

Office of the Executive Director and the Management Board

HIGHLIGHTS

Risk Assessment

The **ANS** panel adopted a total of 9 opinions and 2 statements covering 36 applications. Hi priority is maintained for the evaluation of nutrient sources for food supplements and preparatory work will be started on the re-evaluation of food colours. The **AHAW** panel issued 2 opinions on Carp welfare and on Seabass and Seabream welfare. The opinion on Blue tongue "risk of transit" was also discussed in light of new information from the EC. The **BIOHAZ** panel published the opinion on TSE infectivity in milk products from small ruminants and on food safety aspects of farmed fish. A paper on the panel's challenges during the next 10 years has been adopted. The **CEF** panel adopted 7 opinions related to 148 substances of the "FGE19" flavouring substances group: 82 were considered to pose no genotoxicity concerns and data were required for 66 substances. A new statement on Bisphenol A was issued on request of the EC. The **CONTAM** unit in collaboration with the **DATEx** unit responded to the urgent request of the EC for scientific advice on possible risk arising from melamine in food imported from China. A statement was issued 3 days after the request. The **FEEDAP** panel adopted 7 opinions and 7 guidance documents related to the authorisation of feed additives under regulation EC 1831/2003. One generic opinion on vitamin A was also adopted. In the **GMO** area 3 public consultations were concluded on the guidance on GM plants for applicant, on the comparative food safety evaluation of GMO and on the guidance for GM plants for non-feed/food purposed. The panel adopted 5 opinions, 2 on feed additives (co-opinions with FEEDAP), 1 on a new GM plant application for maize and 2 art.29 opinions on request of DG ENV. The scientific colloquium report on environmental risk assessment of GMO plant was published. The **NDA** panel has adopted 2 opinions on Article 14 risk reduction claims, 17 on Article 14 claims referring to children's health and development and 1 on Article 13 claim on newly developed scientific evidence. The Panel also adopted a Novel food opinion on Vitamin K2 and one opinion on lutein. The **PLH** panel Chair and the unit participated in the special advisory Forum meeting devoted to plant health. A self-task for the development of guidelines for pest risk assessment has been initiated. The **PPR** panel adopted the terms of references for 3 new self task mandates on methodology for modelling dietary exposure to pesticide residues, on toxicological relevance of pesticides active substances and on dermal absorption. A public consultation on this latter has been launched. The **Scientific Committee** endorsed during the 32nd plenary meeting the draft opinion on Nanotechnology and commented on EFSA's Strategic Plan 2009-2013. On 4-5 November EFSA hosted the 4th meeting of Chairs and Secretariats of the Scientific Committees and Panels of the Commission and EU Agencies involved in risk assessment.

Scientific Cooperation and Assistance

In **Scientific Cooperation**, a report on the activities of the Focal Points during their first year was prepared and presented to the Advisory Forum. On this basis the Advisory Forum renewed the Focal Point Agreements. Over 1000 experts have submitted application forms to the Expert Database. The Interim Review of the Strategy for Cooperation and Networking was prepared together with a revised art.36 list of organisations. Seminars were organised in Budapest and Warsaw to attract scientific experts to join EFSA's Scientific Committee and Panels. **AMU** started a self mandate on the use of systematic literature review in risk assessment. The **Emerging Risk** unit issued the EFSA "Crisis Management Plan. **PRAPeR** established the Pesticides Steering Committee comprising representatives from each Member State and the European Commission. 32 EFSA conclusions were finalised and delivered to the Commission as well as 11 reasoned opinions on MRLs. The **Zoonoses** unit published a Report on the Analysis of the baseline survey on *Salmonella* in turkeys.

Advisory Forum

At its meetings in Paris and Copenhagen discussions were held on the EFSA Strategic Plan and Nanotechnology. In October EFSA hosted the first meeting of Advisory Forum representatives on plant health with a focus on the cooperation between the EU Member States and EFSA in this area.

Communications carried out a wide range of activities including a communication campaign throughout Member States concerning the renewal of Scientific Committee and Panel members. A series of events for press were also organized including a media breakfast in Brussels.

Administration provided legal assistance for technical meetings concerning the Scuola per l'Europa in Parma and a roundtable organized in Rome between EFSA's Executive Director and Undersecretary of State Gianni Letta. As a follow up of this meeting the Italian Minister of European Policies visited EFSA on 17 November. On 10 November the Joint Research Centre (JRC) and EFSA signed a Memorandum of Understanding to facilitate technical cooperation. Following an initiative by the French presidency EFSA's Executive Director presented the Draft Strategic Plan 2009-2013 at the EU Chief Veterinary Officers and Chief Officers on Plant Health on November 7th. On 14 October a joint seminar on the health effects of climate change on food and water safety and nutrition was organised by the WHO, the FAO and EFSA. During the last Stakeholders Platform meeting the new Chair of the Platform Dr Andreas Varlamos, from EKPIZO, the Greek Consumers Organisation and member of BEUC, was elected.

RISK ASSESSMENT

Panel on food additives and nutrient sources added to food (ANS)

The second plenary meeting of the ANS Panel was held from 23 to 25 September 2008 in Parma and a 2nd meeting for both working groups A and B took place from 28 to 30 October 2008 in Parma. The third plenary was organised for the period from 25 to 27 November 2008.

The ANS Panel has adopted in its 2nd Plenary 4 opinions on Calcium Sulphate, Vitamin B12, Benfotiamine and Pantethine. In addition one opinion on Calcium L-threonate was adopted by written procedure on 24 October 2008. . During the 3rd Plenary further 4 opinions and 2 statements were adopted on Aspartate sources, Calcium fluoride, Sodium monofluorophosphate, Chromium polynicotinate and on Silver hydrosol (nanoparticulate material) and Tin chloride respectively. Two more opinions will be submitted to a written procedure for possible adoption during the month of December: Taurine and D-glucuronolactone in 'energy drinks' and Methionates as nutrient sources for use in food supplements. Hence, a total of 9 opinions and two statements have been adopted so far by the ANS Panel and two additional opinions are foreseen to be adopted by the end of 2008. In total, these opinions and statements will cover 36 applications

Three negotiated procedures were launched and the contracts have been signed: Pre-evaluation of documents from several application dossiers for nutrient sources originating from an orotic acid, pre-evaluation from several application dossiers for nutrient sources in the form of enriched yeasts and commenting on the SCF 2001 guidance on submission for food additive evaluations and its possible evolution in view of their practical use and of the evolution of science, technology and risk assessment paradigms and practices.

The third working group meeting for WG meeting A will take place in Parma from 16 to 18 December, whilst working group B will hold a one-day meeting in Brussels on 16 December 2008. For 2009 seven Plenary meetings of the Panel and six meetings for each standing working group are planned.

