,  
1 March, 2013

Signed by:  
Catherine Geslain-Lanéelle,  
Executive Director

#### **Annex 4: Report on the Implementation of the Internal Control Standards**

The ongoing review of compliance with EFSA's Internal Control Standards (ICS) has provided the organisation with reasonable assurance on the level of implementation of the Standards. It shows there are no signs of deterioration compared with the 2011 declaration of assurance. The review critically appraises the effectiveness and efficiency of the system based on a detailed and broad review of all 16 Standards. As such, the review, which is scheduled to be concluded by March 2013, is likely to highlight a number of standards where improvements must be made to ensure effective compliance. The preliminary results have indicated that the following Standards need to be improved in 2013:

1. ICS 2 – Ethical and organisational values (e.g. complexity of ethical guidance, efficiency/ accessibility of channels for reporting alleged wrong-doings)
2. ICS 3 – Staff allocation and mobility (e.g. EXO Planning & Monitoring function, balance of workload among teams, transparency in the contract renewal process, phasing-in of the Human Resource Allegro system)
3. ICS 4 – Staff appraisal and career development (e.g. implementing rules on promotion/reclassification, transparency and documentation of the promotion exercise)
4. ICS 5 – Objectives and performance indicators (e.g. need for meaningful performance indicators, ability to prioritise)
5. ICS 11 - Document management (e.g. implementation of Document Management System, absence of quality manual, document search functionality in the EFSA portal)

In October 2012, a risk identification/analysis exercise involving EFSA senior and middle management personnel was undertaken in order to:

1. Update the full risk register,
2. Identify the critical risks,
3. Establish an efficient and effective action plan to address the critical risks.

The workshop assessed and validated the risk register and the critical risks which, by nature, require immediate attention from EFSA management and the establishment of an efficient and effective action plan to address current weaknesses. The following are the risks identified as critical, i.e. have the potential to endanger the delivery of EFSA's major objectives, cause serious damage to EFSA's partners, result in critical intervention at political level, or seriously impact EFSA's image and reputation:

1. EFSA is unable to attract the required expertise (knowledge workers or Panel/working group members)
2. Inadequate partnership with national and international organisations engaged in risk assessment
3. Over-ambitious deadlines and workloads triggered by external pressure and/or inadequate planning
  - Resource allocation based on historical reasons
  - Mismatch between limited resources and expected deliverables
  - Insufficient openness and transparency in the risk assessment process
4. IT investment, IT governance and strategy misaligned with organisational priorities
5. Inconsistent and inaccurate external perception of the role of EFSA

The Internal Control Coordinator will develop action plans in 2013 addressing the critical and significant risks retained. This is an integral part of the Annual Management Plan 2013.

**Annex 5: List of negotiated procedures**

A total of 11 negotiated procedures (7 in 2011) are reported here for a total amount of €0.85 m (€0.36 m in 2011). The increase is mainly due to the six 2012 negotiated procedures related to the new building consumables (power, water, urban heating and waste collection) for an amount of €0.43 m. The remaining negotiated procedures launches are part of the pilot project aiming at harmonising chemical occurrence data with the national agencies.

2012 Negotiated procedures under Article 126 a-g and Article 127 a-d of EU Financial Regulation				
N°	Procedure type	Contractor name	Subject of contract	Contract amount
1	Neg Art 126 1b	INSA	Pilot projects on implementation of Food Ex2 (Monopoly)	35,000
2	Neg Art 126 1b	EVIRA	Pilot Projects on the implementation of FoodEx2 as part of the standard Sample Description for the electronic transmission of harmonized chemical occurrence data on EFSA (6 NP 126B OF 35K EACH°	35,000
		STATE GENERAL LABORATORY		34,900
		ISTITUTO ZOOPROFILATTICO SPERIMENTALE-ICT-TERAMO		34,704
3	Neg Art 126 1b	BVL	Pilot Projects on the implementation of FoodEx2 as part of the standard Sample Description for the electronic transmission of harmonized chemical occurrence data on EFSA	34,973
		DTU (DK)		35,000
		National Food Chain Safety Office (HU)		35,000
		Food Research Institute (SK)		35,000
		ANSES (FR)		35,000
		Food and Veterinary Service (LV)		35,000
		University Dunarea de Jos Galati (RO)		32,000
4	Neg Art 126 1b	IREN	Rifiuti	94,773
5	Neg Art 126 1b	AUSL	Energia Elettrica - DUS B - Recovery Disaster Site	15,833
6	Neg Art 126 1b	IREN	Energia Elettrica -	79,167
7	Neg Art 126 1b	IREN	Fornitura acqua potabile e fognatura depurazione	49,000
8	Neg Art 126 1b	IREN	Teleriscaldamento	196,000
9	Neg Art 126 1b	Informa UK Ltd	Subscription EU Food Law	20,940
10	Neg Art 126 1b	Bartlett Media LTD	Subscription to EU Food Policy	10,000
11	Neg Art 126 1b	Bartlett Media LTD	Annual subscription to EU Food Policy for all EFSA staff	1,700
<b>Total</b>				848,991

