European Food Safety Authority

Draft Annual Activity Report of the European Food Safety Authority for 2009

Document describing the activities of the Authority in 2009

CONTENTS

I Highlights 2009

Corporate
Scientific outputs reach 636
Commissioner Vassiliou re-visits EFSA and the foundation stone of the Final Seat is laid
Full implementation of DOI policy
Satisfaction survey of experts is carried out and an action plan is implemented
Strategic Approach to International Activities is adopted and implementation begins
Memorandum of Cooperation signed with Japan, discussions with China, New Zealand-Australia and WHO
EFSA delegation visits key US risk assessment institutions
Memorandum of Understanding signed with ECHA
First Baccalaureate awarded at the European School: all 12 students are successful
Mandate for Stakeholder Consultative Platform is renewed
Business continuity plan is formalised

Risk Assessment
First series of Article 13 opinions on health claims is published
Opinions in dairy cow welfare are adopted
Joint opinion on antimicrobial resistance in collaboration with EMA, ECDC and SCENIHR
Internal and external quality review programme is fully operational
Guidance on pesticide persistence in soil is issued
Opinion on the safety of ractopamine is adopted
First Annual Report on Pesticide Residues is published
First re-evaluation of the cultivation of a GMO (MON 810) is completed
Rapid responses to nicotine in mushrooms, 4-methylbenzophenone in breakfast cereals and cold treatment of strawberry plants
133 meetings are held with Member States and stakeholders on scientific issues, 341 meetings on all issues
Scientific Committee and eight Scientific Panels are renewed
Scientific Committee advises on transparency in risk assessment and alternatives to animal testing
ESCO Working Group report on risks and benefits of folic acid fortification is published

Scientific Cooperation & Assistance
Focal Points are renewed
Article 36 and procurement budget reaches €6.8 m
IT platform for exchanging information with Member States is implemented
Crisis simulation exercises are held with Member State and Commission participation
EFSA and ECDC publish joint Community Zoonoses Report 2007
EFSA approach to public consultation on scientific outputs is published
Proposal for pan-European food consumption survey (EUMenu) is elaborated

Communication
Key corporate publications are available in all 23 official EU languages
Usability and accessibility of EFSA website are enhanced
New *EFSA Journal* web-area is launched
Joint press briefing with ECDC and DG SANCO on 2007 Community Zoonoses Report
Overall approach agreed with Advisory Forum for development of risk communication guidelines

Administration
A total of 15 new human resources policies/guidelines are introduced
New legislation adopted by the Italian authorities for the European School
Staff survey is repeated and action plan implemented

II Overview of Scientific Activities

The overall workload remained high and several initiatives were taken to strengthen planning, increase support for the Scientific Panels and Scientific Committee, and streamline processes. The number of outputs (636) delivered in 2009 was significantly less than predicted in Management Plan 2009 (1395) due mainly to procedural difficulties associated with health claims, in particular delays in the receipt of questions and quality issues, as well as delays in the submission of pesticide evaluations and non-receipt of some mandates. The unpredictability of some aspects of EFSA's workload points towards the need for a mid-year review of targets and EFSA will consider such a biannual planning system in future. Collaboration with the European Commission was increased to forecast and prioritize the incoming work, e.g. via the Roadmap agreed with DG Health and Consumers (DG SANCO). Furthermore, 341 meetings were held with Member States and stakeholders to exchange views, provide information and discuss the work. The Mandates Review Committee was established to support the allocation of incoming questions.

Additional support for the Panels and Scientific Committee was provided by outsourcing preparatory work through contracts and grants worth €6.8 million in 2009. The recommendations derived from the experts' survey were implemented to enhance the level of support provided by EFSA. Membership of eight of EFSA's Scientific Panels and Scientific Committee was renewed in summer 2009. The vast majority (79%) of existing members reapplied for a further 3-year term and the overall number of applicants for each position in the Panels or Scientific Committee increased by 7% compared with the previous call.

The proportion of scientific outputs adopted within deadline was 85%, against a target of 95%, due mainly to difficulties in application procedures, requirements for additional information identified at a late stage of the adoption process, and workload prioritisation. Special effort was devoted to decreasing the time between adoption/endorsement and publication of scientific outputs by analysing the publication process post-adoption and introducing and implementing a standard operating procedure (SOP). For scientific outputs with no associated press releases or web-stories, 75% were published within the target of 15 working days. The internal and external quality review (INEX) process was fully implemented for the first time and the opinion on transparency in risk assessment adopted by Scientific Committee in April has become an important reference document for the INEX programme. The recommendations presented by the first report of external reviewers on the quality of published scientific outputs together with the results of internal reviews will form the basis for further improvements in the quality of EFSA's scientific work. The Declaration of Interests (DOI) Policy adopted by EFSA's Management Board in 2007 was fully implemented and favourable outcomes were obtained in the conclusions of the Internal Audit Service of the European Commission. In total, over 1500 experts were involved in the implementation of the policy in 2009.

Support for risk assessments was provided in the form of data collation for exposure assessment, meta-analyses for hazard characterisation, and systematic literature reviews. This activity has increased both in terms of the number of projects as well as the number of Panels supported. In relation to pesticide safety reviews, requests in 2009 mainly concerned the resubmission of dossiers; most of these had been received by the end of the year. It is expected that this workload will peak in 2010.

III Provide scientific opinions and advice to the European Commission, European Parliament and Member States (Activity 1)

III.1 Overview of Activity 1

The number of scientific outputs finalised in 2009 was 559 (Activity 1 only), an increase of 57% over 2008. However, due to unexpected difficulties in the health claims process (delays, number and quality), delays in the submission of pesticide evaluations and non-receipt of questions, the target for 2009 of 1300 outputs was not met. Implementation of the integrated approach to the provision of scientific advice resulted in 5 joint opinions. These included a joint BIOHAZ/GMO opinion on the use of antimicrobial resistance (AMR) genes as markers in GM plants and joint FEEDAP/GMO opinions on feed additives. In addition, a joint opinion on AMR in collaboration with

EMEA, ECDC and SCENIHR and a joint scientific report on meticillin-resistant *Staphylococcus aureus* (MRSA) in collaboration with ECDC and EMEA were issued. Application processes within ANS, CEF, FEEDAP, GMO, NDA and PRAPeR were analysed and follow-up actions will continue in 2010. The efficiency gains coupled with the increase in resources devoted to these units in recent years has been accompanied by a significant increase in their productivity, from 165 adopted opinions in 2008 to 435 in 2009. It is anticipated that the workload associated with applications will remain high in the foreseeable future. The main milestones reached in the area of applications in 2009 were the completion by the CEF Panel of most of the evaluations of the 2600 flavouring substances and smoke flavourings in the 2005 mandate (10 await finalisation in 2010) and the finalisation of the evaluation of nutrient sources for food supplements by the ANS Panel. The NDA Panel adopted the first series of Article 13 health claims and the first opinions on dietary reference values. The first re-evaluation of the cultivation of GMOs was completed (MON 810). CONTAM finalised its evaluation of risks to animal health of natural plant toxicants in animal feed and issued opinions on regulated shellfish toxins. In total, the PRAPeR Unit delivered conclusions on 28 substances in 2009, including 9 new active substances, 9 resubmitted substances and 7 existing active substances included in Annex I for which the peer review had been postponed. The use of alternative conference formats was increased to facilitate the input of experts and to meet challenging timelines particularly in units dealing with applications, for example, PRAPeR organised 23 tele-conferences with Member State experts. Urgent advice was provided on nicotine in wild mushrooms, possible risks associated with 4-benzophenone and hydroxybenzophenone originating from food contact materials, and the cold treatment of strawberry plants to eliminate *Bemisia tabaci* from consignments to be shipped to the EU from the USA.

III.2 Scientific Committee

Further advice on the implications of animal cloning were sought from the Scientific Committee, in particular to provide further details on the recommendations included in the animal cloning opinion published in 2008. An EFSA statement was published in June 2009. The Scientific Committee was also requested to prepare a guidance document for the safety assessment of applications involving the application of nanoscience and nanotechnologies to food and feed. Work was started on providing practical recommendations for the risk assessment of food-related applications of nanotechnologies to the extent possible with current knowledge. The guidance will be finalised by summer 2010. Antimicrobial resistance approaches, a cross-cutting activity for EFSA, were addressed by both the GMO and BIOHAZ Panels with the support of the Chair of the Scientific Committee who chaired a joint working group on this topic. The Scientific Committee adopted a document focusing on transparency in the scientific outputs produced by EFSA. This document deals with general principles to be applied in the identification of data sources, criteria for inclusion/exclusion of data, confidentiality of data, assumptions and uncertainties.

III.3 Risk Assessment

Animal health and welfare

The AHAW Panel adopted 13 scientific opinions on animal welfare issues covering the welfare of dairy cows, stunning and killing of fish species, general approaches to fish welfare and the concept of sentience in fish. In addition, a statement on research needs for the welfare of farmed fish was adopted. Scientific opinions on *Brucella suis* in swine and epizootic hemorrhagic disease were adopted. An internal scientific report on the new pandemic influenza (H1N1) was completed as a first preparedness response in collaboration with several other units. Under Article 36, external reports on tuberculosis in wildlife in the EU, Crimean Congo haemorrhagic fever, epizootic haemorrhagic disease, viral haemorrhagic septicaemia virus, Bonamia spp. and animal welfare risk assessment guidelines in relation to transport were finalised. Two Article 36 calls were launched on animal welfare risk assessment guidelines (husbandry and management) and the impact on animal health and welfare of genetic selection in livestock species, respectively. A technical meeting on genetic selection in broiler breeding was held with stakeholders (NGOs, industry, farmer associations and Member State experts) to discuss data sources and availability and risk assessment approaches to support the mandate on health and welfare aspects of genetic selection in broilers. In addition, a public call for data was launched for this mandate.

Food additives and nutrient sources added to food

A total of 72 scientific opinions and statements were adopted by the ANS Panel corresponding to 157 application dossiers. To finalise the evaluation of nutrient sources, 23 scientific opinions and 36 scientific statements corresponding to 144 application dossiers were adopted. The risk assessment of other food additives (e.g. evaluation of new food additives and re-evaluation of food colours) continued and the panel adopted 12 scientific opinions (10 application opinions and 2 generic opinions) and one statement in this area. Two contracts issued in 2008 for the preparation of pre-evaluation documents for the evaluation of nutrient sources for food supplements were finalised in May 2009. Four new contracts were signed to support ongoing and future mandates on food additive re-evaluation. A meeting was held with the Joint FAO/WHO Expert Committee on Food Additives (JECFA) secretariat to discuss cooperation. Three public calls for data were published in order to collect data for the re-evaluation of various food additives belonging to the functional classes of preservatives, antioxidants, emulsifiers, stabilisers, gelling agents and waxes.

Biological hazards

The BIOHAZ Panel adopted a total of 24 scientific opinions and reports in 2009. A joint opinion on AMR was issued in collaboration with EMEA, ECDC and SCENIHR and a joint scientific report on meticillin-resistant *Staphylococcus aureus* (MRSA) in collaboration with ECDC and EMEA. In addition, BIOHAZ adopted an opinion on MRSA in animals and food and with the GMO Panel issued a joint opinion on the use of AMR genes as markers in GM plants. Other opinions covered: the use of bacteriophages in food production; food safety aspects of dairy cow welfare; *Campylobacter*; BSE resistance in goats; BSE in bovine intestinal casings; risk to human and animal health related to the revision of the BSE monitoring regime in some Member States; and three opinions on animal by-products (ABP). The first EU-wide full quantitative microbiological risk assessment (QMRA) model of *Salmonella* in pigs, funded by Article 36, was concluded in 2009. A workshop was held with experts and stakeholders and the BIOHAZ Panel will deliver its opinion based on the report in 2010. Stakeholder meetings were also held with the European Livestock and Meat Trading Union (UECBV) and the European Fat Processors and Renderers Association (EFPRA). The outsourced project on the fate of *Salmonella* spp. on broiler carcasses was completed.

Food contact materials, enzymes, flavourings and processing aids

A total of 78 opinions were adopted by the CEF Panel of which 38 covered 300 flavouring substances and 29 covered substances used to manufacture materials in contact with foodstuffs. In addition, a total of 11 opinions on smoke flavourings were adopted. Urgent advice was given in form of an EFSA statement on possible risks associated with 4-benzophenone and hydroxybenzophenone originating from food contact materials. A total of 8 meetings with stakeholders (industry, consumer organisations and the Commission) were organised. The ongoing evaluation of 2600 flavouring substances on the market was supported by two contracts and two new contracts were assigned for preparatory work in the area of food contact materials.

Contaminants in the food chain

The CONTAM Panel adopted 14 scientific outputs (12 opinions and two statements). Three opinions covered the impact of metals such as cadmium, arsenic and uranium. In addition, five opinions on regulated shellfish toxins were finalised. The Panel issued a statement addressing the influence of processing on shellfish toxins and a statement on the public health effects of aflatoxins in tree nuts other than almonds, hazelnuts and pistachios. The evaluation of risks to animal health of natural plant toxicants present in animal feed was finalised (two opinions). Following a request from the Commission, CONTAM evaluated the criteria and safety of substances that are transported as cargoes in ship containers that are then used to ship edible fats and oils into the EU (two opinions). In addition, CONTAM in collaboration with DATEX and PRAPeR provided fast track advice on nicotine in wild mushrooms which enabled the Commission to implement timely measures to safeguard public health. A database on veterinary medicinal products used in Third Countries was successfully developed within the framework of an Article 36 project; the database facilitates a proactive approach to preparation for future requests on residue limits of pharmacologically active substances in foodstuffs of animal origin. A background document summarising

information related to the analysis, occurrence, and toxicology of eight mycotoxins and natural plant products was prepared via an Article 36 project to facilitate future risk assessments.

Feed additives

A total of 36 opinions in the framework of Regulation (EC) No 1831/2003 were adopted by the FEEDAP Panel, including 22 opinions for new products or extension of use of authorised products, one for a re-evaluation, three combining a new use and re-evaluation, two for a modification of the terms of authorisation of an authorised product, one for an urgent authorisation and seven requests for the evaluation of supplementary information submitted by the applicants after inconclusive opinions. Other adoptions included: part III of the opinion on carotenoids relating to yellow carotenoids; an opinion on ractopamine; and an opinion on the use of cobalt compounds as additives in animal nutrition. Nine technical hearings were held with industry associations/applicants to discuss issues related to applications. In order to prepare the work for the re-evaluation of all existing feed additives in accordance with Article 10 of Regulation (EC) No 1831/2003, five meetings were organised with Member States, the Commission and the Community Reference Laboratory. In addition, administrative guidance for applicants for the presentation of applications for authorisation of feed additives was updated in 2009. With the aim of improving the management, distribution, archiving and assessment of data included in applications, a procurement procedure was initiated in collaboration with EFSA's IT-Operations (ITOP) unit for the review of systems for the electronic submission of dossiers. An Article 36 grant was awarded for the preparation of a series of monographs on the biological role, content in feed and requirements in animal nutrition of 27 trace and ultra-trace elements.