In addition to the highest priority work on the evaluation of the nutrient sources for the food supplements (deadline May 2009), preparatory work will be done on the re-evaluation of food colours in order to speed up the process.

Panel on animal health and welfare (AHAW)

Between 15 September and 30 November 2008, the AHAW unit held 1 plenary meeting (October 22-23). In October 2 opinions were adopted, one on Carp Welfare and another one on Seabass and Seabream Welfare. Both opinions on fish welfare included a minority opinion based on Prof. Donald Broom's (panel and WG member) statement that the introductory chapters on the welfare, biological functioning and farming of fish should be included. Additionally the Panel further discussed the opinion on Blue tongue on "risk of transit" assessment adopted in September, as a consequence of an information received from the Commission services, in order to assure that the content was according to the terms of reference.

Concerning the grants under Article 36 a project was granted for Tuberculosis in wildlife and another project is being evaluated for possible agreement for two emerging diseases. Additionally, EFSA received the completed scientific report concerning a grant on animal diseases and vectors (CFP/EFSA/AHAW/2007/02.).

Representatives of the AHAW Unit gave presentations on the activities of the Panel at the following events:

23rd Conference of the OIE Regional Commission for Europe in Vilnius, 16-19 September 2008, FAO Expert meeting on capacity building to implement good animal welfare practices in Rome, 1 October 2008 (2 presentations); Conference on Animal Welfare at slaughter and killing for disease control in Hinderås (Sweden), 1-3 October 2008; 5th International Symposium "The Role of Fish Pathology in Sustainable Aquaculture" in Tokyo 18-19 October 2008; OIE Global Conference on animal Welfare in Cairo, 20-22 October 2008 (poster).

Representatives of the AHAW submitted three scientific articles/publications which have been already accepted, i) Animal welfare's impact on the food chain. Trends in Food Science and Technology, ii) Gene expression, Journal of Invertebrate Pathology, iii) Development of a risk assessment methodology for animal welfare in EFSA's scientific opinions, Wageningen Academic Publishers.

Panel on biological hazards (BIOHAZ)

The 43rd Plenary the BIOHAZ Panel was held on 22-23 October.

WG meetings were held as follows: Technical guidance on poultry carcass decontamination on 23 September; the link between Salmonella criteria at different stages of the poultry production chain 3 October and 4 November;

Cooling of eggs 22 Sept and 22 Oct; Qualified Presumption of Safety (QPS) 26 Sept; Meticillin resistant *Staphylococcus aureus* (MRSA) 8 Oct; TSE in milk 14 Oct; Salmonella in pigs 15-16 Oct; TSE testing 21 Oct; Salmonella in breeding flocks of poultry on 7 October and ARM-GMO meetings were held on 9 Oct and 28 Nov.

A stakeholder meeting concerning Qualified Presumption of Safety (QPS) was held between LABIP (Lactic Acid Bacteria Industrial Platform) and BIOHAZ on 8 October.

BIOHAZ and DG SANCO held a joint technical workshop on 17 November. The workshop was on the assessment of new alternative methods for animal by-products (ABP) and provided training to people evaluating ABP dossiers at Member States level. Delegations from 21 Member States, Norway and Switzerland attended.

The "Informal meeting of EU Commission services and agencies to coordinate activities in the field of minimising the risk of resistance arising as a result of the use of antimicrobial substances in veterinary medicinal products" was held at EMEA on 28 October.

At the Plenary of 22-23 October, the BIOHAZ Panel adopted opinions on "TSE infectivity in milk products from small ruminants" and "Food safety aspects of animal welfare of husbandry systems for farmed fish".

A paper concerning the challenges facing the EFSA's BIOHAZ Panel during the next 10 years was adopted by written procedure and forwarded to the Executive Director.

The call for tenders on "Fate of Salmonella spp. on broiler carcasses before and after cutting and/or deboning" was evaluated. As the value of the call is over 60,000 €, the recommendations of the Evaluation Committee were assessed by the Public Procurement Committee.

The first ad hoc WG meeting on bacteriophages took place on 29 October. A new ad hoc WG was formed to deal with *Campylobacter* in broiler meat and the first meeting was held on 27-28 November

A new ad hoc Working group was formed to provide an update on the risk for human and animal health related to the revision of the BSE monitoring regime concerning Slovenia and Cyprus.

Ad hoc Working groups were established on two new applications from Member States: Alternative method for carcass destruction using the bunker system; and the use of FuelCal® technology as a new alternative method of disposal or use of ABP.

Panel on food contact materials, enzymes, flavourings and processing aids (CEF)

The CEF Panel held its 2nd and 3rd Plenary meetings in Parma on 23-25 September and 25-27 November 2008 respectively.

The five standing WG have met as follows: Enzymes (11-12 November in Bruxelles), Flavourings-genotoxicity (21-22 October in Copenhagen), Flavourings 1 (22-24 October in Copenhagen), Flavouring 2 (11-13 November in Parma) and Food Contact Materials (11-13 November in Parma).

A meeting gathering Panel members, EFSA scientific officers and industry federations for flavourings was held in Parma on 25 November 2008.

Meetings were held with Commission in the areas of flavourings, Food Contact Materials and Enzymes.

The highest priority was given to the evaluation of the "FGE.19" flavouring substances, i.e. those which have structural alerts for genotoxicity. Seven opinions related to 148 substances of FGE.19 were adopted. 82 substances were concluded to be of no safety concern related to genotoxicity. Data were required for 66 substances, including important substances currently on market. The Panel has published statements describing the test strategy to evaluate the genotoxic potential of substances of FGE.19. In another statement, substances representative of each sub-group of FGE.19 to be tested have been defined on the basis of structure and reactivity considerations.

On request of Commission, the Panel has issued a new statement on Bisphenol A (BPA). A response to a letter sent to EFSA by three German scientists on BPA has also been prepared. The overall conclusion was that there is no need to revise the conclusions of the opinion of EFSA on BPA in 2006.

The Panel evaluated the 20th and the 21st lists of substances used to manufacture food contact materials. The 21st list includes the first opinion on an additive in nanoparticulate form intended for the production of PET bottles; based on the absence of migration, the Panel concluded that the intended use of the substance does not raise safety concerns. Guidelines for active and intelligent packaging have been discussed; a version is ready to be submitted to public consultation as soon as the corresponding Regulation is adopted.

A contract on safety of irradiated food has been signed with Max Rübner Institut on 13 October 2008 for an evaluation of the corresponding scientific literature.

The evaluation of Flavouring substances in the Community Register (substances currently on the market) should be finalised in 2009. The evaluation of applications for substances to be used for Food Contact Materials is ongoing, with a steady number of petitions. Following the publication of Recycling Guidelines in 2008, the first application for a recycling process has been received and will be evaluated in 2009.