## Glossary

ABAC – Accrual-based accounting  
ABB – Activity-based budgeting  
ABP – Animal by-products  
AF – Advisory Forum  
AFWGC – Advisory Forum Working Group on Communications  
AFSCO – EFSA Advisory Forum and Scientific Cooperation unit  
AGRC – Advisory Group on Risk Communication  
AHAW Panel – Panel on Animal Health and Welfare  
AMR – Anti-microbial resistance  
ANS – Panel on Food Additives and Nutrient Sources Added to Food  
APDESK – EFSA Applications Desk unit  
ARfD – Acute Reference Dose  
BEUC – European Consumers Organisation  
BIOHAZ Panel – Panel on biological hazards  
BIOMO – EFSA Biological Monitoring unit  
BMD – Benchmark dose  
BSE – Bovine spongiform encephalopathy  
CCD – Colony Collapse Disorder  
CDAC – Career Development and Appraisal  
CEF – Panel on Contact Materials, Enzymes, Flavourings and Processing Aids  
CoA – Court of Auditors  
CONTAM Panel – Panel on contaminants in the food chain  
CRL – Community Reference Laboratory  
CVO – Chief Veterinary Officer  
DCM – EFSA Dietary and Chemical Monitoring unit  
DG ENV – Directorate General Environment  
DG SANCO – Directorate General for Health and Consumers  
DoI – Declaration of Interest  
ECB – European Chemicals Bureau  
ECDC – European Centre for Disease Prevention and Control  
ECHA – European Chemical Agency  
EDPS – European Data Protection Supervisor  
EEA – European Environment Agency  
EMCDDR – European Monitoring Centre for Drugs and Drug Addiction  
EMA – European Medicines Agency  
EmRisk – EFSA Emerging Risks Unit  
END – Seconded National Expert  
ENP – European Neighbourhood Policy  
ENVI – The European Parliament Committee for Environment, Public Health and Food Safety  
EP – European Parliament  
ESCO – EFSA Scientific Cooperation projects  
FAO – Food and Agriculture Organization  
FAQ – Frequently asked questions  
FDA – Food and Drug Administration (US)  
FEED – EFSA Feed Additives unit  
FEEDAP Panel – Panel on Additives and Products or Substances Used in Animal Feed  
FIP – EFSA Food Ingredients & Packaging unit  
GD – Guidance document  
GMO Panel – Panel on Genetically Modified Organisms

IAC – Internal Audit Capability of EFSA  
IAS – Internal Audit Service of the European Commission  
INEX – Self, Internal and External Quality Review programme  
JECFA – Joint FAO/WHO Expert Committee on Food Additives  
JEMRA – Joint FAO/WHO Meetings on Microbiological Risk Assessment  
JMPR – Joint FAO/WHO Meetings on Pesticide Residues  
JRC – Joint Research Centre of the European Commission  
MRA – Microbiological Risk Assessment  
MRL – Maximum residue Levels  
MRSA – Meticillin-resistant *Staphylococcus aureus*  
MS – EU Member States  
NDA Panel – Panel on Dietetic Products, Nutrition and Allergies  
NGO – Non-Governmental Organisation  
OIE – Office International des Epizooties  
OECD – Organisation for Economic Cooperation and Development  
OJ – Official Journal  
PLH Panel – Panel on Plant Health  
PPR Panel – Panel on Plant Protection Products and Their Residues  
PRAS – EFSA Pesticides unit  
QMRA – Quantitative Microbiological Risk Assessment  
QPS – Qualified Presumption of Safety  
SAS – EFSA Scientific Assessment Support unit  
SC – Scientific Committee  
SCOM – EFSA Scientific Committee unit  
SCENIHR – Standing Committee on Emerging and Newly Identified Health Risks  
SOP – Standard operating procedure  
TSE – Transmissible spongiform encephalopathy  
USDA – United States Department of Agriculture  
WHO – World Health Organisation