Genetically modified organisms

The GMO Panel adopted 17 scientific opinions covering 21 application dossiers. EFSA published 12 technical reports connected to application dossiers ("overall opinions"), which in addition to the scientific opinion also contain Member State comments and other documents stipulated in the regulation. A total of 14 of the scientific opinions adopted covered applications for placing GM plants on the market under Regulation (EC) No 1829/2003, while 3 were co-adoptions with the FEEDAP Panel (under Regulation (EC) No 1831/2003). A total of 8 generic opinions were adopted, 3 in relation to the evaluation of information submitted in support of Safeguard Clauses invoked by Member States (Article 23 of Directive 2001/18/EC), 2 in relation to a request from the European Commission on the safety assessment of antibiotic resistance marker genes, and 3 on requests for scientific advice related to previously adopted application opinions. In 2009, EFSA organised 4 meetings with Member State experts, 3 with applicants and one with NGOs to discuss applications.

Dietetic products, nutrition and allergies

In 2009, the NDA Panel adopted 174 opinions, most (125) relating to Article 13.1 functional claims covering 937 claims. On children and risk reduction claims, 24 opinions were adopted and 10 opinions were adopted on claims based on newly developed science and/or proprietary data. In the context of the procedure for the authorisation of health claims, the NDA Panel also adopted 2 opinions on the conditions for the use of health claims on essential fatty acids and on plant sterols and stanols. In the area of the safety assessment of novel foods, the NDA Panel adopted 5 opinions corresponding to 5 applications. In addition, the Panel adopted opinions on the appropriate age for the introduction of complementary feeding in infants and the possible exemption from labelling for beta-amylase from barley. In relation to dietary reference values, the NDA Panel launched public consultations on its draft opinions on fats and carbohydrates and organised an expert meeting with Member States to discuss these opinions along with draft opinions on food-based dietary guidelines, general principles of deriving and applying dietary reference values and dietary reference values for water. Revised versions of these documents incorporating the feedback received were adopted. Advice on labelling reference intake values for selected nutritional elements was also adopted. In light of the experience gained from the health claim applications, EFSA provided additional advice to applicants in the form of a frequently asked question document (FAQ) The draft FAQ was subject to public consultation and discussed at a meeting with applicants before finalisation as a technical report of EFSA. Comments received from both the public consultation and meeting were published along with a summary of how comments had been taken into consideration. EFSA also held a meeting with Member States

and the Commission to update them on the evaluation of Article 13.1 health claims and, to this end, a draft briefing document was prepared which was updated and published after the meeting as a technical report of EFSA. A project on the characterisation of probiotics in the framework of health claims evaluation was outsourced.

Plant health

The PLH Panel adopted four outputs in 2009, including opinions on the reliability and the effectiveness of a proposed method to treat wood shavings infested by the pinewood nematode *Bursaphelenchus xylophilus* and an evaluation of a pest risk analysis (PRA) made by the United Kingdom on the oak processionary moth, *Thaumetopoea processionea*. The Panel also produced a statement as an urgent reply on a proposal for cold treatment of strawberry plants to eliminate *Bemisia tabaci* from consignments to be shipped to the EU from the USA. Guidance on the evaluation of pest risk assessments for phytosanitary measures made by third parties was also issued.

Plant protection products and their residues

The PPR Panel adopted one opinion on cumulative exposure assessment of triazole fungicides and six opinions on the update of the Annexes II and III of Directive 91/414 EEC. Opinions on protection goal options and on the development of eco-regions are scheduled to be published in first half of 2010.

III.4 Scientific Cooperation & Assistance

Assessment methodology

The AMU unit provided scientific support for opinions of the CONTAM, PLH, AHAW, BIOHAZ and GMO Panels and the Scientific Committee. This included: data management support for BIOHAZ opinions; epidemiological and statistical analysis for BIOHAZ, CONTAM and PLH; and systematic literature reviews with meta-analyses. An example of the latter was the technical report *"Meta-analysis of Dose-Effect Relationship of Cadmium for Benchmark Dose Evaluation"* which was integrated into the CONTAM opinion on cadmium.

Data collection and exposure

DATEX contributed to several opinions by assessing dietary exposure to a range of substances, in particular contaminants. Information on levels of marine biotoxins in seafood was collected and exposure levels compared with health-based guidance values by the CONTAM Panel. The collection of data on arsenic proved difficult in that little information was available for inorganic arsenic, the major toxic component. Algorithms were produced based on literature information to relate levels of total arsenic to estimates of inorganic arsenic in the respective food groups. Exposure was calculated for adults and for the first time it was possible to provide detailed exposure calculations for different age groups of children covering several Member States. Support was provided to the CEF Panel in selecting a method suitable for assessing exposure to smoke flavourings.

Pesticide risk assessment peer review

Activities in pesticide peer review in 2009 included: new active substances; substances resubmitted for inclusion in Annex I of Directive 91/414/EEC following an initial non-inclusion decision; substances already included in Annex I with inclusion periods expiring; substances included in Annex 1 for which EFSA conclusions are due to be delivered by 31 December 2010 (the so-called "green track", i.e. substances complying with the criteria of clear indications of no harmful effects); and substances for which confirmatory data have been submitted after inclusion. A series of scientific meetings was held with Member State experts in relation to new and existing active substances and microorganisms used as active substances. EFSA received assessment reports for 50 resubmitted substances and 6 substances for Annex I renewal, and opened consultation with Member States, applicants and the general public to provide feedback to the European Commission. For a large proportion of the resubmitted substances the consultation period extends into 2010. EFSA has also received a request from the European Commission to organise a peer review with Member State experts and provide conclusions on 20 resubmitted substances and 6 substances for Annex I renewal. In response to the challenging timelines associated with the resubmission and renewal programmes, the PRAPeR unit increased the use of tele-conferences, organising 23 tele-conferences with Member State experts, for example. EFSA was also invited to

provide comments to the European Commission on the assessment of confirmatory data submitted by the rapporteur Member States for 9 substances.

In total, the PRAPeR Unit delivered conclusions on 28 substances in 2009, including 9 new active substances, 9 resubmitted substances and 7 existing active substances included in Annex I but for which the peer review had been postponed. This number is lower than expected because: EFSA has not been asked by the Commission to draft conclusions on confirmatory data; unforeseen delays in both the Annex I renewal and the resubmission programmes; and, by agreement with the Commission, extension of the deadline for the majority of "green track" substances to 2012. As a result, the number of public consultations launched in 2009 was also lower than expected.

Table 1: Resources for Activity 1

Unit	Staff	Personnel Appropriations	Infrastructure Appropriations	Operational Appropriations	Total Appropriations 2009	2009 Execution	%
ANS	14	1.21	0.31	0.92	2.44	2.35	96%
CEF	14	1.21	0.31	0.78	2.30	2.26	98%
FEEDAP	17	1.43	0.37	0.84	2.64	2.58	98%
PLH	8	0.68	0.18	1.09	1.95	1.88	97%
PPR	6	0.53	0.14	0.69	1.35	1.30	96%
GMO	17	1.43	0.37	0.98	2.78	2.68	97%
NDA	15	1.28	0.33	0.66	2.27	2.20	97%
BIOHAZ	9	0.75	0.20	0.80	1.74	1.66	95%
CONTAM	11	0.90	0.23	0.85	1.98	1.92	97%
AHAW	13	1.05	0.27	0.79	2.12	2.02	95%
PRAPeR	28	2.33	0.61	0.41	3.35	3.32	99%
Other SCA	8	0.68	0.18	3.51	4.36	4.26	98%
Other	13	1.13	0.29	0.00	1.42	1.42	100%
TOTAL	**173**	**14.61**	**3.80**	**12.31**	**30.72**	**29.84**	**97%**

IV Enhance risk assessment methodologies and coordinate scientific networks (Activity 2)

IV.1 Overview of Activity 2

This activity covers the development of risk assessment methodologies as well as scientific cooperation, scientific and technical support activities in the areas of data and information exchange, collation, analysis, and reporting other than those carried out for the direct support of specific scientific opinions. Scientific cooperation takes place at several levels: Member States, organisations in Member States, and with individual experts. Cooperation with Member States has been greatly facilitated by the Focal Points which have become an essential vehicle for implementation of operational activities as evidenced by the number of documents uploaded on the Information Exchange Platform – launched in 2008 – or the number of requests for dissemination or sharing of information between Member States and EFSA. The Focal Points also play a key role in facilitating the implementation of Article 36 and in populating the experts database. Member State collaboration was also enhanced through special Advisory Forum meetings on Plant Health and Animal Health and Welfare, EFSA network meetings on transmissible spongiform encephalopathies (TSEs) and microbiological risk assessments (MRAs) and two workshops on health claims. Comments from Member States on GMOs, feed additives and applications on claims were received via the Extranet. Cooperation with organisations grew in 2009 as the number and value of contracts and grants illustrates. In response to a request from the Advisory Forum, a multi-annual approach will gradually be adopted for this form of cooperation and this will help to strengthen risk assessment capacity in Europe. A framework contract was signed with several organisations to carry out preparatory work in the areas of mammalian and environmental toxicology. The database of experts registered to support EFSA has continued to expand, partly as a result of an initiative taken by EFSA to explore possibilities to share expert databases with

other organisations. The new *EFSA Journal* web-area was launched in December with the key objective of providing experts in the Scientific Panels and Working Groups with an outlet for their work that is visible and influential in the scientific community and at the same time complies with best practices in academic publishing. The Emerging Risk unit drafted a document outlining the development of EFSA's activities in this area. The first results of its methodological work and the application thereof will be collated in an annual report on its 2009 activities. Two crisis exercises were held in 2009. The lessons learned from these exercises are reflected in the updates of the Emergency Manual.

In addition to the data collection and analysis activities carried out for risk assessment purposes (Activity 1), various scientific and technical reports were carried out upon request of the European Commission. Not only have the number of zoonoses-related data collection activities increased but EFSA also issued its first Annual Report on Pesticide Residues and supported the European Commission with its annual report on veterinary residues. Various cooperative projects between the Scientific Committee and Panels(s) on the one hand and Member States on the other hand were completed in 2009 (beta-casomorphins, botanicals, emerging risks, folic acid) and others (isoflavones) were initiated. These are monitored in the joint Steering Group on Cooperation.

A conference on the risk assessment of GMOs for human and animal health and the environment was held in 2009 in Brussels bringing together 150 key actors from Europe and beyond. In light of the upcoming revision of the novel foods regulation, a scientific colloquium was organised to receive early input from stakeholders for the preparation of a revised scientific and technical guidance for applicants for the preparation of novel food applications. Two stakeholder workshops on the fate of pesticides were organised by the PPR unit in May at the Joint Research Centre (Ispra) and in November in Parma, with 70 and 60 participants, respectively.

IV.2 Scientific Committee

The Scientific Committee and its Working Groups contributed to the development, promotion and application of new and harmonised approaches and methodologies for risk assessment in the area of food and feed safety. In particular, the guidance document on transparency in risk assessment was finalised after public consultation. Another guidance document on the use of benchmark dose approach (BMD) in risk assessment was finalised; a workshop will be organised in 2010 to build EFSA's expertise in this area and to ensure the implementation of a harmonised approach across Panels. The opinion on the existing approaches for the replacement, reduction and refinement of animal testing in food and feed risk assessment was also published. The guidance on the safety assessment of botanicals and botanical preparations was finalised, taking into consideration the recommendations made by an ESCO (EFSA Scientific Cooperation) working group on selected cases. A workshop was organised in November 2009 to present the work done by EFSA to stakeholders and Member States, and to discuss the possible way forward on this issue. Work is in progress on the wider applicability of the threshold of toxicological concern concept in EFSA's risk assessment. The opinion on risk-benefit assessment of foods will be finalised in 2010 after for public consultation. A new working group was established to provide a commentary and recommendations on genotoxicity testing strategies in the field of EFSA's activities.

IV.3 Scientific Cooperation & Assistance

Assessment methodology

In December, the AMU unit, supported by a working group of external experts, issued a guidance document on the application of systematic review methodology to food and feed safety assessments. It will be tested during a workshop for EFSA experts and staff in February 2010. Since 2003, there have been reports in Europe and the USA of serious mortality of bees in beehives. In 2006 the term Colony Collapse Disorder (CCD) was first used to describe this phenomenon which is characterized by the rapid loss from a colony of its adult bee population. While the cause of CCD has not been determined, several aetiologies have been proposed. To investigate further possible risk factors, AMU launched a call for a project open to competent organizations under Article 36 of Regulation EC 178/2002. The outcome of this project was published in December 2009.

AMU also published a report on quantitative models describing the spread, establishment or development of plant pests on crops in Europe including geographical and climatic data and/or plant phenology as input factors. The output of this project, which was supported by an Article 36 grant, also includes a structured, electronic inventory of selected and analysed models which will be valuable for future plant pest predictive modelling work.

While foods rich in isoflavones are considered to be part of a healthy diet, questions remain with regard to their impact on health, reduction of disease risk and improvement of quality of life. Following consultation with the Advisory Forum, it was determined that this topic is of interest to several Member States. Consequently, AMU was requested to establish an ESCO working group that will deliver a report in 2010 providing a literature overview of the potential hazards and health benefits associated with isoflavone consumption. AMU also provided epidemiological and modelling support to DATEX (β-casomorphin-7) and to the Zoonoses baseline studies as well as data management support for the annual report on pesticide residues.

Data collection and exposure

A major undertaking for the Data Collection and Exposure (DATEX) Unit was the formation of a Working Group to review available scientific evidence of possible health effects of β-casomorphins and related peptides, and in particular β-casomorphin-7 (BCM7), a peptide sequence present in the milk protein β-casein. A few studies had suggested that BCM7 might contribute to increased risk of certain non-communicable diseases, such as autism, cardiovascular diseases and type I diabetes. EFSA undertook this work as part of its regular monitoring and assessment of possible emerging risks associated with the food chain. The Working Group concluded that a cause and effect relationship could not be established between the dietary intake of BCM7, related peptides or their possible protein precursors and non-communicable diseases.

A comprehensive food consumption database is being populated with information at the most detailed level available in each collaborating Member State for children and adults. It is expected that the database will be operational from 2010 to enable more precise exposure calculations in relation to beneficial or harmful substances or agents in food. Guidelines to further harmonise food consumption data collection were issued during the year. In a cooperative effort with Member States, EFSA took a major step to further improve the quality of European food safety exposure assessments. A draft guidance document on how to best handle left-censored data (data below the detection limit) was developed by a Working Group coordinated by the DATEX unit. The unit investigated default assumptions used across EFSA for estimating risk with the aim of harmonising such use across disciplines. The document will be published during 2010.