Guidelines for the evaluation of Enzymes and of Flavourings are being prepared in the respective working groups; they should be adopted by mid 2009 according to the FIAP regulation.

The evaluation of a processing aid is planned for the January Plenary. A working group on safety of irradiation of food is being set up. This work will be coordinated with BIOHAZ.

Panel on contaminants in the food chain (CONTAM)

The CONTAM Panel did not meet in plenary during the reporting period (15 September to 30 November 2008). Eleven working group and audio conference meetings were held during this period related to requests on undesirable substances in animal feed – section natural plant products (4 meetings), undesirable substances in animal feed – section nitrite (2 meetings), marine biotoxins (3 meetings), and heavy metals (cadmium) in food (2 meetings). In addition, a first kick-off audio conference meeting was held related to the work of the new established WG on arsenic in food.

EFSA has received a request for urgent scientific advice on the risks for public health due to the possible presence of melamine in composite food products imported from China into Europe from the European Commission. Due to the urgency of this request EFSA issued a statement following Art. 13b of the “Decision concerning the establishment and operations of the scientific committee and panels”. The statement was jointly prepared by the EFSA DATEX and CONTAM units taking into account scientific advice from some CONTAM panel members. The EFSA statement on melamine (EFSA-Q-2008-695) was issued on 24 September 2008 three days after the request was received. The European Commission adopted interim measures on 26 September 2008 (Commission Decision 2008/757/EC) and adopted a new decision on 14 October 2008 (Commission Decision 2008/798/EC) imposing special conditions governing the import of products containing milk and milk products originating in or consigned from China.

Applications for two Article 36 calls which were launched to facilitate the work of the CONTAM Panel, CFP/EFSA/CONTAM/2008/01 (scientific information on mycotoxins and natural plant toxicants) and CFP/EFSA/CONTAM/2008/02 (survey on the use of veterinary medicinal products in third countries) were received and grants for both calls have been awarded.

In the above mentioned period the CONTAM Panel has received a request on risks for public health due to the presence of melamine in infant formula and other milk products (EFSA-Q-2008-695).

Panel on additives and products or substances used in animal feed (FEEDAP)

The FEEDAP Panel held ten Working group meetings and three Plenary meetings, during which seven scientific opinions, one generic opinion on Vitamin A and seven technical guidance documents were adopted. In addition, one technical hearing on carotenoids and vitamins and one consortium on silage additives were organised, as well as a meeting on feed additives to present the new guidance.

Five of the scientific opinions are related to applications for authorisation of feed additives under Regulation (EC) No 1831/2003, of which one on coccidiostats (Cycostat 66G (robenidine hydrochloride) for chickens for fattening and turkeys, EFSA-Q-2007-180), two on micro-organisms (Biosaf Sc 47 (*Saccharomyces cerevisiae*) for dairy buffaloes (EFSA-Q-2008-010) and 035 (*Bacillus subtilis*) for chickens for fattening (EFSA-Q-2008-423)), one for an enzyme (Ronozyme® NP (6-phytase) for chickens for fattening (EFSA-Q-2007-133)) and one on other zootechnical additives (Advastat® (Acarbose 10%) for cattle for fattening and dairy cows for milk production (EFSA-Q-2007-172)). Two opinions are related to a previous negative EFSA opinion (Bioplus 2B (*B. licheniformis* and *B. subtilis*) for turkeys for fattening (EFSA-Q-2008-332) and L-valine for all animal species (EFSA-Q-2008-413)).

Seven technical guidance documents were adopted to help applicants in the preparation and presentation of dossiers for the authorisation of feed additives according to Regulation (EC) No 1831/2003 and its implementing rules (Commission Regulation (EC) No 429/2008): one on the preparation of dossiers per category (sensory additives – colourants, EFSA-Q-2008-403), one on microbial studies (EFSA-Q-2008-461), one on extrapolation of data from

major species to minor species (EFSA-Q-2008-409), one on environmental risk assessment (EFSA-Q-2008-408), one on user safety (EFSA-Q-2008-407), one on consumer safety (EFSA-Q-2008-406) and one on additives already authorised for use in food (EFSA-Q-2008-404).

Work is in progress for the procurement on 'Pre-assessment of Environmental Impact of Zinc and Copper used in animal nutrition' which was signed on 25 August 2008. One Art. 36 on post-market monitoring of feed additives (CFP/EFSA/FEEDAP/2007/01) was completed and another on 'Selected trace and ultratrace elements: Biological role, content in feed and requirements in animal nutrition. Elements for risk assessment' was signed.

The work on the mandate on Ractopamine (EFSA-Q-2008-433) is expected to be completed by April 2009.

Panel on Genetically Modified Organisms (GMO)

The GMO Panel held one plenary session (29-30th October). 19 working group (WG) meetings were held (26 days): Two meetings for genetically modified microorganisms WG, two for molecular characterization WG, three for food/feed WG, three for environmental risk assessment WG, four for antibiotic resistance marker genes mandate WG and one for coordination of the general mandate on update of guidance for environmental risk assessment. For self tasks, one meeting for the non-target organisms WG, two for the allergenicity WG, and one meeting for the statistics of field trial design WG was held.

Three public consultations were closed for the updated draft guidance on GM plants for applicants, for the draft final report for statistical analysis of data for comparative food safety evaluation of GMOs, and for the draft guidance for risk assessment of GM plants for non-food/feed purposes. Comments received are now addressed

In the context of cooperation with Member States for the environmental risk assessment for cultivation dossiers, a second meeting with the UK competent authority took place as well as a first meeting with the Czech competent authority. Member state competent authorities in the regulatory committee for directive 2001/18/EC were informed about progress of the mandate to update environmental risk assessment guidance for applicants. GMO Panel experts met appointed French experts concerning French safeguard clause on MON810 maize. Technical assistance was provided to DG SANCO: two with member states during SCFCAH meetings regarding the updated Guidance document for food and feed and in a meeting with the US department of trade regarding asynchronous authorisation of GMO. EFSA was invited to address meeting of the council ad hoc working group on GMO. EFSA met with stakeholders in a COPA-COGECA working group meeting on GMO and in a JRC-IPTS meeting in Seville regarding asynchronous authorisations in Europe. EFSA met with the scientific community during a COST meeting.

Five GMO opinions were adopted: 2 FEEDAP-GMO co-opinion on the feed additives Ronozyme NP (EFSA-Q-2007-133) and Avizyme 1505 (EFSA-Q-2007-020); 1 opinion on a new GM plant application for maize 59122 x NK603 (EFSA-Q-2005-247); two Article 29 scientific opinions on the request of DG Environment related to previously assessed GM plants: one to review recent scientific studies selected and provided by DG Environment on the cultivation of maize Bt11 and maize 1507 (EFSA-Q-2008679) and one on the safeguard clause invoked by France in relation to maize MON810 (EFSA-Q-2008-077).