On request of the European Commission, DATEX analysed data collected by Member States for acrylamide and furan and issued two reports. The acrylamide report reviewed the impact of voluntary measures taken by industry to reduce acrylamide levels. Although there seemed to be a trend towards lower exposure, it is not yet clear if the measures have had the desired effect. The furan report was an interim step in better understanding levels of furan in food and was complemented by two projects granted under Article 36 covering the influence of food preparation methods on furan formation and exposure to furan by inhalation during cooking. The resulting data sets will enable EFSA to produce a more robust assessment of exposure through different routes including inhalation. A report on the presence of dioxins in food and feed was drafted. The unit also assisted the Commission for the first time in preparing the statistics for the annual veterinary medicine residue report.

Emerging risks

The ESCO Working Group on Emerging Risks published a technical report on emerging risks which, along with previous reports from the Scientific Committee, forms the basis of EFSA's first annual report on emerging risks due in early 2010. A technical report describing the evaluation of different web monitoring systems for the identification of emerging risks was published. This report describes the evaluation of a media monitoring tool, MedISys, developed by the Joint Research Centre, and its comparison with ProMED-mail for its usefulness in identifying emerging risks. A database on bioactive compounds from plants was delivered through an outsourced project and a call was launched and awarded on modelling, predicting and mapping the emergence of mycotoxins in cereals in the EU due to climate change. EMRISK is also responsible for coordinating EFSA's preparedness

for responding to urgent issues. To this end, the procedures put in place by EFSA for dealing with such urgent requests (the Emergency Manual) have been updated, building on the experience gained in handling urgent issues and internal training exercises. An exercise held with Member States and DG-SANCO was coordinated by EMRISK with the specific aim of simulating communication in "crisis" situations. The exercises were planned and executed in collaboration with an external consultant (funded through procurement) and an expert working group.

Pesticide risk assessment peer review

On 1 September 2008, Regulation (EC) No 396/2005 came into effect. As a result, the PRAPeR Unit was involved in procedures for setting and amending maximum residue levels (MRLs) for which Member States intend to authorise new uses of pesticides and in the framework of establishing import tolerances (Article 10 of Reg. 396/2005). In 2009, 101 MRL applications were submitted by the European Commission pertaining to the amendment of approximately 400 MRLs. In response to these requests, EFSA issued 70 reasoned opinions (addressing 76 requests). In addition, EFSA provided three reasoned opinions concerning specific requests of the European Commission for active substances for which consumer health risks were presumed. In the MRL review programme (Article 12 of Reg. 396/2005), EFSA received background information from Member States for 137 active substances which are now assessed by EFSA. In collaboration with Member States and the European Commission, a work plan for prioritisation and finalisation of the reasoned opinions was established. It was not possible to finalise the expected numbers of Article 12(1) and 12(2) reasoned opinions as outlined in Management Plan 2009 for the following reasons:

- delayed submission of documents by Member States;
- higher priority given to routine MRL applications (Article 10 of Regulation 396/2005) and prioritised allocation of available resources in the PRAPeR Unit to this task;
- the number of routine MRL applications and the reasoned opinions issued by EFSA in response to these applications (Article 10 of Regulation 396/2005) was higher than expected, further limiting the capacity available for Article 12 applications.

The PRAPeR Unit updated the database on toxicological reference values of pesticides, taking into account new or amended values established in the EU or by international bodies. The database comprises more than 1100 acceptable daily intake (ADI) values and 900 acute reference dose (ARfD) values. A call for tender was launched aimed at enhancing the scientific database on MRLs recommended by Codex Alimentarius. This information is necessary for performing a comprehensive risk assessment as required in the MRL review programme under Article 12, and to provide risk managers the information whether the MRLs established by Codex Alimentarius are safe for European consumers. In collaboration with the CONTAM, DATEX and EmRisk Units, PRAPeR prepared a statement in response to the request for an urgent scientific opinion on the risk for public health due to the presence of nicotine in wild mushrooms.

In 2009, EFSA published the first Annual Report on Pesticide Residues for 2007. The report summarises the results of approximately 74,000 samples analysed in 2007 by Member States to ensure compliance with the legal provisions. In brief, the report found that 96 % of the samples analysed were compliant with the legal maximum residue levels (MRLs) and 4% exceeded them, compared to 5% in 2006. These data were used to estimate the actual consumer exposure to pesticide residues via food; the results of this assessment are also included in the report. Because of deficiencies identified in the current reporting format, EFSA developed a new data model to submit the results of monitoring activities. This new data format was tested in a pilot project with 6 Member States that submitted the results of the monitoring results derived in 2008 for approximately 6 million determinations of pesticides in 27,000 samples. The Unit launched a call for tender regarding scientific and technical assistance for the drafting of the next annual report on pesticide residues.

Scientific cooperation

The Focal Point network, which started in 2007, continued its work in supporting the Advisory Forum Members. To this end, multi-annual Focal Point agreements were signed with all 27 Member States to consolidate the existing

network. In September 2009, the 3 EU-candidate countries joined the Focal Point network. Many Focal Points, in particular in Central European countries, organised events to raise awareness of the work of Member States and EFSA. The Scientific Cooperation unit (SCO) prepared a report on Focal Point activities in 2009. The priorities of the Focal Point network included the exchange of information on training activities and on projects such as data collection and research funding.

The extended list of Article 36 organisations that support EFSA now comprises 370 organisations and the 2010 work programme was adopted by the EFSA's Management Board in 2009 to ensure an early start to its implementation. Training was provided to Focal Points in 2009 to enable them to enhance support for the Article 36 organisations in their countries and IT tools are under development to improve networking. An assessment report, based on a survey of activities covered by EFSA's grant and procurement schemes, was prepared. EFSA's expert database has continued to grow and now includes around 2000 experts from over 60 countries. This growth results from cooperation activities initiated this year with Member States and international organisations to enhance the use of this database. Five regular activity reports on the expert database project were issued during 2009.

The ESCO Working Group on the "Analysis of Risks and Benefits of Fortification of Food with Folic Acid" completed its work. Its report, incorporating the outcomes of a scientific event in Uppsala, was issued and submitted by the Executive Director to the Scientific Committee for consideration by the NDA Panel. The Information Exchange Platform (IEP) provides a tool for Member States and EFSA to exchange information on risk assessment activities undertaken by Member State organisations with a mandate similar to EFSA's. To date, the IEP has published over 400 scientific documents. In addition, it provides work plans and other country specific information. Starting in April, nine monthly reports have been provided to users.

A new web-area for the *EFSA Journal* was launched in December to facilitate the inclusion of the Journal in bibliographic databases. The enhancement of the Journal is aimed at providing an outlet of EFSA's scientific work that is visible and influential in the scientific community and at the same time complies with best practice in academic publishing. The summary report on colloquium no. 12 (Campylobacter) was published in March. On 19–20 November, approximately 100 scientists and stakeholders from 25 countries attended EFSA's 13th scientific colloquium: *What's new on Novel Foods* in Amsterdam.

Zoonoses

The harmonisation of monitoring and reporting of zoonoses in EU was continued in 2009 with the aim of improving the quality of the data received and analysed at the Community level. In particular, four reports on specifications for harmonised monitoring and reporting of zoonotic parasites (*Trichinella*, *Echinococcus*, *Cysticercus* and *Sarcocystis*) in animals by EU Member States were published as outcomes of an Article 36 grant project. In addition, the unit coordinated two other Article 36 grant projects aiming to harmonise the monitoring and reporting of rabies and Q fever in animals as well as the survey methods for zoonotic agents in food among the Member States. Furthermore, the unit itself, supported by the Task Force of Zoonoses Data Collection and external working groups, issued specifications for harmonised surveys on two zoonotic pathogens, verotoxigenic *E.coli* and *Yersinia enterocolitica,* in animals and food. These specifications are intended to guide Member States in their national monitoring activities highlighting the importance of good survey design. On the request of the Commission, technical specifications for an EU-wide survey on *Listeria monocytogenes,* an important foodborne pathogen, in ready-to eat foods were also prepared for a survey that will take place in 2010.

Data from the annual zoonoses reporting by the Member States and from the three EU-wide baseline surveys carried out in 2008 were successfully validated using a new SAS-based data management system with automatic validation criteria. Special efforts were made to improve the analyses of the annual zoonoses and baseline survey data from both the IT and methodological aspects. To this end, web-based data warehouse and GIS (geographic information) systems were developed to facilitate easier data handling and access. Furthermore, the development of statistical and spatial analyses of zoonoses data as well as analyses of temporal trends were further addressed

by two expert working groups that provided recommendations for the most appropriate methods to be applied in future development. The improved analytical methodology was previously used in the Community Summary Report on zoonoses in 2008 and in the Summary Report on foodborne outbreaks in 2007 which were prepared in collaboration with the European Centre for Disease Prevention and Control (ECDC). Once again *Salmonella* and *Campylobacter* were found to be the most frequently reported zoonotic pathogens in the EU. Two reports on the EU-wide baseline surveys on methicillin-resistant *Staphylococcus aureus* (MRSA) and *Salmonella* in breeding pigs were published. In all reports, special emphasis was placed on clear communication of findings and analyses.

IV.4 Risk Assessment

Animal health and welfare

A guidance document on good practice in conducting scientific assessment in animal health using modelling was adopted. A special Advisory Forum meeting on animal health and welfare was held in May to discuss topics of common interest and it is proposed to repeat this exercise to promote closer collaboration between Member States and EFSA. A technical report presenting the outcome of a survey undertaken by the AHAW Unit on the organisation, approach and procedures applied in risk assessments on animal health and welfare in Member States was published. Work on the development of risk assessment methodologies will continue, including an Article 36 project on commodity-based import risk assessments.

Food additives and nutrient sources added to food

The ANS Panel adopted a statement on data requirements for food additive applications with the aim of providing a basis for the future preparation of guidance on food additive applications. A procurement contract to obtain comments on the existing guidance for food additive applications and proposals for further development of an updated guidance was finalised in May. Stakeholders were also consulted in writing on the existing guidance. New guidance for food additive applications is planned.

Biological hazards

Meetings of the Microbiological Risk Assessment and the BSE-TSE networks were held in June and October 2009, respectively. The opinion on the maintenance of the list of Qualified Presumption of Safety (QPS) microorganisms was adopted.

Food contact materials, enzymes, flavourings and processing aids

The CEF Panel adopted guidelines for the evaluation of active and intelligent packaging and the evaluation of food enzymes. Public consultations were held for three guidance documents on enzymes, active and intelligent packaging, and flavourings. Eight meetings with industry were organised to discuss and clarify the requirements laid down in the guidance document for evaluation of enzymes. In addition, opinions on the clarification of the margin of safety applied for smoke flavouring evaluations and dietary exposure assessment of smoke flavourings were adopted. A safety assessment of the extraction solvent dimethylether was completed.

Feed additives

The FEEDAP Panel finalised the technical guidance document for sensory additives, which completes a set of guidance documents for applicants in the preparation and presentation of applications. The external report of an Article 36 project on mycotoxin-detoxifying agents used as feed additives was received and will be used by the FEEDAP Panel in the preparation of the guidance document. An Article 36 grant was awarded for the preparation of a report to collect and synthesise scientific data and information on the potential of microorganisms and enzymes used in food and feed to induce respiratory sensitisation. The final report on a procurement project for the pre-assessment of the environmental impact of zinc and copper used in animal nutrition is expected in January 2010.

Genetically modified organisms

The GMO Panel adopted draft scientific opinions on guidance for the statistical analysis of data generated for comparative food safety evaluation and guidance on the risk assessment of GM plants for non-food or non-feed

purposes. Both were subject to public consultation, comments from which were incorporated in the adopted versions. The GMO Panel adopted one draft guidance document for applicants concerning the allergenicity of GM plants and GM microorganisms; a public consultation was launched in December 2009 and adoption of the final document is scheduled for 2010. In the process of developing guidance, meetings were held with Member State experts (2), applicants (1) and third parties (2). In addition, a conference on the risk assessment of GMOs for human and animal health and the environment was held in September 2009 in Brussels bringing together 150 key actors from Europe and beyond. In order to support the work of the GMO Panel in developing guidance for the risk assessment of GM animals, three outsourcing projects were signed.

Dietetic products, nutrition and allergies
In the light of the upcoming revision of the novel foods regulation, a scientific colloquium was organised to receive early input from stakeholders for the preparation of revised scientific and technical guidance for applicants for the preparation of novel food applications.

Plant health
The PLH Panel adopted a guidance document for evaluating PRAs made by third parties to justify phytosanitary measures under Council Directive 2000/29/EC. The second Special Advisory Forum on Plant Health meeting took place in October and the agenda included data requirements, emerging risks and pest surveillance. Collaboration with the JRC on modelling used for predicting establishment and spread of harmful organisms resulted in the launch of ClimPest, a framework for modelling pest climatic suitability. An Article 36 project on an inventory of data sources for PRAs (PRASSIS) was completed and an Article 36 call for a comparative approach to case studies for PRAs was signed. A renewed collaborative project with Agricast, JRC Ispra was agreed and signed at the end of 2009. The guidance document on a harmonised framework for the assessment of risks of organisms harmful to plants and plant products was endorsed by the Panel and the comments received from public consultation incorporated into the document for adoption and publication in 2010.

Plant protection products and their residues
The PPR Panel adopted an opinion on the assessment of exposure in soil – this is related to the guidance document on persistence of pesticides in soil that is under development. The guidance document on risk assessment for birds and mammals was published in December by a joint Working Group comprising Member State representatives, the European Commission and EFSA. Reports produced via Article 36 grants were used in the preparatory work for the production of guidance documents on emissions from protected crop systems (e.g. greenhouses) scheduled for adoption in 2010, exposure of workers, operators, bystanders and residents and for an opinion on the establishment of common assessment groups of active substances for cumulative risk assessment and the evaluation of the toxicological relevance of pesticide metabolites.

An outsourcing contract was signed for preparatory work for guidance on dermal absorption. Guidance documents for the evaluation principles of the toxicological burden of metabolites, degradation and reaction products of pesticides in food commodities and on persistence in soil (to be published in the first half of 2010) were completed via contracts with the JRC. Two stakeholder workshops on the “fate” of pesticides were organized by the PPR unit in May in JRC (Ispra) and in November in Parma, with 70 and 60 participants, respectively. In 2010, work on updating the two existing guidance documents on ecotoxicology (terrestrial and aquatic) will continue.

Table 2: Key Performance Indicators for Activities 1 and 2

Indicator	Target	Actual/Status
Outputs adopted within legal or agreed deadline	95%	85%*
Outputs published within 15 working days of adoption**	80%	75%
Expert DOIs approved for meetings	100%	IAS follow up-audit showed 100% success report in implementing the MB decision on DoIs.
Self-review of outputs	100%	92%
Internal review of outputs	Completed before external review	Completed
External review of outputs	Before end 2009	Completed
Renewal of Scientific Committee Panels	By mid-2009	Completed
Action plan based on experts' Survey	Ongoing	Partially implemented, ongoing in 2010

**Delays were due to difficulties in application procedures, requirements for additional information identified at a late stage of the adoption process and workload prioritisation*

***The target for outputs with associated news activities (press releases/web stories) is 20 days*

Table 3: Resources for Activity 2

Unit	Staff	Personnel costs	Infrastructure costs	Operational costs	Appropriations 2009	Execution	%
SCO	13	1.1	0.32	0.80	2.18	2.07	95%
DATEX	7	0.6	0.18	1.40	2.19	2.12	97%
EMRISK	8	0.7	0.20	0.32	1.21	1.13	93%
AMU	10	0.8	0.25	0.21	1.30	1.23	95%
ZOONOSES	14	1.2	0.36	1.18	2.76	2.73	99%
Risk Assessment	29	2.4	0.72	3.26	6.42	6.37	99%
Scientific Committee	8	0.7	0.20	0.31	1.20	1.17	98%
Other	11	0.9	0.27	1.09	2.28	2.22	98%
TOTAL	**100**	**8.5**	**2.50**	**8.57**	**19.52**	**19.04**	**98%**

Table 4: Scientific outputs in 2009

Activity		Risk Assessment Units											Scientific Cooperation & Assistance Units						Total
		SC	AHAW	ANS	BIOHAZ	CEF	CONTAM	FEEDAP	GMO	NDA	PLH	PPR	PRAPeR	AMU	DATEX	Em Risk	SCO	Zoonoses	
Application Opinions of the Scientific Committee/Panels	I			33	2	78		36	17	165									**331**
Reasoned Opinions	I												76						**76**
Conclusions on Pesticides Peer Review	I												28						**28**
Applications sub-total				*33*	*2*	*78*		*36*	*17*	*165*			*104*						***435***
Generic Opinions of the Scientific Committee/Panels	I	1	15	2	15		12	3	7	9	2	7							**73**
	II	1			1	3			2			1							**8**
Statements of the Scientific Committee/ Panels	I		1	37	2		2		1		1								**44**
	II																		
Guidance of the Scientific Committee/ Panels	I																		
	II	3	1	1		2		1			1								**9**
Statements of EFSA	I	1			2	1	1		1	1									**7**
	II												1						**1**
Guidance of EFSA	I																		
	II							1		2		1			1				**5**
Scientific or Technical Reports		7	2			2			16			5	1	1	4	2		14	**54**
Total		**13**	**19**	**73**	**22**	**86**	**15**	**41**	**44**	**177**	**4**	**14**	**106**	**1**	**5**	**2**		**14**	**636**

Table 5: Other outputs in 2009

	Risk Assessment											Scientific Cooperation & Assistance						
	SC	AHAW	ANS	BIOHAZ	CEF	CONTAM	FEEDAP	GMO	NDA	PLH	PPR	PRAPeR	AMU	DATEX	Em Risk	SCO	Zoonones	
Contracts and grants	2	2	3	1	4	5	2	3	1	2	8	2	11	12	2	27	9	**96**
Plenary meetings	6	8	8	9	7	6	8	8	8	6	7	9		3		3	3	**99**
Working Group meetings	28	90	13	105	21	51	48	95	52	31	85	37	17	18	6	5	27	**729**
Meetings with third parties (stakeholders, Member States etc.)	2	4	1	29	16	5	17	14	28	7	12	35	49	32	32	37	21	**341**
Public consultations	1	2	3	1	3			1	1	2	4	48						**66**
Presentations, lectures etc.	25	25	1	14	15	23	11	37	3	2	31	29	22	28	31	82	39	**419**
Papers in scientific literature	1	7	2	8		4	0	2	2	0	2		4	6		3	2	**43**
Queries (support for Communications and LPA activities)	3		154	11	150	127	22	104	130	1	12	12	6		6	20	10	**768**
Others		1		0		0	0		0	1			24	2	7	3	3	**41**

V Communicate scientific advice and facilitate dialogue with interested parties (Activity 3)

V.1 Overview

In 2009, EFSA continued to implement its communications activities, guided by the three overarching objectives of promoting coherence in communications through strengthened cooperation with relevant national, European and international authorities; building simplicity and accessibility in its communications; and increasing visibility and understanding of EFSA's scientific work. The Authority also began the review of its *Communications Strategy* endorsed by the Management Board in 2006. The review, which is expected to be completed in 2010, takes into account: changes in the communications landscape; growth in EFSA's capacity, internal organisation and scientific outputs; and developments in the Authority's external relationships and networks. The qualitative research carried out amongst EFSA's key customers, partners and stakeholders in autumn 2009 and the re-running in 2010 of a Eurobarometer survey on consumer perception of food risks will help feed this review.

Coherence

- EFSA continued to work closely with Member States to foster coherent communications through networks and to better understand how EFSA's scientific work is being communicated and reported in Member States. A template was developed for Focal Points to report on their target audience networks and the impact of their activities in Member States.
- Cooperation through the Advisory Forum Working Group on Communications (AFWGC) and Focal Point networks was reinforced, for example through joint communications activities, and the development of a tailored good practice guide for Focal Point website management.
- Developed, with the AFWGC, an overall approach and outline for risk communications guidelines to help support coherence in risk communications across the EU, reinforcing the key principles of communications and building appreciation of the role and value of communications--a project to be completed in 2010.
- Coherence was strengthened through: continued pre-notification of public announcements on EFSA's scientific work; proactive exchanges on key issues such as GMOs, food colours and nanotechnology; and the exchange of information on "emerging issues" in individual Member States, focusing on the implications for communications.
- Liaised closely with Member States and the European Commission on specific issues: communicated on fast-track assessments on 4-methylbenzophenone found in some breakfast cereals; the health risks linked to nicotine in wild mushrooms; and ensured there was information on EFSA's website to address potential food safety concerns about the novel flu A/H1N1.
- Shared best practices and skills with EU Member States - a standing item on the AFCWG agenda. For example, lessons learned from rapid reaction issues, such as dioxins in Irish pork from December 2008, was discussed at the February 2009 meeting.
- EFSA, as Head of the Troika for the EU Agencies Heads of Communication and Information Network, defined activities for the year and coordinated communications activities to raise awareness of the EU Agencies, including meeting the former EU Communications Commissioner Margot Wallström on the Agencies work in communications. EFSA also prepared a brochure setting out the role and contribution of the EU agencies, a media factsheet and planned interviews with key pan-European media in the light of the European Commission's ongoing evaluation of the EU agencies.
- Improved internal EFSA planning and processes to ensure integrated communications: strengthened the format of the Communications Review Committee meetings to include presentation of handling plans on key communications issues, in addition to discussion of the key activities flagged for communications in the EFSA monthly calendar of scientific activities; developed SOPs on the drafting, review and dissemination of press releases and web stories, as well as on planning of communication activities; and initiated meetings with EFSA Panel Chairs to seek their views on new and upcoming communications opportunities.
- Re-issued media handling guidelines to staff and to scientific experts to ensure a common approach towards handling questions and requests for interviews across EFSA.

Simplicity

- Strengthened media relationships to increase and improve understanding of EFSA's work through more regular contact with journalists. This was reinforced through media encounters with the Executive Director to explain better EFSA's work. A media briefing on zoonoses, which included EFSA, ECDC and Commission spokespeople, helped journalists to better understand the issues and actors involved across the risk assessment and risk management interface.
- Organised media training for EFSA scientific staff as a part of EFSA's communications strategy, to prepare them for media interviews. Around 26 staff members received training which gave the Press Office the possibility to meet press requests in a greater number of languages, notably German.
- Implemented a tailored communications approach on a wider range of scientific outputs, providing a greater number of web news stories (50), some targeted at the specialised press, while maintaining a steady flow of press releases (21) geared towards the mainstream media.
- Continued to use existing multimedia for live webcasting of Management Board meetings and began research on how multimedia could add value in future to EFSA's website.
- Presented EFSA's activities and its mandate at various events, such as the Society of Environmental Toxicology and Chemistry's (SETAC) European conference, Festa dell'Europa, reaching international, regional and local audiences, through attractive and easy-to-understand exhibition stands and posters, outlining, for example, EFSA's role in the EU food safety system.
- Continued to improve the usability and accessibility of EFSA's website through single entry points and search functions for scientific documents and events, a new web-based subscription service for all EFSA newsletters and better access to key topics from other areas of the site.
- Strengthened online communications in the EU Agencies network by: organising a knowledge-sharing workshop for Agency Web staff; benchmarking Agency online communications practices through a survey; and by creating and maintaining a contact list of Agency Web Managers.
- Gained insight into the users of EFSA's website through an online popup survey.

Visibility

- Continued to raise awareness of EFSA scientific outputs through proactive media work: 34% of EFSA's opinions (27% of all EFSA scientific outputs) were supported by press releases and web news stories in 2009. It should be noted that one communications initiative can support several scientific outputs, as was the case in 2009 for health claims where one press release was issued to announce the publication of 94 scientific opinions of the NDA Panel on Article 13 claims.
- EFSA-related media coverage in 2009 remained steady at around 9,038 articles. This was below 2008's total of some 11,600 articles; however, last year's strong increase in media coverage (+ 60%) was driven by the number of rapid reaction issues such as melamine and dioxins in Irish pork which generated many articles, and the high-profile opinion on animal cloning which triggered interest worldwide. Key issues covered by the media in 2009 were health claims and GMOs. Favourability remained at around 90% neutral (due to a change in provider of media monitoring service providers, data are provided for the 10-month period January –October 2009 for the sake of coherence of data). Negative articles amounted to around 6% and were dominated by GMO coverage--much of it political-- and trade press criticism of the procedures related to health claims applications. However, claims played out positively in the consumer press where EFSA was portrayed as helping to protect public health. The top 5 countries which reported on EFSA in 2009 were Germany, France, UK, Italy and the Netherlands (the same top five countries as in 2008), representing over 50% of coverage; the rest was shared between other EU Member States and countries such as the USA, Canada and Australia. About one-third of EFSA coverage was in the mainstream media, 44% on websites and 21% in specialised publications.
- Organised interviews with EFSA Directors and scientific staff in key European media including the *Financial Times*, *Suddeutschezeitung, Le Monde*, *Il Sole 24 Ore*, and *El País* and specialised publications such as *EU Food Law*, *Nutraingredients*, and the *EU Observer*.

- Organised an informal press briefing, in cooperation with ECDC and the European Commission, to discuss the 3rd EFSA-ECDC annual Community Report on Infectious Diseases Transmissible from Animals to Humans.
- Provided a dedicated web area for the revamped *EFSA Journal* to improve the visibility of all of EFSA´s published scientific outputs.
- Significantly expanded outreach of EFSA through the availability of key publications (Annual Report, Strategic Plan, etc.) in all 23 EU languages.
- Produced 139 publications including: two volumes of the Annual Zoonoses report; two Scientific Colloquia reports; 20 scientific posters; two supplements and two articles in scientific journals alongside EFSA's family of thematic newsletters, EFSA in focus.
- Organised 19 events including: a Scientific Colloquium on novel foods; a conference on GMO risk assessment in Brussels; and joint EFSA-Member State events in Austria, Greece (twice), and Slovenia (twice). The Authority was represented at international scientific conferences (e.g. SETAC Europe, European Food Science Day).
- Launched the online general inquiries service, Ask EFSA, to better streamline and respond to user queries through FAQs, easy-to-use forms for submitting queries, and prompt individual responses within a maximum of 15 working days to all questions received. The strong emphasis on relevant and upfront FAQs increase efficiency, for users and for EFSA. For commonly-asked queries, the user can find the answer straight away on EFSA's website, allowing EFSA to focus on individual responses to more complex questions.

Evaluation and analysis

In 2009, EFSA sought to analyse the impact of its communications activities through, for example, more in-depth monitoring of the website's use, a questionnaire to gain more structured feedback from members of the Advisory Forum on media activities in Member States on its press releases, and research with its target audiences to better understand how EFSA is perceived externally. The Authority also continued to build its communications base by procuring new services and providers in media analysis/monitoring, events support, webcasting and consumer perception surveys.

Table 6: Key Performance Indicators for Communications

Indicator	2009	Change vs. 2008
Web visits	2,420,103	+14.1%
Highlights subscribers	25,690	+21.5%
Media coverage	9,038	–22%*
Media queries	694	+2%
Press releases	21	–30%**
Web news stories	50	+28%
Interviews	72	–37%
Events	19	+5.6%
Publications	139	+121%
Ask EFSA	1,702	–41.2%***

**Reflects the strong media coverage in 2008 generated by rapid response issues (melamine etc.) and the high profile opinion on animal cloning*

*** When taken together with web news stories, the combined value is more or less constant but reflects a different mix of communication activities*

****The provision of an online FAQ section has reduced the number of queries received.*

V.2 Cooperation with Member States: Advisory Forum

Five Advisory Forum plenary meetings took place in 2009 to provide a platform for EFSA and Member States to exchange information and views and discuss priorities for risk assessments, emerging issues and scientific cooperation. In addition, two special Advisory Forum meetings on plant health and animal health and welfare as well as

national expert meetings/Member State consultations were organised in the areas of dietary reference values, health claims, GMOs, aspartame and botanicals. The Steering Group on Cooperation met twice in 2009 to gain an overview on the implementation of ESCO activities and to discuss the medium-term planning of future cooperation between EFSA and the Member States.

V.3 Relations with EU institutions

European Commission

EFSA continued to ensure effective working relations with the Commission, in particular through the "Roadmap" agreement and regular bilateral meetings with DG SANCO that establish consensus on priorities and deadlines. In October, Commissioner for Health Androulla Vassiliou visited EFSA for the second time since her appointment. The highlights of the discussions included animal cloning, nanotechnology, GMOs, nutrition and data collection. The Commissioner addressed EFSA staff and visited the European School (Scuola per l'Europa) in Parma. During her visit, the ceremonial laying of the foundation stone of EFSA's Final Seat took place. EFSA attended numerous meetings of the European Commission's Standing Committee on the Food Chain and Animal Health (SCOFCAH) in relation to issues such as GMOs and microbiological hazards and Commission representatives participated in a range of EFSA meetings. A weekly bulletin of highlights of European institutions was prepared and distributed to Management Team and was further circulated to EFSA's Management Board.

European Parliament

Particular attention was focused on building awareness of EFSA's role in European food safety in the newly-elected European Parliament. The Executive Director appeared before the Committee on Environment, Public Health and Food Safety (ENVI) in October where she presented EFSA's work programme. In addition, a series of bilateral meetings were organised between the Executive Director and MEPs on issues of specific relevance to EFSA. EFSA representatives regularly participated in the meetings of the relevant Committees to monitor and contribute where appropriate to the legislative process in relevant areas including pesticides, animal health and welfare, nanotechnologies, cloning and budgetary procedures.