EFSA published the scientific colloquium summary report of the colloquium on Environmental Risk Assessment of GMO plants – challenges and approaches.

The procurement call (CFT/EFSA/GMO/2008/01) entitled "defining environmental risk assessment criteria for GM fishes to be placed on the EU market" was re-launched as a negotiated procedure

New mandates to assess scientific information submitted in support of Austria's two safe guard clauses were received from EC, one on MON863 and a second one on oilseed rape Ms8, Rf3, Ms8xRf3.

Panel on dietetic products, nutrition and allergies (NDA)

The NDA Panel held 10 Working group meetings and one Plenary meeting and adopted scientific opinions on 2 Article 14 risk reduction health claims, 17 Article 14 health claims referring to children's health and development and 1 Article 13 (5) claim (claims based on newly developed scientific evidence and/or for which protection of proprietary data is requested). The Panel also adopted a Novel food opinion on Vitamin K2 and one opinion on the safety, bioavailability and suitability of lutein for the particular use by infants and young children.

With respect to an overview of health claim applications, EFSA has received 233 Article 14 applications (i.e. children and risk reduction claims). 70% of these applications have not been validated yet as EFSA is seeking more information from the applicants or clarification from Member States. The NDA Panel has adopted 28 opinions covering 35 applications; 13 applications have been withdrawn; 28 applications are in progress. With respect to Art. 13(5) claims (based on new science and/or proprietary data), EFSA has received 9 applications, 2 applications have been withdrawn, 2 opinions have been adopted, and 5 applications are in progress.

In November 2009 the European Commission sent a revised list of Article 13 claims including 3138 main entries and around 8000 similar health relationships. The revised list of botanicals is still missing and it is expected that 1000 botanical claims will be added. This means that, in total, EFSA is asked to evaluate around 4000 Article 13 health claims. EFSA has pre-screened the health claims received up to now according to 6 defined criteria and will send back to the Commission those claims for which further clarification or information is needed. It is expected that around 50% of the claims received will be sent back. EFSA is targeting to meet the deadline for those claims which were included in the July list, have not been modified in the November list, and passed the pre-screening.

Panel on Plant health (PLH)

The Panel held 1 plenary meeting (22-23 October) and 17 working group meetings (including web-conferences). The experts continue to work on two on-going mandates: (i) evaluation of the pest risk analysis made by South Africa on citrus black spot *Guignardia citricarpa* and (ii) guidance document on evaluation of pest risk assessment documents prepared by third parties for phytosanitary purposes.

In October, the PLH Unit and the Chair of the Panel participated in 1st Special Advisory Forum meeting devoted to plant health. The event aimed at exchanging of information and opinions between EFSA and the Member States for strengthened cooperation in the field of plant health.

With regard to the citrus black spot and due to new findings, a time extension of 2 months has been requested from the Commission to enable completion of the opinion and its adoption in December 2008.

Service Level Agreement on scientific collaboration between EFSA PLH and JRC on "Model framework for the assessment of EU climatic suitability for the establishment of organisms harmful to plants and plant products (CLIMPEST project) has been finalised and prepared for official approval.

A new mandate on evaluation of the pest risk analysis made by UK on processionary moth has been submitted by the Commission/SANCO. After thorough discussion amendment of the terms of reference was proposed to the Commission.

In anticipation of the undertaking of preparation of benchmarking PRAs in 2009, a self-task for development of guidelines for pest risk assessment has been approved by the ED and the work on it initiated.

Panel on plant protection products and their residues (PPR)

The PPR Panel held one plenary meeting on 23-24 September, and adopted the terms of references for a new mandate (self tasking) to provide guidance on probabilistic methodology for modelling dietary exposure to pesticide residues (EFSA-Q-2008-754). It is intended to finalise this guidance by the end of the current mandate (mid 2009). The Panel further adopted the terms of reference for another self task to develop an opinion on approaches to evaluate the toxicological relevance of metabolites and degradates of pesticide active substances in dietary risk assessment (EFSA-Q-2008-756). The Panel also agreed the terms of reference for revision of the Guidance Document on dermal absorption (EFSA-Q-2008-755). A public consultation on the existing guidance documents has been launched on 14 November 2008. The 1st draft of the opinion on pore water concentrations as metrics for the assessment of ecotoxicological effects in soil (EFSA-Q-2008-429) was presented during this plenary meeting.

15 Working groups have taken place between 15 Sept and 30 Nov 2008. With regard to the opinion on risk assessment for a selected group of pesticides from the triazole group (EFSA-Q-2007-183) the final report of the contractor was accepted with some amendments in a Steering Group meeting on 22 Sept 2008 and the Panel discussed the possibilities of the report being published. The opinion on neuro-toxicological effects of deltamethrin (EFSA-Q-2008-373) is progressing and will be adopted in Dec 2008. The final report elaborated by the contractor (Art. 36) on the Guidance Document for pesticide exposure assessment for workers, operators, bystanders and residents (EFSA-Q-2008-261) has been submitted at the beginning of October and the Steering Group accepted it

during their meeting on 17 Oct 2008. The development of a new Guidance Document on emissions from protected crop systems (EFSA-Q-2008-260) is ongoing and a draft project plan is currently on the web for public consultation.

A procurement for data collection has been launched in September. The revision of the Guidance Document on persistence in soil (EFSA-Q-2007-184) is ongoing and will benefit from the collaboration agreement signed by EFSA and JRC on 10th November. For specific tasks for support from JRC to EFSA, individual agreements will be set up under this collaboration agreement. Public consultations have been launched on the Guidance Documents “Aquatic Ecotoxicology” and “Terrestrial Ecotoxicology” on 20 October 2008.

SCIENTIFIC COOPERATION AND ASSISTANCE

Scientific Cooperation (SCO)

Focal Points have reported on their activities during their first year. They focused on building national networks, exchanging scientific information and supporting scientific cooperation in Europe. Based on their input, a summary Report was prepared and presented to the Advisory Forum. At its November meeting in Copenhagen, the Advisory Forum appreciated the support of the Focal Points and decided to renew the Focal Point Agreements.

The Advisory Forum was also informed about the work of the Article 36 network and the update of the Article 36 List (i.e. new organisations designated by Member States to support EFSA in its tasks). A total of 137 new designation proposals were received on top of the 243 organisations currently on the List. The Work Programme for 2009 on grants and procurements has been prepared. These items are on the agenda of the next Management Board meeting.