EU Presidency, Council of Ministers and Member States

In the context of EFSA regular liaison with EU Presidencies, EFSA's Executive Director met representatives from the Czech and Swedish Ministries responsible for food safety and EFSA affairs in April and September, respectively. An international conference on science-based food regulations was co-organised with the Ministry of Agriculture of the Czech Republic and the Institute of the Chemical Technology in Prague in April. EFSA representatives participated in meetings of Council Working Parties to explain EFSA' s role in food and feed safety, and to provide technical and scientific assistance to Member State representatives. A series of visits to Member States including Latvia, Lithuania, Estonia and Austria was organised to enhance EFSA's knowledge of food safety arrangements in those countries and to interact with both risk assessors and risk managers at the national level. In addition, high level delegations from the national food safety agencies of Spain and France and the Dutch Ministry of Agriculture visited EFSA in Parma.

Relations with EU Agencies

As co-ordinator of the network of the Head of EU Agencies for 2009/2010, EFSA headed a troika involving the previous and future coordinators (EMCDDA and ECDC). In October, EFSA organised a meeting in Parma where the Heads of Agencies discussed key issues such as the on-going work of the inter-institutional working group set up by the European Commission on the regulatory framework of EU agencies, and the preliminary findings of the evaluation of the agencies.

V.4 International Relations, Pre-accession Programme and European Neighbourhood Policy (ENP)

In January, EFSA's *Strategic Approach to International Activities* was adopted by the Management Board. It identified four key objectives and the process of identifying and prioritising the actions required to implement those objectives was started taking into consideration broader Community context. In parallel, cooperation with key international partners was strengthened. In March, an EFSA delegation visited the US Centers for Disease Control and Prevention

(CDC), Animal and Plant Health Inspection Service (APHIS), Food Safety and Inspection Service (FSIS), Agriculture Research Service (ARS), Environment Protection Agency (EPA) and the Food and Drug Administration (FDA). An exchange of Liaison Officers between EFSA and FDA was implemented in 2009 and there has been a regular exchange of information and experience with WHO, OIE and FAO. In December, a Memorandum of Cooperation was signed with the Japanese Food Safety Commission. Discussions are ongoing with risk assessment authorities in Canada, Australia and New Zealand. EFSA provided scientific support for the Commission delegation to Codex Alimentarius and contributed, in particular, to the EU position on ractopamine.

The EU pre-accession programme includes the Candidate countries, Croatia, Turkey and the Former Yugoslav Republic of Macedonia (FYROM) and the Potential Candidate countries Albania, Bosnia & Herzegovina, Kosovo under UN Security Council Resolution 1244/99, Montenegro and Serbia. EFSA's contribution to the pre-accession programme focused on providing the countries with information on EU food safety via training seminars, study tours, workshops, and conferences and the participation of representatives from the pre-accession countries in EFSA meetings and networks as observers. A pre-accession seminar on "EFSA and the EU Food Safety system" was organised in Montenegro in November which was attended by 35 experts from Potential Candidate countries. Other pre-accession seminars included: "Animal Health and Welfare" in Skopje in June for 38 experts from FYROM; and the Pre-Accession Seminar on Risk Assessment Methodology for 40 experts from Croatia and FYROM in Croatia in September. Experts from the beneficiary countries participated as observers in 23 EFSA meetings during 2009.

As part of the European neighbourhood policy, EFSA jointly with the Commission's services organised a seminar in Brussels in July on EFSA's role in European food safety in which 15 of the 16 ENP countries participated. EFSA supports ENP countries in meeting EU food safety standards and in exchanging information on risk assessment and risk communication.

V.5 Stakeholder activities

The activities of the Stakeholders Consultative Platform have been growing steadily since its establishment in 2005 and 2009 was no exception. This was evident from the increased number of both plenary and technical meetings that were held and the increased levels of interaction with EFSA such as the consultation on EFSA's Draft Management Plan 2010 and EFSA's approach to public consultation on scientific outputs. In October, the Management Board approved a new list of 24 members and 21 associated members of the Platform and the renewed Platform had its inaugural meeting in December in Parma. In July, a delegation from the European Consumers Organisation (BEUC) visited EFSA to exchange views and information and the Authority presented its activities in the field of nanotechnology at the annual meeting of the Transatlantic Consumer Dialogue (TACD, a forum of EU and US consumer organisations) in Brussels.

V.6 Italian authorities

EFSA has regular dialogue with the Italian authorities on settlement issues. Since 2008, a biannual roundtable is organised with the Italian Government's Undersecretary of State, and the meeting of February 2009 was successful in discussing progress related to issues such as the European school. New legislation to facilitate the operations of the European School was adopted by the Italian authorities in mid-2009. The first conferring ceremony for the Baccalaureate at the School was held in July; all candidates were successful.

Table 7: Key Performance Indicators for external relations

Indicator	Outcome
Number of appearances of the Executive Director at the European Parliament	1
Joint events with EU Presidencies	2
Number of international agreements signed (negotiations Initiated)	1
Number of training seminars for Pre-Accession countries	4
No. of Stakeholder Platform plenary meetings	3
Number of pre-notifications on EFSA's scientific work	50
Final Seat agreement	Contract signed in June
European School	New legislation adopted by Italian authorities in mid-2009

Table 8: Resources for Activity 3

Unit	Staff	Personnel costs	Infrastructure costs	Operational costs	Appropriations 2009	Execution	%
Advisory Forum	2	0.2	0.1	0.6	0.8	0.70	90%
LPA	5	0.5	0.2	0.7	1.3	1.06	81%
Press Office	12	1.0	0.4	0.1	1.5	1.51	99%
Web	9	0.8	0.3	1.9	3.0	2.93	98%
Pub & events	15	1.3	0.5	0.7	2.5	2.53	99%
Other	5	0.5	0.2	0.6	1.2	1.21	97%
TOTAL	48	4.20	1.66	4.6	10.4	9.96	96%

VI Manage and provide administrative support (Activity 4)

VI.1 Overview

Several milestones were reached in 2009 across the spectrum of administrative support activities. From an organisational viewpoint the preparation of EFSA's Business Continuity Plan was an important achievement. The joint efforts of Human Resources and IT-Operations resulted in the launch of the staff Intranet Portal in July. The portfolio of training opportunities available to staff was significantly expanded and the average number of training days per staff member was 8. This was supplemented with 15 new HR policies and HR/administrative guidelines and the staff survey was repeated with significantly increased participation levels and higher ratings achieved compared with 2008. From an IT perspective, several other important projects were delivered: the new EFSA Journal web-area and other website enhancements; an ABB management tool; contracts database; and staff appraisal (CDAC) and training workflows. In total, over 40 applications were enhance in support of the Science, Communication and Administration directorates, more than 20,000 service desk calls were processed and technical support was provided for over 180 tele-conferences. The Legal and Policy Affairs Unit was proactive in detecting and highlighting legal risks in all areas of operation and responded to all requests within 48 h. The Rules of Procedures of the Scientific Committee and Panels were reviewed and adopted and rules for networks were established. In the Finance and Accounting areas, payments were increased by 3% over 2008 and the Court of Auditors concluded that EFSA accounts were legal and regular. A new Financial Regulation and Implementing Rules for EFSA were introduced in 2009 as well as a new mission guide and new expert compensation guide. The grant and procurement programme, valued at €6.8 m was fully executed and the 2010 programme was adopted by the Management Board in October to facilitate its execution. In December, a partial release (€2 m) of €4.5 reserve set by the European Parliament was achieved to implement key IT projects. Budget execution

for 2009 was 97% the execution of credits carried over from 2008 increased to 87% compared with 78% in the previous year.

VI.2 Human Resources

Career development

EFSA completed its second Career Development and Appraisal (CDAC) exercise. As a result, 23 staff members were reclassified/promoted to the next grade in their function group. In relation to training, a budget of €520 k was spent, with expenditure devoted to courses related to science, language training, EU affairs, communication, financial management, IT courses and team-building activities. The average number of training days per staff member in 2009 was 8.9 days. Induction sessions were enhanced to provide newcomers with a comprehensive set of information. Job descriptions were monitored (89% of staff members have a job description compared with 40% in 2008) and progress was made to ensure the timely completion of probation reports. The average number of probation reports received on time to September 2009 was 100%. IT programmes were implemented to automate some career development processes; these will be fully operational in 2010.

Recruitment

The HR team was reorganised to prioritise career development, training and staff welfare. Resources dedicated to recruitment were reduced in line with the lower number of recruitments planned. The 2009 Recruitment Plan anticipated 20 additional Temporary Agent posts and 4 additional Contract Agent posts compared to 2008. All selection procedures were finalised and the execution rate of the Recruitment Plan was 100%. In 2009, 53 Temporary Agents, 20 Contract Agents and 5 Seconded National Experts were recruited, an execution rate of 92% of the Establishment Plan. The difference between the execution rates of the recruitment and establishment plans reflects the need to allow for staff turnover and internal mobility. In addition, 16 trainees were selected and offered placements for a 5-month in-service training contract in order to acquire practical experience in the areas of science, communication or administration.

Working environment

Based on the 2008 staff survey results and the follow-up action plan, the first staff intranet portal was launched in July 2009. An Editorial Committee composed of content providers representing all Directorates and the Executive Director's Office ensures regular updating of information as well as publication of daily news items. Other internal communication initiatives were implemented, for example the breakfasts with the Executive Director: in 2009, a total of 350 staff members met the Executive Director to exchange views and discuss various proposals. The second Staff Survey was prepared in close coordination with a specialist consultancy and launched on November 16.

Table 9: Key Performance Indicators for Human Resources

Indicator	Outcome
Execution of Establishment Plan	92%
Recruitment Plan	100%
Number of staff reclassified/promoted	12.5% of eligible staff
Average number of training days per staff member	8.9
Average number of days lost due to sick leave per staff member	5.2
Staff turnover rate	7.8%
Staff satisfaction survey response rate	73%

VI.3 Legal and Policy Affairs

Legal support

EFSA regularly reviews its internal rules and procedures and their implementation in order to strengthen the legal soundness of its operations. Legal support is provided to all operations and in particular for 2009 in relation to the implementation of the DOI Policy, the legal framework of GMOs, health and nutrition claims and plant health. The rules of procedure of EFSA's Scientific Committee, Scientific Panels and Working Groups were reviewed and adopted by

Management Board in 2009. Discussion of the rules of procedure for EFSA Networks was postponed until the first quarter of 2010. On request of the Advisory Forum, a document was drafted outlining EFSA's position on outstanding issues related to the collection, management and sharing of data with EU Member States. Adherence to horizontal legal principles such as independence (e.g. DOI Policy), transparency (e.g. access to documents rules) and confidentiality (e.g. data protection) were regularly monitored. Following discussions with local authorities on further steps needed to fully implement the Agreement signed with the Municipality and STU in 2005, a draft of a supplementary agreement is being finalised with the Municipality.

Data protection

EFSA is pursuing compliance with Regulation (EC) N° 45/2001 on protection of individuals with regard to the processing of personal data, which during 2009 involved the following main areas of activity:

(1) Notifications for prior checking with the European Data Protection Supervisor (EDPS) of personal data processing operations likely to present specific risks to the rights and freedoms of data subjects. These notifications result in binding recommendations of the EDPS in the form of an Opinion, during 2009 issued on the following matters:
- EFSA selection and recruitment procedures for statutory staff as well as for seconded national experts and trainees
- EFSA staff leave management
- Assessment and reporting on staff's probationary periods
- Processing of health data at EFSA
- Annual & specific declarations of interest of persons involved in the EFSA constituent bodies

(2) Notifications to the Data Protection Officer (DPO) of personal data processing revealing a lower risk level and for which EDPS checking is not required, including:
- EFSA Newsletter & Highlights
- EFSA contacts database
- Journalist database
- Use of the PRAPeR peer review workspace on the EFSA extranet

A mapping of personal data processing in EFSA carried out by the DPO resulted in the identification of a total of 41 personal data processing operations at EFSA, of which 16 were notified to the DPO by the end of 2009.

Requests for access to documents

A total of 23 requests for public access to documents were received during 2009, mainly in the areas of GMOs, nutrition, flavourings and food additives.

Table 10: Key Performance Indicators for Legal and Policy Affairs

Indicator	Outcome
Inconsistencies in application of regulatory framework	Application of the regulatory framework was regularly monitored and any inconsistencies were not escalated further
No. of legal actions lodged against EFSA	2
Responsiveness	All requests addressed within 48 h

VI.4 Finance and Accounts

Finance

Budget Management and Activity-based budgeting (ABB)

Budget execution was monitored and reported to the Management Team on a monthly basis. As required, deviations from target budget execution were signalled and corrective actions taken. Comprehensive budget and financial reports are made available online to the financial community. The allocation of human and financial resources during the year was monitored by activity and reallocations were implemented when required. Detailed figures of budget execution are reported in Annex 1.

Financial Management

The volume of commitments and payments increased by 7% and 10%, respectively compared to 2008. Dedicated financial and procurement training was provided in order to enhance ownership by the Authorising Officers or budget holders and improve the quality of the financial and procurement files submitted. The management of the centralised budget lines (mission, shuttle, flights, translation, catering, amounting to €5 million) was improved and workflows were updated to be compliant with the new mission guide for instance. Centralisation of the administration of the 1000 scientific meetings organised annually by EFSA (total budget of €9 million) is under evaluation with a view to enhancing the efficiency of the process.

Procurement and Grants

Procurement procedures to the value of €15.6 million were launched in Communication and Administration. In addition, the value of the 15 grants and 50 procurement procedures launched in scientific cooperation in 2009 was €6.8 million. In total, this represented 33% of EFSA's overall budget. New guidance manuals, templates and training were provided to all Units. The planning and monitoring of scientific outsourcing were reviewed. Approximately 60 new contracts and grants were signed in 2009 for the whole organisation. Grant committee meetings were held every month to monitor contracts and grants in the Risk Assessment and SCA Directorates.

Management Tools

A new Contracts Database was made available to all procurement actors allowing them to monitor contract execution. A new release of the mission workflow application was launched and the ABB application for budget development was further developed to automate the ABB reporting – the latter process will be fully automated next year. The integration of various data sources for ABB reporting, i.e. financial systems, posting criteria, meetings and mission reporting were finalised and adapted to the five core activities (Activities 1-4 and Support) in 2010. Due to the revised schedule of the Commission, migration to the accrual-based accounting (ABAC) system was postponed until mid-2011. A new Finance Portal on EFSA's Intranet was set up allowing easy access to all budget, finance, procurement, workflow and training documents. A weekly Finance Newsweek is published on the Portal to enhance the financial awareness of staff.

Internal Control Standards

The results of the self-assessment of Internal Control Standards were presented to all Staff and an action plan developed and implemented to improve internal control effectiveness. A new structure for Internal Control Standards was adopted and a workshop aimed at identifying and addressing the main risks faced by EFSA was organised in December 2008.