The Information Exchange Platform, a tool to exchange scientific information with and between Member States and EFSA, was further developed. Over 200 documents were already uploaded, since the Platform was launched in September.

By end November over 1000 experts have submitted application forms to the Expert Database. Currently the application forms are being validated; to date more than 400 experts are included in the database. Since end November the search tool for experts has been available to EFSA and Member States (via the Advisory Forum).

To attract scientific experts to join EFSA's Scientific Committee and Panels as well as the working groups, seminars were organised in Budapest (30 October) and Warsaw (27 November). More than 50 scientists from the new Member States attended each seminar; the programme included presentations by EFSA scientific staff and current Panel Members as well as round table discussions.

The strategy on raising EFSA's scientific visibility was brought forward, focussing on the development of the EFSA Journal to an online scientific journal which meets the requirements of bibliographic databases for indexation. A meeting with CABI, a specialised bibliographic database, is scheduled for early December in London.

Two Special Issues, to which the Unit on Scientific Cooperation (SCO) significantly contributed, were issued: one on Bluetongue published in *Preventive Veterinary Medicine Vol 87, 2008* and another one on EFSA's Scientific Forum: *From Safe Food to Healthy Diets* published in *Trends in Food Science & Technology* Volume 19, Supplement 1, Nov 2008.

The SCO Unit assisted the ESCO Working Groups on “Risks and benefits of food fortification with folic acid” and on “Fostering harmonised risk assessment approaches in Member States”. The Unit significantly contributed to the final Report of the latter, based on input received from Member States via the Focal Point network. The Report was discussed at the Advisory Forum and at the Scientific Committee Meeting in December.

The Interim Review of the Strategy for Cooperation and Networking was prepared. Input from Member States, gathered as replies to the questionnaire sent out in September, was analysed and used as a basis for the Report. After discussions at the Advisory Forum, the Interim Review is now tabled for the December meeting of the Management Board.

Assessment Methodology Unit (AMU)

The Assessment Methodology Unit provided scientific, statistical and modelling assistance and participated in working groups of the Zoonoses unit (baseline studies), the DATEX unit (beta caseine), the BIOHAZ panel (QMRA,

fate of *Salmonella* spp. on broiler carcasses before and after cutting and/or deboning, *Salmonella* criteria poultry production chain, technical guide on poultry decontamination) and the CONTAM panel (cadmium systematic literature review and meta-analysis for cadmium dose-response models). AMU started a self mandate and created a multidisciplinary working group to write a guidance document on the use of systematic literature review in risk assessment.

To follow on from the survey on colony collapse disorder (CCD) in bees an Art 36 grant has been awarded for an EU-wide review of literature on the topic and description of active surveillance programmes to facilitate an objective assessment of all possible causes of CCD. The key objectives are to critically analyse existing surveillance programmes (to be able to assess the value of information coming out of these programmes), to assess their effectiveness in measuring colony losses at a European scale and to identify risk factors for colony loss in order to further orient research activities. The 9-month project will start in January 2009.

To establish an inventory of quantitative models describing the spread, establishment or development of plant pest on crops in Europe including climatic data and / or plant phenology as input factors, another Art 36 grant has been awarded under the title "Systematic review of pest risk models using climatic data and plant phenology". This project will also start in January 2009.

The AMU unit is also responsible for the collection, reporting and coordination of the progress indicators and the monthly scientific activities of the SCA and RA directorates.

Data Collection and Exposure Unit (DATEX)

After completing and publishing the Concise European Food Consumption database on the EFSA website, the DATEX Unit continued their work to refine food consumption estimates to improve the accuracy of exposure assessments. With the assistance of the Permanent Representations in Brussels, collaborating partners with access to detailed food consumption information at individual consumer level were identified in most Member States. During the last quarter the DATEX Unit has been very busy signing contracts for Member States to share this information with EFSA. The target of signing contracts with up to 17 Member States during 2008 seems to be achieved or maybe even surpassed indicating an excellent collaborating spirit in the European Union towards EFSA.

The European Commission needed urgent assistance in assessing the potential impact of melamine in imported food products from China. The DATEX Unit managed to collect commercial information on milk powder content in implicated products and to calculate a worst case exposure scenario well within the given time frame. The information was integrated into an EFSA statement issued jointly by the CONTAM support Unit and DATEX.

In its opinion of 22 June 2005 on exposure assessment the Scientific Committee focused on data availability and harmonisation and identified a lack of established guidance regarding methods for dealing with uncertainty in exposure assessment and probabilistic approaches. The Scientific Committee recommended the EFSA to consider further work in these areas. One such area of concern is the handling of chemical contaminant data reported to be below the limit of detection (LOD). Laboratory data on low-level chemical contaminants are typically left-censored; that is, there is a lower limit of contamination below which values cannot be accurately determined. EFSA's activity in data collection is often confronted with situations where complex datasets with sizeable amounts of censored data need to be handled. This presents difficulty in statistical analysis of the data.

In an initiative by the DATEX Unit a Working group was formed to estimate the accuracy of the currently used substitution methods for censored data in relation to the use of more advanced alternative statistical approaches to calculate means and percentiles for the concentration of chemical contaminants in food, as well as to apply regression models to such data.

Pesticide Risk Assessment Peer Review (PRAPeR)

The PRAPeR Unit held five PRAPeR experts' meetings and three PRAPeR experts' teleconferences with Member States' experts, four bilateral teleconferences with the European Commission and one teleconference with Member States and the European Commission. In addition, PRAPeR had meetings with representatives from ECHA and ECPA, and was represented at two Working group (Legislation) meetings, one Working Group (Residues) meeting, one meeting of the OECD Working Group on Pesticides, one ECPA conference, and four working group meetings organised by the Commission on residue issues. EFSA hosted one TAIEX meeting where EFSA discussed with

experts of the Russian Federation the scientific background of maximum residues levels setting in Europe in order to increase acceptance of the European maximum residues levels food standards in Russia.

Following a specific recommendation from the report of the Working Group on the efficiency of the pesticide peer review process, PRAPeR established the Pesticides Steering Committee. The Steering Committee comprises representatives from each Member State and the European Commission, and will play a key role in the future planning of the pesticide peer review process. The first meeting is scheduled to be held in Parma on 11/12 December 2008.

Regarding the implementation of Regulation (EC) No 396/2005 on maximum residue levels EFSA has organised an expert meeting where the possibility to change the reporting format for monitoring data was explored.

Thirty two EFSA conclusions were finalised and delivered to the Commission. One new resubmission application was submitted to EFSA under the accelerated procedure in accordance with Commission Regulation (EC) No 33/2008.

11 reasoned opinions regarding the potential consumer health risk associated with 15 active substances of concern were finalised in which EFSA recommended lowering a number of MRLs. Two reasoned opinions regarding applications for maximum residues levels setting have been finalised.

One new resubmission application was submitted to EFSA under the accelerated procedure in accordance with Commission Regulation (EC) No 33/2008. The EU-Commission requested EFSA to conduct a peer review for a second resubmission application. Approximately 50 such resubmission applications are expected to be submitted to EFSA during 2008 – 2010.

In accordance with Articles 12a and 25a of Commission Regulation (EC) No 1095/2007, in the period up to 31 December 2010, EFSA has to deliver a view on the 69 'green track' substances from the 3rd and 4th stages of the review programme that were considered to meet the 'not harmful' criteria. In 2009 EFSA may be asked to carry out a peer review for the 7 active substances included in the Annex I Renewal Programme, in accordance with Commission Regulation (EC) No 737/2007.

24 applications regarding the setting, amending, or deletion of MRLs have been submitted to EFSA.

A self-mandate regarding the review of MRLs for 39 active substances for which the decision on inclusion or non-inclusion has entered into force after 2 September 2008 (Article 12(1) of Regulation 396/2005) and about 100 active substances for which the decision on inclusion or non-inclusion in Annex I of Directive 91/414/EEC will be taken within the next months was launched. The reasoned opinions on these compounds have to be provided within one year of the entry into force of the decision on inclusion or non-inclusion.

The self-mandate regarding the preparation of the Annual Report on Pesticide Residues as required in Article 32 of Regulation (EC) No. 396/2005 was accepted.

Emerging Risks Unit (EMRISK)

The unit provided scientific and administrative support to the ESCO Working Group on Emerging Risks. Four working group meetings were organized, which took place both in Parma as well as other locations in Europe.

Several meetings with potential network partners and stakeholders within Europe and beyond (incl. EC, MS, FAO, WHO, ECDC, EEA, SAFEFOODERA etc.) were held. Presentations at conferences, workshops and meetings of experts and decision makers were given. During the period of the melamine scare the Emerging Risks unit supported communication between EFSA, the Commission and Public Health experts in Europe (Health Security Committee and ECDC).

An interim report for the ESCO Working Group on Emerging Risks to the steering committee and a draft final report for the EFSA Executive Director were produced. The EFSA "Crisis Management Plan" was revised, finalized and issued. A strategy paper for the medium term planning of the Emerging Risks unit, describing its mission, mandate and activities, was completed.

Two calls for tender (1st - "Delivery of a database on bioactive constituents of food plants" and 2nd - "Development of a SAS Macro to import, analyze and visualize data from the DG-SANCO Rapid Alert System for Food and Feed Safety as a tool for "early warning" under the Multiple Framework Contract for "Assistance to the Assessment Methodology Unit for statistical analysis and ad hoc consultation upon request") were launched and evaluated.

The unit is preparing to establish together with DG SANCO a network of experts working on emerging risks. Relevant working groups with specific objectives and time frame will support this work. The network shall follow-up the activities of the ESCO working group.

Animal Diseases Transmissible to Humans Unit (ZOOLOSES)

The Zoonoses unit held one meeting of its Network of national representatives, the Task Force on Zoonoses Data Collection, on 16 October. The main issues addressed at the meeting included the preparation of the draft Community Summary Report 2007 that is done in collaboration with ECDC and the analyses of the Community-wide baseline surveys on zoonotic agents. In addition an agreement was made on the amendments to be incorporated in the web-based reporting system and on starting activities related to data collection on vector-borne zoonoses. In October the draft Community Summary Report 2007 was sent for consultation to the Member States.

The unit organised six working group meetings between mid September and end November: Two of the meetings concerned the preparation of a baseline survey protocol for *Listeria monocytogenes* in ready-to-eat foods, two on harmonisation of the monitoring of VTEC and *Yersinia* and two meetings were about the development of the analyses of trends in zoonotic agents and the statistical methods applied to this end. A coordination meeting between EFSA, ECDC and EFSA's Zoonoses Collaboration Centre was organised in October to discuss the analyses of the food-borne outbreak data from 2007.

In October, the unit published a Report on the Analysis of the baseline survey on *Salmonella* in turkeys in the EU, Part B. The report revealed a number of risk factors related to occurrence of *Salmonella* in turkey flocks.

The Zoonoses unit published five calls for contracts related to analysis of the EU-wide baseline surveys. One of these calls was on statistical analyses of the data received, and the others concerned the analyses of the *Salmonella* and MRSA serotypes, validation of the sampling scheme used and assistance in analyses of the *Campylobacter* data.

The unit is preparing itself for the analyses of the three baseline surveys that will take place in 2009 and 2010, and new working groups are being set up to support the analyses. Also the in-depth analyses of the *Salmonella* serovars and antimicrobial resistance data will be started with the contractors in the near future and the analyses of the food-borne outbreaks data is on-going.

SCIENTIFIC COMMITTEE & ADVISORY FORUM

Scientific Committee (SC)

The Scientific Committee endorsed during the 32nd plenary meeting held on 25-26 November the draft opinion on Nanotechnology for public consultation. The Scientific Committee (SC) also commented on the EFSA Strategic Plan 2009-2013 and adopted a new mandate to explore the applicability of the Threshold of Toxicological Concern (TTC) concept to all areas of chemical risk assessment addressed by EFSA.

The progress of the Working Group on Risk-Benefit Assessment and of the ESCO Working Group on Botanicals were presented respectively during the Stakeholder Platform meeting held on 20-21 October 2008 in Brussels, and the meeting of the Steering Group on Cooperation held in Berlin on 23-24 October.

On 4-5 November, EFSA hosted the fourth meeting of the Chairs and Secretariats of the Scientific Committees and Panels of the Commission and EU Agencies involved in risk assessment. The participants discussed challenges in risk assessment, best risk assessment practices, special topics on data collection and emerging risks and newly emerging developments in risk assessment.

Advisory Forum (AF)

At the 28th Advisory Forum (AF) plenary meeting in Paris on 18-19 September 2008, the AF discussed EFSA's draft strategic plan for 2009-2013, EFSA's draft opinion on general principles for establishing dietary reference values, the draft EFSA programme for grants and procurement in 2009, health claims and the pesticide peer review. The AF meeting also included a joint session with DG Research to discuss research priorities within EFSA's remit.

At the 29th AF plenary meeting in Copenhagen on 20-21 November 2008, the AF discussed nanotechnology, transparency and quality assurance of risk assessments, the status of the AF IT Working Group, the progress of the ESCO projects, and the review of the implementation of the strategy on cooperation and networking.

The first meeting of the AF representatives on plant health was held in Parma on 8-9 October 2008 with a focus on the cooperation between the EU Member States and EFSA in this area.