Table 11: Key Performance Indicators for Finance

Indicator	Outcome
Budget execution	97%
Budget carryover	€9.5 m (vs. €15.5 m 2008)
Budget transfers	€2.6 m (vs. €4.4 m 2008)
Payment time	21 calendar days (average)
Interest paid on late payments	€1267
Audit outcomes	No critical or important issues identified in relation to contracts, grants or procurement by internal or external audit processes
Volume of transactions	+7% in commitments; +10% in payments (vs. 2008)

Accounts

The number of transactions executed increased by 6% compared with 2008. The average execution time was 2.8 days for payments. The increase in volume was reflected in the management of the new legal entity files and bank accounts for suppliers and experts. EFSA has now more than 7400 records in its third party (bank accounts) central database.

Migration to ABAC is scheduled for 2011. An internal audit was performed on the mission reimbursements of experts. In the Court of Auditors' report on EFSA's annual accounts for 2008, there are no comments on accounts and in the Court's opinion the transactions underlying the annual accounts are in all material respects legal and regular.

Table 12: Key Performance Indicators for Accounts

Indicator	Outcome
Execution time	2.8 calendar days (average)
Audit outcomes	No comments on accounts; annual accounts legal and regular
Volume of transactions	+6% (vs. 2008)

VI.5 Information Technology & Operations

Infrastructure & Support Team

Activity	Subject	Outcome
Provide scientific opinions and advice to the European Commission, the European Parliament and the Member States (Activity 1)	Technical supported for data collection in the areas of pesticide residues, zoonoses and food consumption	• Pesticide residues data collection completed in Sep. • Zoonoses data collection • completed in Jun. • Food consumption data collection completed in Nov.
	New tools to enable reporting across diverse databases (data warehousing).	Acquisition and installation of data warehousing tools (Microstrategy) complet in Mar.
	Collection and reporting on Member State user requirements through the leadership of an IT working group on Data Warehousing and Web Reporting.	• Survey of Member State needs completed in Sep. • Technical report delivered in Dec.
	Automated tool to manage Article 36 institutions.	Article 36 database delivered in Dec.
	Update of existing automated tools to manage the Database of Experts.	Delivered new releases of database in Jun and Sep.
	New Information Exchange Platform.	Delivered new releases of the Information Exchange Platform in Mar and Oct.
	New web area to support the EFSA Journal.	New web area delivered in Dec.
Enhance risk assessment methodologies and coordinate scientific networks (Activity 2)	Automated tool to register all mandates received, the questions implemented and the scientific output produced, including the automated production of Progress Indicators.	• First release of Risk Assessment Workflow completed in Jan. • New releases completed Jun and Sep.
	Update of existing automated tools to manage Declaration of Interests.	Delivered new releases in May, Jul and Sep.
	Support for FEEDAP unit in the evaluation of existing tools and solutions to manage Electronic	Technical support to FEEDAP provided on request.

	Submission and Evaluation of Application Dossiers.	
Communicate scientific advice a facilitate dialogue with interested parties (Activity 3)	Update of the EFSA Website.	Implemented new functionalities, e.g. advanced search capability and enhanced newsletter in Jul.
Manage and provide administrati support (Activity 4)	Management and improvement of IT infrastructure.	Ongoing management of infrastructure. Redundancy in various sectors (internet connection, electrical supply, disaster recovery, storage) to enha resilience completed in Nov.
Manage and provide administrati support (Activity 4) (contd.)	Improvements in internal processes and organisation by initiating a number of long term process improvement projects.	Definition of a Security Policy, Business Continuity Plan, Disaster Recovery Plan and Information Management Plan completed in Dec.
	Improvements in documentation on organisation-wide processes (archiving, parking, user access, etc.).	Definition of various policies (parking policy, mobile phones policy, etc.) complet incrementally in 2009.
	Final Seat monitoring project.	Project plan delivered in Aug.
	Business Continuity Plan project and delivery.	Draft of Business Security Plan delivered in Dec.
	New office spaces.	New offices for 50 people released In Mar (Cannocchiale building).
	Maintenance of all current premises.	Performed regular and extraordinary maintenance tasks for all buildings.
	EFSA internal meetings and events.	Supported over 3000 meetings/events.
	Statutory requirements for health and safety.	Performed two evacuation trainings and three Commission for Health and Safety meetings.
	Video, web and audio conferences.	Supported 60 audio conferences, 72 web conferences and 41 video conferences.
	Service Desk requests.	Supported over 15,000 requests.
	Customer satisfaction.	Satisfaction rating of 89% for Service Desk solutions.
	Update of the automated workflow for Mission Order and Mission Reimbursement.	New release deployed in Sep to implement the new Mission Guide.
	Staff moves	Organised 160 staff moves and 114 Unit moves.
	New automated tool to manage a database of Contracts and Grants.	New tool delivered in Mar.
	New automated workflow to manage the initial part of the CDAC process.	New workflow delivered In Feb.
	New automated workflow to manage Training Requests.	New workflow delivered in Nov.
	Update of existing workflow to manage	New workflow delivered in Dec.

	Leave Requests.	
	New Intranet Portal.	Portal delivered in Jun.
	Improved monitoring of IT governance.	Completed 3 COBIT (Control Objectives for Information and related Technology) assessments with incremental improved scores.

Table 13: Key Performance Indicators for IT and Operations

Indicator	Outcome
COBIT scores	20% improvement in COBIT scores over 2008
User satisfaction rating for Service Desk	89%
Project delivery	All high-priority 2009 projects successfully delivered
No. of meetings supported	3000+
No. of staff/unit moves	160 staff moves and 114 unit moves
No. of teleconferences	173

Table 14: Resources for Activity 4

Unit	Staff	Personnel costs	Infrastructure costs	Operational costs	Appropriations 2009	Execution	%
Human Resources	21	1.7	0.4	0.0	2.1	2.09	98%
IT & Operations	28	2.3	0.4	0.0	2.7	2.68	98%
Finance	19	1.6	0.4	0.0	2.0	1.96	99%
Legal & Policy	6	0.5	0.4	0.0	0.9	0.92	99%
Account	4	0.4	0.4	0.0	0.8	0.78	100%
Library	1	0.1	0.4	0.0	0.5	0.46	99%
Other	11	0.9	0.4	0.0	1.3	1.26	97%
TOTAL	**90**	**7.5**	**2.8**	**0.0**	**10.3**	**10.14**	**98%**

VI.6 Quality Management

The aim of EFSA's Quality Management is to promote a culture of continuous improvement by implementing a quality management system to ensure harmonisation and consistency through EFSA's internal procedures and a common methodology. In addition, Quality Management coordinates and supports EFSA's quality assurance programme (INEX) whereby its scientific outputs are being self (all outputs), internally (selected) and externally (selected) reviewed. In 2009, EFSA implemented its external review process whereby a selected number of scientific outputs were reviewed by a working group of external and independent experts. The conclusions, recommendations and areas for improvement are being considered and implemented in 2010. EFSA's Quality Management continued with the development and implementation of its Standard Operating Procedures, mainly in the area of Science and Communications.

Table 15: Key Performance Indicators for Quality Management

Indicator	Outcome
Successful adoption of Quality Plan 2009	Completed
No. of SOPs implemented	14
INEX procedures implemented	See Performance Indicators for Activities 1 and 2: Table 2, p. 16

VI.7 Audit

A risk assessment exercise was conducted in the last quarter of 2008 to determine the audit priorities and the IAS/internal audit capacity (IAC) audit plan for the next 3 years (fixed audit plan for 2009 and reserve list of audit for 2010 and 2011). The IAS/IAC audit plan 2009 was sent to the Executive Director and the Audit Committee for further endorsement. The final audit plan 2009-2011 was adopted by the Audit Committee of January 29, 2009. The Audit Committee assists the Management Board by ensuring that the work of the IAS and the IAC is properly conducted and taken into account by the Management Board and the Executive Director and receives appropriate follow-up. It also guarantees the independence and objectivity of the Internal Auditors.

Table 16: Key Performance Indicators for Audit

Recommendations	Total	IAS	IAC
Total received before 2009	21	17	4
Total received in 2009	56	24	32
Subtotal	77	41	36
Total implemented	34	19	15
% implemented	44%	46%	42%

VI. 8 Strategy and Prospective

During 2009 the Strategy and Prospective function within EFSA provided for adoption to the Management Board the *Strategic Approach to International Activities* for the Authority. With the assistance of the Commission and the Board, impact assessment tools and impact indicators were developed with a view to piloting these in 2010. The focus of EFSA's strategic work in 2009 was to open discussions on both a Science Strategy and a Communications Strategy so that these could be further developed and finalised in 2010. A report concerning EFSA's ability to react when risks to the food or feed chain requiring an urgent responses was commissioned and delivered in 2009 with a particular emphasis on the dioxin contamination of Irish pork. Regular prospective overviews of global developments in risk assessment in relation to food and feed were provided to all EFSA staff.

Table 17: Key Performance Indicators for Strategy and Prospective

Indicator	Outcome
Impact assessment	Document submitted to MB in Dec 2009
Prospective overviews for all staff	15 issues
Strategic documents	Strategic Approach to International Activities adopted; planning started for Science Strategy and review of Communications Strategy

VI. 9 Secretariat of the Management Board

A number of important enhancements to the support provided to EFSA's Management Board were introduced in 2009. These included the introduction of weekly activity reports covering all areas of operation of the Authority and a weekly institutional update from the Legal and Policy Affairs unit which covers developments relevant to EFSA's activities at the European Parliament, Commission, Council and Presidency. In terms of the logistics of Management Board meetings, documentation was provided to Board members at least 10 calendar days in advance and follow-up actions were dealt with promptly within the target of 2 working days after the meeting where possible. Written procedures were performed effectively and meeting minutes were routinely provided to the Board within 10 days.

Table 18: Key Performance Indicators for Management Board Secretariat

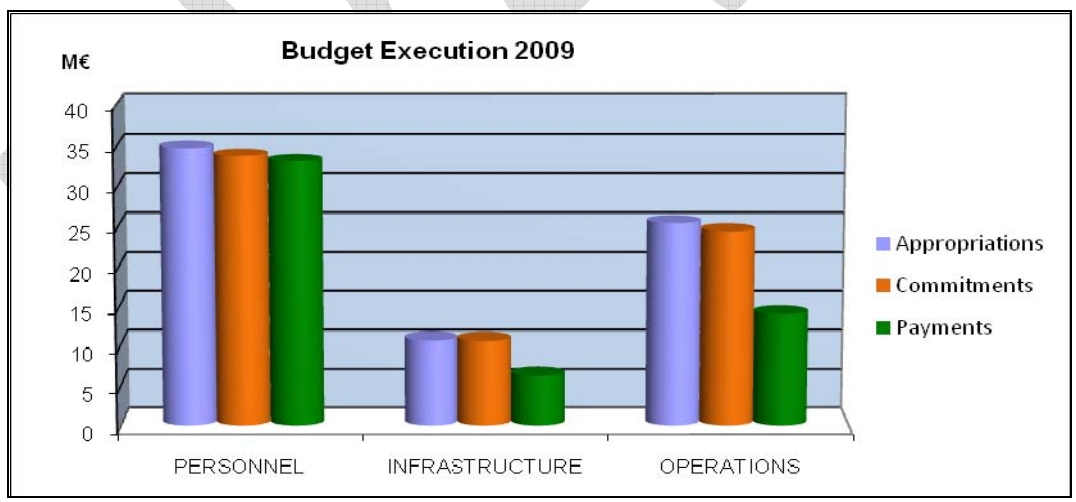
Indicator	Outcome
Activity reports	Delivered weekly
Minutes of MB meetings	Delivered 10 days after meetings
Meeting documents	Delivered 10 days before meetings
Institutional updates	Delivered weekly

Annex 1: Budget Execution 2009

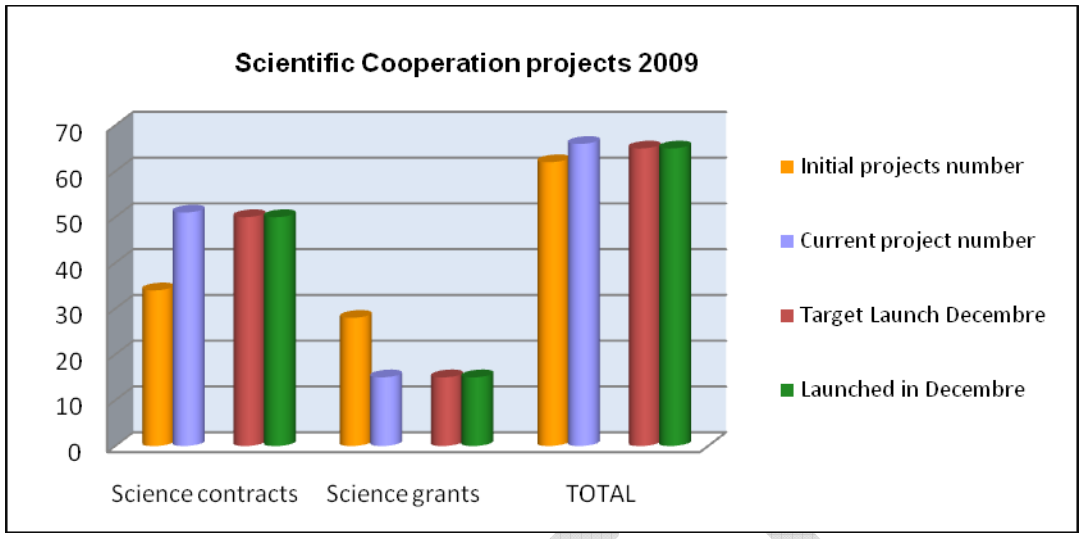
In 2009,

- €68.92 million or 97.1% of the €70.96 million budget including the Pre-accession program was committed. The commitment level was 1% below the target set for the year i.e. 98%.
- €53.47 million or 75.4% of the total appropriations were paid. This payment level stands 3% below the target at €55.6 million.
- €9.5 million of payment appropriations were carried forward to 2010 or 13% of the executed budget (24.4% in 2008).

Title	Appropriations	Commitments	% Committed	Payments	% Paid	RAL
PERSONNEL	34.77	33.81	97%	33.12	95%	0.69
INFRASTRUCTURE	10.75	10.69	99%	6.30	59%	4.40
OPERATIONS	25.44	24.42	96%	14.05	55%	10.37
of which Pre-accession	0.51	0.35	69%	0.23	46%	0.11
TOTAL	70.96	68.92	97%	53.47	75%	15.45



The budget execution in Title I (97% committed) is mainly driven by staff remuneration. Without the late December decision of the Council to reduce the salary adjustment coefficient, the execution under Title I would have reached 98%. Title II reached a 99% budget execution after the lifting of the €2 million reserve beginning of December which allowed conducting core IT and infrastructure projects. Under Title III, 96% of the appropriations were committed or 2% below the target. In 2009, science contracts were awarded an amount of €4.3 million on top of the grant agreements for an amount of €3.5 million.