COMMUNICATIONS DIRECTORATE

Communications activities:

Since the last Management Board meeting, the Communications Directorate has carried out a number of communications activities aimed at raising EFSA's visibility in Europe:

- On 23 September a Europass conference on "Sicurezza nell'alimentazione animale: tra normative e prospettive future" was organised in Parma in cooperation with the Europass office and the Province of Parma. A joint press release was distributed to local media.
- On 3 October EFSA co-organised the EFSA-AFSSA joint event in Paris entitled "Health risk assessment in the context of food, animal and plant imports in the European Union". The meeting discussed proposals for strengthening and adapting the current food safety system, particularly the health risks associated with imports. 170 participants from across the EU attended. On this occasion, the press office organised a one-to-one background briefing between EFSA's Executive Director and Olivier Andrault from Que Choisir (French specialised consumer publication). The discussion focused on EFSA's work in the field of nutrition and health claims as well as EFSA's current scientific work.
- A call to renew Scientific Committee and Panel members was launched on 23 October and a communication campaign was implemented throughout Member States including a direct mail campaign to relevant authorities and institutions, leaflets, posters, advertisements in newspapers and leading scientific journals, and online material for partner websites.
- On 6 October the press office organised a media breakfast in Brussels. The Executive Director met three Brussels press correspondents (Expresso, International Herald Tribune and Associated Press). The aim was to explain and dialogue with media in a more informal setting, with respect to EFSA's role and mission and discuss such issues as EFSA's co-operation with the FDA, the melamine crisis, bisphenol A, nanotechnology and GMOs.

- On 7-10 October, EFSA was present at the Prion2008 event in Madrid. This annual conference is an important event where all the latest scientific research findings in the field of transmissible spongiform encephalopathies (TSEs) are presented from around the world. It provided EFSA with the opportunity to network with experts and to learn about the latest research which it needs to consider in its risk assessments. It also gave EFSA the chance to present its own work on TSEs and its role in the European food safety system, through posters and its exhibition stand. About 800 experts from all over the world attended.
- On 14 October EFSA organised a joint event with the WHO and FAO in Rome on the effects of climate change on nutrition and food and water safety. EFSA's first joint press release with these two organisations was distributed to the media and posted on the EFSA, WHO and FAO websites. Professor Silano, Chair of the Scientific Committee, gave media interviews to Italian news agency ANSA and broadcaster Isoradio following the event.
- On 30 October an EFSA workshop was organised in Budapest and the press office arranged interviews with EFSA's Director of Risk Assessment for two key Hungarian newspapers: Népszabadság (the biggest national newspaper) and Napi Gazdaság (the main financial daily). The interviews were a good opportunity to talk about EFSA's role and activities, as well as the Authority's aim to involve more scientists from the new EU Member States in its work through the renewal of the panels and the Scientific Committee.
- Communications facilitated the 4th meeting of Chairs and Secretariats of Commission and Agency Scientific Committees/Panels involved in risk assessment on 4-5 November in Parma.
- On 10 November a new Co-operation Agreement was signed between the European Commission's Joint Research Centre (JRC) and EFSA and announced through a joint press release.
- On 19 November the Finnish Food Safety Authority (EVIRA) organised a health claims seminar that was attended by EFSA's Executive Director and EFSA's Director for Risk Assessment. The Member of the Management Board Sinikka Turunen was also present. The Executive Director gave an interview to the daily newspaper Helsingin Sanomat and YLE FST5 (TV) and the Director for Risk Assessment was interviewed by FinFood (specialised magazine), YLE (radio) and YLE FST5 - Finland's Svenska Television and specialised magazine Kehittyvä Elintarvike (Developing Foodstuffs).
- On 20 November, Danish food safety experts and EFSA came together in a joint event to discuss EFSA's work and role in the European food safety system from a European and a Danish perspective. At the meeting in Copenhagen, the Executive Director outlined EFSA's objectives and strategy. The Director of Scientific Cooperation and Assistance talked about scientific exchange and networks. Participants also heard about the relevance of EFSA for Danish agriculture. EFSA's Member of the Management Board Peter Gaemelke delivered a speech on that occasion.
- The Advisory Forum meeting followed the joint event and on that occasion the press office organised an interview with EFSA's Director for Risk Assessment for the Danish specialised magazine Ingeniøren.
- On 25 November the Europass conference on "La sicurezza nella nutrizione: gli alimenti funzionali e le indicazioni per la salute" took place in Bologna in cooperation with Europass and the Province of Bologna. A joint press release was issued.
- On 25 November EFSA's Director for Communications attended a roundtable in Parma on "Lo tsunami silenzioso, Prezzi dei prodotti agricoli, bioenergie, ambiente e minacce alla sicurezza alimentare" and gave a speech on EFSA organization and work, focusing on future challenges and emerging risks
- On 27 November, following the Warsaw workshop entitled "Join EFSA in Assessing Food Safety Risks in Europe!", the press office arranged interviews with Professor Vittorio Silano, Chair of the Scientific Committee, for PAP (press agency) and Rzeczpospolita (daily). The interviews focused on animal cloning.
- On 27-28 November EFSA's Director for Communications attended the CIAA Congress in Brussels and in a roundtable on "Serving consumers" gave a presentation on "Helping consumers to select healthy diets: the role of the European Food Safety Authority". Approximately 500 participants attended the congress.

Corporate / Science Press material: Press releases / News alerts / Web news stories:

The Press Office issued a number of press releases and web news stories on topics such as melamine, nanotechnology, pesticides, health claims, the renewal of Scientific Committee and Panels, which all received good media coverage across Europe.

Press Releases:

- Italian government acts to reinforce cooperation for EFSA (15/09/08)

- EFSA assesses possible risks related to melamine in composite foods from China (25/09/08)
- EFSA Management Board discusses 2009-2013 Strategic Plan (2/10/2008)
- World Food Day event to discuss health implications of climate change (14/10/2008)
- EFSA consults on draft opinion on nanotechnologies and food and feed safety (17/10/2008)
- EFSA invites scientific experts to join its Scientific Committee and Panels (23/10/2008)
- EFSA evaluates TSE risk from small ruminants' milk (6/11/2008)
- New Co-operation Agreement Signed: Between the European Commission's Joint Research Centre (JRC) and the European Food Safety Authority (EFSA) (10/11/2008)

Web News Stories:

- New EFSA body to coordinate pesticide risk assessment (23/09/08)
- EFSA Stakeholders elect new chair, discuss strategy, plans ahead (22/10/2008)
- EFSA begins work on health claims list (23/10/2008)
- EFSA identifies risk factors for Salmonella infections in turkey flocks in the EU (27/10/2008)
- EFSA sets out goals for contributing further to animal health in Europe (5/11/2008)
- EFSA's scientific advice on aquatic species susceptible to specified diseases (13/11/2008)
- EFSA assesses risks linked to transmission of bluetongue during animal transit (18/11/2008)

In the period Jan-Oct 2008, there was a 36% increase in the number of articles compared to the same period in 2007 (9,905 and 6,335 articles respectively). Coverage in September-October 2008 was 38% higher than in September-October 2007. EFSA's Press Office aims to increase overall media coverage by at least 15% in 2008.