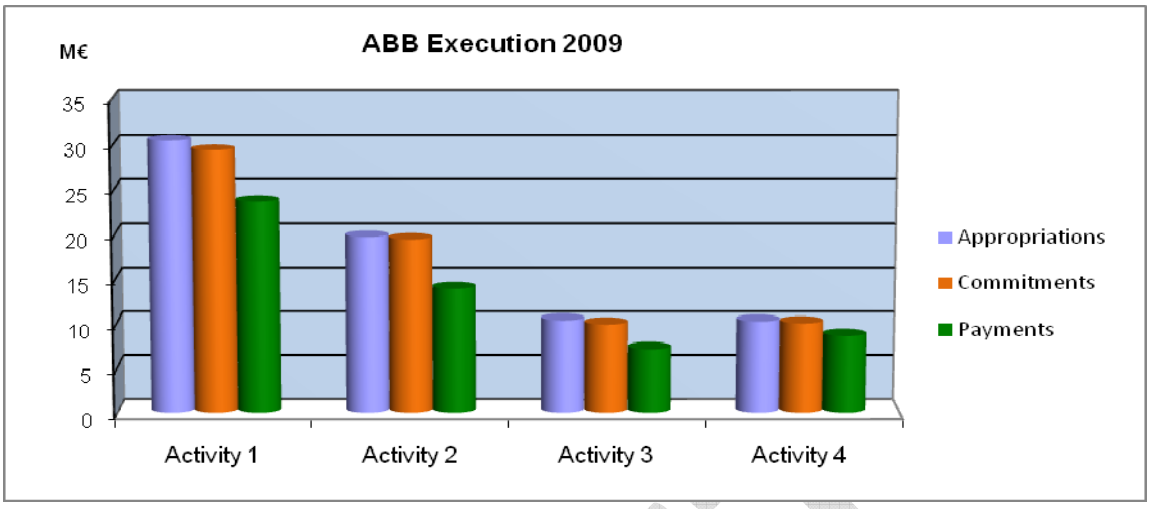


The budget execution of the main operations conducted is as follows:

Actions- M€	Appropriations 2009	Commitments	% Committed	Payments	% Paid	Appropriations carried over
Science meetings	8.10	7.56	93%	6.95	85%	0.61
Science contracts	4.37	4.33	99%	1.00	22%	3.33
Science grants	3.56	3.53	99%	0.94	26%	2.59
Communication C&E	0.45	0.45	99%	0.30	65%	0.15
Advisory Forum	0.56	0.49	87%	0.44	77%	0.55
TOTAL	17.04	16.365	96%	9.63	56%	6.73

In terms of Activity-based budgeting, the budgetary execution of the activities is as follows: the commitment execution level of the activities oscillates around 98% average for administration and activity 2 and 96% for communication and activity 1. This is mainly driven by the high proportion of staff costs and Infrastructure expenditure levelling out the operational execution difference.

Activity – M€	Appropriations	Commitments	% Committed	Payments	% Paid	RAL
Activity 1	30.72	29.84	97%	24.05	78%	5.79
Activity 2	19.52	19.04	98%	13.58	70%	5.46
Activity 3	10.42	9.96	96%	7.18	69%	2.78
Activity 4	10.30	10.09	98%	8.67	84%	1.42
TOTAL	70.96	68.92	97%	53.47	75%	15.45



Budget execution of carry-over appropriations

The payment execution under appropriations carried over from 2008 reached 87% with €13.55 million paid. €1.95 million of these appropriations were not utilised mainly as a result of delays incurred in delivering the grant programme for 2007 and 2008.

Title – M€	*Payment Appropriations*	*Executed Payments*	*% Paid*	*Appropriations cancelled*
PERSONNEL	1.30	1.19	91%	0.11
INFRASTRUCTURE	4.87	4.81	99%	0.06
OPERATIONS	9.33	7.55	81%	1.78
GRAND TOTAL	15.50	13.55	87%	1.95

Year-on-year

Year-on-year, budget execution increased by €4.7 million which represents an increase of 7%. A noticeable increase in Activity 2 (+33%) is notable. It mirrors the increased activities related to applications in particular. This was counter balanced by a decrease in Activity 1 (–5%). Overall, payments increased by €4.8 million which represents a 10% increase. The Management & Administration allocation in the global budget reduced from €11.0 million in 2008 to €10.1 million in 2009 (–8%) as a result of increased automation of processes and efficiency gains.

In M€	Budget Execution 2009	Budget Execution 2008	Change	Payments December 2009	Payments December 2008	Change
1- Provide Scientific Advice & Opinion	29.84	31.37	-5%	23.68	25.46	-7%
2- Risk assessment methodologies	19.04	14.36	33%	13.95	8.74	59%
3- Communication and dialogue	9.96	7.49	33%	7.18	5.46	31%
4- Management and Administration	10.09	11.00	-8%	8.67	9.06	-4%
TOTAL	**68.92**	**64.23**	**7%**	**53.47**	**48.73**	**10%**

Detailed Budget Execution

BL	Chapter	Commitment	Executed Commitment Amount	% Committed	Payment Appropriation	Executed Payment Amount	% Paid	RAL
1100	Basic salary	18.887.000	18.710.358	99%	18.887.000	18.710.358	99%	0
1101	Family allowance	1.931.000	1.906.853	99%	1.931.000	1.906.853	99%	0
1102	Transfer and expatriation allowance	2.397.000	2.365.510	99%	2.397.000	2.365.510	99%	0
1103	Secretarial allowance	11.000	10.704	97%	11.000	10.704	97%	0
1113	Stagiaires	124.000	96.238	78%	124.000	96.238	78%	0
1115	Contract staff	3.295.000	3.249.694	99%	3.295.000	3.249.694	99%	0
1130	Insurance against sickness	655.000	645.876	99%	655.000	645.876	99%	0
1131	Insurance against accidents and occupational disease	142.000	134.173	94%	142.000	134.173	94%	0
1132	Unemployment insurance for temporary staff	246.000	233.487	95%	246.000	233.487	95%	0
1140	Birth and death allowance	4.000	3.966	99%	4.000	3.966	99%	0
1141	Annual leave travelling expenses	468.000	462.520	99%	468.000	462.520	99%	0
1147	Call on duties	25.000	22.739	91%	25.000	22.739	91%	0
1170	Freelance and joint interpreting and conference service interpreters	5.000	2.480	50%	5.000	2.480	50%	0
1171	Translation centre Luxembourg (administrative matters)	188.000	188.000	100%	188.000	188.000	100%	0
1172	Payment for administrative assistance from the Community institutions	217.000	203.449	94%	217.000	200.867	93%	2.582
1175	Interim services	1.017.000	905.925	89%	1.017.000	809.934	80%	95.991
1176	Consultancy	30.000	29.000	97%	30.000	0.00	0.00%	29.000
1177	Other services	85.000	84.695	100%	85.000	54.187	64%	30.509
1180	Miscellaneous expenditure on recruitment	147.000	118.011	80%	147.000	85.689	58%	32.322
1181	Travel expenses (including for members of the family)	48.000	17.679	37%	48.000	17.679	37%	0
1182	Installation, resettlement and transfer allowances	241.000	196.905	82%	241.000	196.905	82%	0
1183	Removal expenses	210.000	202.140	96%	210.000	172.293	82%	29.848
1184	Temporary daily subsistence allowance	180.000	148.194	82%	180.000	148.194	82%	0
1190	WEIGHTINGS	2.335.200	2.242.500	96%	2.335.200	2.242.500	96%	0
	Chapter 11	**32.888.200**	**32.181.096**	**98%**	**32.888.200**	**31.960.845**	**97%**	**220.251**
1300	Mission and travel expenses	175.000	142.032	81%	175.000	113.531	65%	28.501
1301	Shuttles	59.000	59.000	100%	59.000	55.376	94%	3.624
	Chapter 13	**234.000**	**201.032**	**86%**	**234.000**	**168.908**	**72%**	**32.125**
1400	Restaurants, meals and canteens	32.000	28.515	89%	32.000	26.399	82%	2.116
1410	Medical service	178.000	151.180	85%	178.000	71.412	40%	79.767
1420	Further training, language courses and retraining for staff	550.000	477.271	87%	550.000	244.243	44%	233.028
	Chapter 14	**760.000**	**656.966**	**86%**	**760.000**	**342.055**	**45%**	**314.911**
1520	Visiting experts, National Experts on Detachement	601.000	597.145	99%	601.000	552.990	92%	44.155
	Chapter 15	**601.000**	**597.145**	**99%**	**601.000**	**552.990**	**92%**	**44.155**

BL	Chapter	Commitment	Executed Commitment Amount	% Committed	Payment Appropriation	Executed Payment Amount	% Paid	RAL
1600	Special assistance grants	5.000		0.00%	5.000	0.00	0.00%	0.00
1610	Social contacts between staff	95.000	61.558	65%	95.000	39.343	41%	22.215
1620	Other interventions	55.000	55.000	100%	55.000	6.793	12%	48.207
1630	Early childhood centres and other creches	50.000	26.000	52%	50.000	22.070	44%	3.930
1640	Complementary aid for the handicapped	6.000		0.00%	6.000	0.00	0.00%	0.00
	Chapter 16	**211.000**	**142.558**	**68%**	**211.000**	**68.207**	**32%**	**74.351**
1700	Reception and entertainment expenses	80.000	34.628	43%	80.000	30.520	38%	4.108
	Chapter 17	**80.000**	**34.628**	**43%**	**80.000**	**30.520**	**38%**	**4.108**
	Title 1	**34.774.200**	**33.813.425**	**97%**	**34.774.200**	**33.123.524**	**95%**	**689.900**
2000	Rent	2.559.924	2.558.832	100%	2.559.924	2.549.753	100%	9.078
2010	Insurance	33.196	33.196	100%	33.196	33.196	100%	0
2020	Water, gas, electricity and heating	492.423	492.423	100%	492.423	424.370	86%	68.053
2030	Maintenance	111.500	111.500	100%	111.500	9.575	9%	101.925
2031	Cleaning	183.017	183.017	100%	183.017	167.399	91%	15.618
2040	Refurbishment of premises/ Fitting out	566.573	566.110	100%	566.573	91.081	16%	475.030
2050	Security and surveillance of buildings	698.664	698.664	100%	698.664	535.620	77%	163.044
2080	preliminary to construction, acquisition or rental of immovable property	122.790	122.790	100%	122.790	0.00	0.00%	122.790
2090	Other expenditure on buildings	97.844	97.844	100%	97.844	92.095	94%	5.749
	Chapter 20	**4.865.931**	**4.864.376**	**100%**	**4.865.931**	**3.903.089**	**80%**	**961.287**
2100	Purchase/ Maintenance of equipment	1.246.638	1.246.636	100%	1.246.638	228.178	18%	1.018.458
2101	Purchase / maintenance of software	501.050	501.050	100%	501.050	220.966	44%	280.084
2103	Software development	2.253.306	2.253.306	100%	2.253.306	763.442	34%	1.489.864
2104	User Support	492.750	492.750	100%	492.750	218.900	44%	273.850
	Chapter 21	**4.493.744**	**4.493.742**	**100%**	**4.493.744**	**1.431.487**	**32%**	**3.062.256**
2200	Technical equipment and installations	69.411	69.411	100%	69.411	4.038	6%	65.372
2201	Hire or leasing of technical equipment and installations	8.000	8.000	100%	8.000	6.500	81%	1.500
2202	Maintenance and repair of technical equipment and installations	5.000	5.000	100%	5.000	5.000	100%	0
2210	Purchase of furniture	55.425	55.425	100%	55.425	20.357	37%	35.068
2250	Library stocks, purchase and preservation of books	10.000	9.102	91%	10.000	9.102	91%	0
2251	Special library, documentation and reproduction equipment	5.000	4.313	86%	5.000	4.313	86%	0
2255	Subscriptions and purchase of information media	28.000	27.083	97%	28.000	11.791	42%	15.292
	Chapter 22	**180.836**	**178.333**	**99%**	**180.836**	**61.101**	**34%**	**117.232**

BL	Chapter	Commitment	Executed Commitment Amount	% Committed	Payment Appropriation	Executed Payment Amount	% Paid	RAL
2300	Stationery and office supplies	167.000	166.993	100%	167.000	145.804	87%	21.189
2320	Bank charges	2.000	226	11%	2.000	226	11%	0
2330	Legal expenses	57.000	50.321	88%	57.000	50.321	88%	0
2340	Damages	18.300	18.300	100%	18.300	0.00	0.00%	18.300
2350	Miscellaneous insurance	28.800	28.800	100%	28.800	5.284	18%	23.516
2353	Removals and associated handling	11.846	11.846	100%	11.846	6.873	58%	4.973
2390	Publications	15.000	5.214	35%	15.000	5.214	35%	0
	Chapter 23	**299.946**	**281.700**	**94%**	**299.946**	**213.722**	**71%**	**67.977**
2400	Postal charges	75.000	75.000	100%	75.000	51.361	68%	23.639
2410	Telecommunications subscriptions and charges	282.350	282.350	100%	282.350	219.469	78%	62.881
2411	Purchase and installation of equipment	199.993	199.993	100%	199.993	165.864	83%	34.129
	Chapter 24	**557.343**	**557.343**	**100%**	**557.343**	**436.694**	**78%**	**120.649**
2500	Management Board meetings	352.000	317.748	90%	352.000	250.988	71%	66.760
	Chapter 25	**352.000**	**317.748**	**90%**	**352.000**	**250.988**	**71%**	**66.760**
	Title 2	**10.749.800**	**10.693.242**	**99%**	**10.749.800**	**6.297.081**	**59%**	**4.396.161**
3000	ANS: Scientific co-operation with external experts	496.372	496.200	100%	496.372	30.000	6%	466.200
3002	ANS: Travel / subsistence and indemnities expenses for members of the Panel and its Working Groups	528.450	496.600	94%	528.450	485.312	92%	11.288
3010	CEF: Scientific co-operation with external experts	360.000	357.309	99%	360.000	61.065	17%	296.244
3012	CEF: Travel / subsistence and indemnities expenses for members of the Panel and its Working Groups	510.000	494.076	97%	510.000	462.975	91%	31.100
3020	FEEDAP: Scientific co-operation with external experts	69.284	69.284	100%	69.284	15.000	22%	54.284
3021	FEEDAP: Subventions for studies and evaluations	113.050	113.050	100%	113.050	34.000	30%	79.050
3022	FEEDAP: travel / subsistence and indemnities expenses for members of the Panel and its working Groups	704.000	695.858	99%	704.000	646.066	92%	49.792
3030	PLH: Scientific co-operation with external experts	201.844	200.000	99%	201.844	0.00	0.00%	200.000
3031	PLH: Subventions for studies and evaluations	630.000	623.801	99%	630.000	249.520	40%	374.280
3032	PLH: Travel / subsistence and indemnities expenses for members of the Panel and its Working Groups	340.979	312.282	92%	340.979	287.141	84%	25.141
3040	PPR: Scientific co-operation with external experts	464.195	464.006	100%	464.195	71.011	15%	392.995
3041	PPR: Subventions for studies and evaluations	197.082	196.270	100%	197.082	84.508	43%	111.762
3042	PPR: Travel / subsistence and indemnities expenses for members of the Panel and its Working Group	652.820	632.819	97%	652.820	537.973	82%	94.846
3050	GMO: Scientific co-operation with external experts	397.225	397.225	100%	397.225	44.555	11%	352.670
3052	GMO: Travel / subsistence and indemnities expenses for members of the Panel and its working Groups	904.400	829.589	92%	904.400	787.626	87%	41.963
3062	NDA: Travel / subsistence and indemnities expenses for members of the Panel and its Working Groups	730.700	719.410	98%	730.700	619.634	85%	99.776
3070	BIOHAZ & BSE-TSE: Scientific co-operation with external experts	274.563	274.563	100%	274.563	0.00	0.00%	274.563
3071	BIOHAZ & BSE-TSE: Subventions for studies and evaluations	239.260	239.260	100%	239.260	0.00	0.00%	239.260
3072	BIOHAZ & BSE-TSE: Travel / subsistence and indemnities expenses for the members of the Panel and its Working Groups	811.438	732.306	90%	811.438	695.991	86%	36.316

BL	Chapter	Commitment	Executed Commitment Amount	% Committed	Payment Appropriation	Executed Payment Amount	% Paid	RAL
3080	CONTAM: Scientific co-operation with external experts	14.500	14.500	100%	14.500	0.00	0.00%	14.500
3081	CONTAM: Subventions for studies and evaluations	388.940	378.625	97%	388.940	91.189	23%	287.436
3082	CONTAM: Travel / subsistence and indemnities expenses for members of the Panel and its Working Groups	534.800	512.191	96%	534.800	445.417	83%	66.775
3090	AHAW: Scientific co-operation with external experts	5.000	3.000	60%	5.000	0.00	0.00%	3.000
3091	AHAW: Subventions for studies	433.677	433.677	100%	433.677	107.515	25%	326.161
3092	AHAW: Travel / subsistence and indemnities expenses for members of the Panel and its Working Groups	692.200	605.507	87%	692.200	579.930	84%	25.576
	Chapter 30	**10.694.778**	**10.291.406**	**96%**	**10.694.778**	**6.336.429**	**59%**	**3.954.977**
3100	Scientific cooperation	722.502	693.498	96%	722.502	693.498	96%	0
3102	Travel / subsistence and indemnities expenses	73.475	68.682	93%	73.475	67.903	92%	779
3110	Data collection exposure	222.200	222.200	100%	222.200	57.500	26%	164.700
3111	Data collection exposure : subvention for studies and evaluations	1.094.344	1.091.879	100%	1.094.344	296.971	27%	794.908
3112	Data collection : Travel/subsistence and indemnities expenses	160.000	130.789	82%	160.000	121.087	76%	9.702
3120	Emerging risks	50.560	50.560	100%	50.560	15.168	30%	35.392
3121	Emerging risks : subvention for studies and evaluations	250.000	250.000	100%	250.000	75.000	30%	175.000
3122	Emerging risks: Travel/subsistence and indemnities expenses	81.501	64.543	79%	81.501	60.880	75%	3.663
3130	Assessment methodology	120.000	115.270	96%	120.000	0.00	0.00%	115.270
3131	Assessment methodology : subvention for studies and evaluations	22.500	22.500	100%	22.500	0.00	0.00%	22.500
3132	Assessment methodology: travel/subsistence and indemnities expenses	120.000	115.203	96%	120.000	113.116	94%	2.087
3142	PRAPeR: travel/subsistence and indemnities expenses for the members of the Expert Group and its Working groups	286.970	284.831	99%	286.970	284.831	99%	0
3143	MRL: scientific cooperation with external experts	100.490	100.490	100%	100.490	3.850	4%	96.640
3145	MRL: travel/subsistence and indemnities expenses for members of the Expert Group and its Working Groups	43.805	35.290	81%	43.805	35.290	81%	0
3150	Zoonoses: Scientific cooperation with external experts	741.009	740.409	100%	741.009	7.544	1%	732.865
3151	Zoonoses: subventions for studies and evaluations	133.971	133.970	100%	133.971	0.00	0.00%	133.970
3152	Zoonoses: travel/subsistence and indemnities expenses for members of the Task Force and its Working Groups	301.000	285.591	95%	301.000	263.606	88%	21.985
	Chapter 31	**4.524.327**	**4.405.704**	**97%**	**4.524.327**	**2.096.242**	**46%**	**2.309.462**
3200	Advisory Forum Plenary	249.624	233.638	94%	249.624	207.834	83%	25.804
3201	Advisory Forum WG COM	92.384	90.144	98%	92.384	90.144	98%	0
3202	Advisory Forum WG IT	11.500	11.493	100%	11.500	5.193	45%	6.300
3203	Advisory Forum horizontal WG	199.000	144.809	73%	199.000	121.459	61%	23.351
3204	Advisory Group on Risk Communication (AGRC)	10.941	10.940	100%	10.941	10.940	100%	0
3210	SC: cooperation with external experts	129.851	126.901	98%	129.851	0.00	0.00%	126.901
3211	SC: subventions for studies and evaluations	55.449	45.851	83%	55.449	0.00	0.00%	45.851
3212	SC: travel/subsistence and indemnities expenses for members of the Scientific Committee and its Working Groups	615.000	547.758	89%	615.000	459.430	75%	88.328
	Chapter 32	**1.363.749**	**1.211.533**	**89%**	**1.363.749**	**894.999**	**66%**	**316.535**

BL	Chapter	Commitment	Executed Commitment Amount	% Committed	Payment Appropriation	Executed Payment Amount	% Paid	RAL
3300	Stakeholder relations	47.000	36.435	78%	47.000	28.147	60%	8.288
3301	Crisis support	60.000	928	2%	60.000	928	2%	0
3302	International Liaison	30.000	23.399	78%	30.000	22.199	74%	1.200
3310	Pre-accession	505.190	347.590	69%	505.190	232.816	46%	114.774
3320	Strategy & Prospective	20.574	20.000	97%	20.574	20.000	97%	0
	Chapter 33	**662.764**	**428.351**	**65%**	**662.764**	**304.090**	**46%**	**124.262**
3400	Media Relations	95.609	94.512	99%	95.609	5.433	6%	89.079
3410	Web Development	27.026	27.010	100%	27.026	15.314	57%	11.696
3411	Web-streaming (all)	250.126	250.126	100%	250.126	191.313	76%	58.813
3420	Corporate, Public & Scientific C&E	446.056	444.256	100%	446.056	294.135	66%	150.121
3421	Press/Media C&E	8.200	7.616	93%	8.200	4.813	59%	2.804
3430	Publications	819.700	806.250	98%	819.700	444.148	54%	362.102
3440	Publicity/Marketing Material	74.000	73.983	100%	74.000	60.435	82%	13.548
3450	Evaluation	770.036	738.467	96%	770.036	69.642	9%	668.825
3451	Media Monitoring	245.019	245.019	100%	245.019	6.959	3%	238.060
	Chapter 34	**2.735.772**	**2.687.239**	**98%**	**2.735.772**	**1.092.191**	**40%**	**1.595.048**
3501	Data collection IT	778.100	778.088	100%	778.100	168.723	22%	609.365
3502	Networking of organization	210.000	209.711	100%	210.000	46.025	22%	163.686
3503	Dedicated IT systems to support the operations	1.383.700	1.383.667	100%	1.383.700	426.567	31%	957.100
3512	Library: access to databases / documents	193.000	186.614	97%	193.000	178.278	92%	8.337
3513	Mission of staff related to operational duties	1.250.000	1.233.506	99%	1.250.000	1.078.043	86%	155.463
3514	Shuttles	918.000	914.500	100%	918.000	859.894	94%	54.606
3515	Archives and scanning	72.000	71.210	99%	72.000	7.511	10%	63.699
3520	Translation	648.000	616.512	95%	648.000	561.921	87%	54.591
3521	Interpretation	1.000	0	0%	1.000	0.00	0.00%	0
	Chapter 35	**5.453.800**	**5.393.809**	**99%**	**5.453.800**	**3.326.963**	**61%**	**2.066.846**
	Title 3	**25.435.190**	**24.418.043**	**96%**	**25.435.190**	**14.050.913**	**55%**	**10.367.129**
	GRAND TOTAL	**70.959.190**	**68.924.709**	**97%**	**70.959.190**	**53.471.519**	**75%**	**15.453.191**

Annex 2: Establishment Plan 2009

The distribution of staff by activity at the end of 2009 is as follows:

Activity	Officials & Temporary Staff	Contractual Agents	National Detached experts	Total
A.1 Provide scientific opinion and advice to the European Commission, the European Parliament and the Member States	140	27	6	173
A.2 Enhance risk assessment methodologies in Europe	82	16	2	100
A.3 Communicate scientific advice and dialogue with interested parties	34	11	3	48
A.4 Manage and provide administrative support	70	20	0	90
TOTAL	**326**	**74**	**11**	**411**

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, with the exception of the probable delay in the delivery and availability of the final seat of EFSA. That delay may have indirect financial repercussions insofar as it would require EFSA to allocate more financial resources than anticipated for the payment of rents in the coming years.

Parma,

Catherine Geslain-Lanéelle

Annex 4: Report on the Implementation of the Internal Control Standards 2009

The evaluation of Internal Control Standards performed at November 2009 has provided EFSA management with reasonable assurance on the level of implementation of Internal Control Standards. However the evaluation has highlighted three areas which require particular attention and follow up in the 2010 Annual Management Plan:

- ICS 6 - Risk management
- ICS 10 - Business continuity
- ICS 11 - Document management

The complete state of play of the 16 internal control standards at November 2009 is as follows:

Standard	Status	Further actions foreseen in 2010
1- Mission	Partially Implemented	EFSA will initiate a process to ensure that the work plans of all units and individuals across the organisation are consistent with the corporate mission.
2 – Ethical and organisational values	Partially Implemented	Integration of different related procedures and rules in a concise and user-friendly code of ethics/rules of procedures. Definition of communication channels for ethical matters will be included.
3 – Staff allocation and Mobility	Implemented	Revision of staff job descriptions to ensure consistency with mission statements.
4 - Staff evaluation and development	Implemented	1) Harmonise the content of the CDAC. 2) Closely monitor any delays in the CDAC exercise. 3) Reinforce the transparency and documentation of the promotion exercise. 4) Implement a new IT system to manage training.
5 – Objectives and performance indicators	Implemented	Actions to address significant risks will be included in the Annual Management Plan.
6 – Risk management process	Partially implemented	An overall risk management policy will be formalised in 2010.
7 – Operational structure	Partially implemented	1) Allocate appropriate resources to the Internal Control Coordinator function.

		2) Review the sensitivity of posts annually in connection with the CDAC exercise. 3) Identify mitigating factors to reduce risks linked to sensitive functions.
8 – Processes and procedures	Partially implemented	See action foreseen in ICS 6 above.
9 - Management supervision	Partially implemented	1) Set up a register recording IC weaknesses 2) Complete a review of internal control including a survey to identify weaknesses in the system. 3) See action foreseen in ICS 6 above.
10 – Business continuity	Partially implemented	1) To mitigate this risk, EFSA is finalising a Business Continuity Plan which will be validated and implemented in 2010. 2) Revise/update the decision on the continuity of operations and communicate effectively to staff.
11- Document management	Partially implemented	1) This risk is being mitigated by the current development of a corporate document management and information security policy which will be implemented in 2010. 2) Adopt a global policy on information security and ensure its implementation. 3) Define and implement a training policy on information security issues
12 – Information and communication	Partially implemented	1) Strive to consolidate planning tools to link communication activities with available resources. 2) Complete the risk assessment workflow (RAW) project aimed at building a reliable information system to support communication activities. 3) See action foreseen in ICS 2
13 – Accounting and financial reporting	Implemented	1) Budget execution and financial reporting carried out by finance unit on a monthly basis.

		2) A finance "newsweek" is available on the intranet reminding and informing staff on financial regulation issues. 3) Accounting procedures are available on the intranet.
14 – Evaluation of activities	Partially implemented	Development of a comprehensive evaluation plan for all important (material) projects and processes.
15 – Assessment of Internal Control Systems	Partially Implemented	1) Complete a review of the internal control system including a survey to identify weaknesses (ICAT survey). 2) A formal Internal Control weakness register will be implemented in 2010 3) See action 1 foreseen in ICS 7 above.
16 – Internal Audit Capability	Implemented	Ensure that the IAC has adequate resources to perform the audit work plan.

Annex 5: List of negotiated procedures 2009

Contract no.	Contractor	Subject	Value
Negotiated procedures concluded in 2009 under Art. 126 a-g or Art 127 a-d of EU FR			
1	Cariparma	Banking Services for EFSA	€0,00
2	Management Centre Europe	Leadership for Senior Managers	€6.200,00
3	TNS Opinion & social in consortium together with Taylor Nelson Sofres plc. and The European Omnibus Survey Scrl	Eurobarometer	€ 638.431,19
4	I.V.R.I	Servizi di Sicurezza/Vigilanza'	€169.395,20
5	Technical University of Denmark	Supplementary services not included in its ongoing contract	€100.000,00
6	Caffé latte	Fornitura di caffè e bibite per le riunuioni dell' EFSA	€240.000,00
7	Elsevier	Production of special issue on the "Toxicology and applied Pharmacology"	€12.450,00

Glossary

ABAC – Accrual-based accounting
ABB – Activity-based budgeting
ABP – Animal by-products
AF – Advisory Forum
AFWGC – Advisory Forum Working Group on Communications
AGRC – Advisory Group on Risk Communication
AHAW Panel – Panel on animal health and welfare
AMR – Anti-microbial resistance
AMU – Assessment Methodology Unit
ANS – Panel on Food Additives and Nutrient Sources Added to Food
ARfD – Acute Reference Dose
BEUC – European Consumers Organisation
BIOHAZ Panel – Panel on biological hazards
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
DATEX – Data Collection and Exposure Unit
DG ENV – Directorate General Environment
DG RDT – Directorate General Research and Technical Development
DG SANCO – Directorate General for Health and Consumers
DOI – Declaration of Interest
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
EMEA – 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)
FEEDAP Panel – Panel on Additives and Products or Substances Used in Animal Feed
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 on Plant Health
PPR Panel – Panel on Plant Protection Products and Their Residues
PRA – Pest risk assessment
PRAPeR – Pesticides Risk Assessment Peer Review Unit
QMRA – Quantitative Microbiological Risk Assessment
QPS – Qualified Presumption of Safety
SC – Scientific Committee
SCA – EFSA Scientific Cooperation & Assistance Directorate
SCENIHR – Standing Committee on Emerging and Newly Identified Health Risks
SCO – EFSA Scientific Cooperation Unit
SOP – Standard operating procedure
TSE – Transmissible spongiform encephalopathy
USDA – United States Department of Agriculture
WHO – World Health Organisation