Web developments

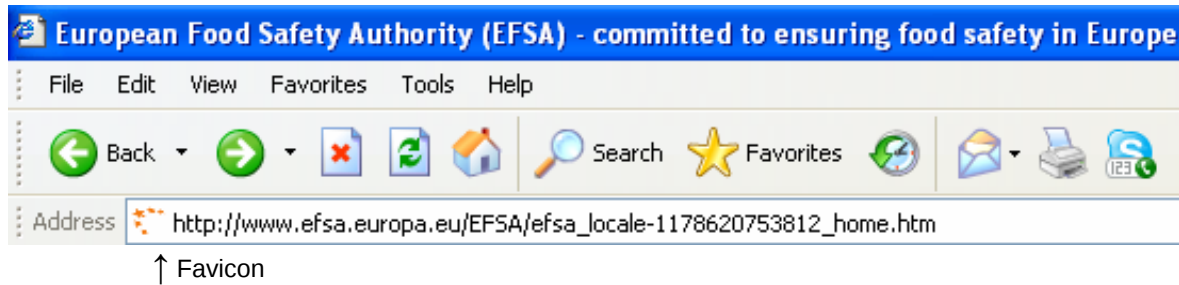
October visits to the website were up by 22.5% compared to the same month last year, and the webcast of the Paris Management Board meeting had 996 views, a 258% increase on the average MB meeting webcast views of 278. Reaching the largest MB webcast audience to date, the steep increase was achieved through a promotion campaign directed to subscribers of the EFSA Highlights e-newsletter.

The most significant improvements on the website during the period have been in the areas of content, outreach, process improvement, usability, and content management system development. Content initiatives included the launch of the call to renew the scientific committee and panels; upgraded Advisory Forum and Focal Point pages - including links to new 17 national Focal Point web areas - and new corporate photos of the Executive Director. In addition, the content of the "Latest website updates" page was fundamentally rebuilt into an effective "What's new" portal.

New 'key topics' sections were produced on issues such as antimicrobial resistance, animal health, animal welfare and fish welfare, while existing sections on issues such as bluetongue and pesticides were updated to reflect the latest developments. More content was developed to enhance clarity and transparency, including integrating the newly adopted Definitions of EFSA's scientific outputs into the site navigation and new sections on working groups and expert groups belonging to the Scientific Cooperation & Assistance Directorate. Various events and initiatives, including the December Scientific Colloquium, joint events including a joint seminar for World Food Day and expert seminars in the new Member States, were promoted via the web and the email newsletter.

An important process related initiative was the successful improvement to the working procedures between EFSA and external IT service suppliers. Along with a more accurate match of resources to requirements, this has resulted in the removal of significant delivery bottlenecks. This has allowed for the implementation of several content management system projects, including more dynamic functions such as the Scientific Documents query on the site homepage, which now feature real-time updates requiring no manual maintenance.

Core initiatives which improved web usability include a new sitewide dates format which better caters to both EU and non-EU users (12 February 2008 instead of 12/02/2008); a more user friendly structure of Press Release and News Story content, and a new homepage page title and meta description for better bookmarking and search engine results usability. Following an in-house design project a favicon was published to the website:



Publications

Since the last MB meeting, various scientific and corporate publications have been produced, supported by EFSA's strengthened team of dedicated French and German language proofreaders. These include:

Scientific:

- The second editions of EFSA's thematic family of electronic newsletters, EFSA in focus, are being prepared and will be translated for the first time into French, German and Italian.
- The report from EFSA's 8th and 10th Scientific Colloquium – '*Environmental Risk Assessment of Genetically Modified Plants - Challenges and Approaches*' and '*Pest risk assessment - Science in support of phytosanitary decision making in the European Community*' - were printed and distributed. Reports from the 9th and 11th Colloquia ('*Nutrient Profiling for foods bearing Nutrition and Health Claims*' and '*Acrylamide carcinogenicity - New evidence in relation to dietary exposure*') are being laid out and should be printed soon.
- Two special issues of leading scientific journals were published covering EFSA's work - *Preventive Veterinary Medicine* and *Trends in Food Science & Technology*.
- A CD-ROM containing all opinions related to BSE/TSE adopted by the BIOHAZ panel was printed for the Prior2008 conference.
- In addition scientific posters were prepared for the events: Prior2008 (October, Spain), GIS conference (November, UK), 4th International Symposium on Food Packaging (November, Prague), Conference of the European College of Veterinary Public Health (December, Greece).

Corporate:

- EFSA news 18 and the third edition of Moving Together were sent for printing in all four official EFSA languages in November.
- The EFSA corporate brochure was translated into Danish for the joint event in Copenhagen on 20 November.

ADMINISTRATION

On 16-17 October 2008 EFSA hosted at its premises the conference of the European Law Academy of Trier on recent development in European food law. The Legal & Policy Affairs Unit (LPA) continued to ensure legal support for all operations of EFSA. Specifically relevant continued to be the implementation of the Health and Nutrition Claims regulation and recent regulations impacting on the pesticides sector. Also the processing of the EFSA Policy on Declarations of Interests constitutes an area of ongoing regulatory advice.

The LPA provided support for the liaisons with the Italian authorities. In particular, legal assistance was provided for the technical meeting on the Scuola per l'Europa of Parma, which took place in Rome on the 30th October representing the first follow up of the roundtable organized in Rome on the 15th September between the Executive Director and the Undersecretary of State, Gianni Letta. A second follow up on the transport links should be organized before Christmas.

As a follow up of the meeting in Rome of the 15th September it was agreed that further contacts (in addition to those already had between EFSA's Executive Director and the Mayor of Milan) with the Municipality of Milan should have been enhanced in view of the EXPO 2015 focused on food safety. The LPA provided support for the liaison with the Municipality of Milan and the EXPO2015 dedicated institution, supporting the organization of a meeting on the 19th November where preliminary contacts on common initiatives were established.

On the 17th of November the Italian Minister for European Policies visited EFSA. Discussion during the meeting with the Executive Director focused mainly on issues related to the settlement of EFSA in Parma (Scuola per l'Europa, transport issues). Minister Ronchi and the Executive Director visited also the Scuola per l'Europa where the Minister had the chance to see the premises as well as having a meeting with the Director of the School. The Minister reconfirmed his support to EFSA.

Cooperation with EU Institutions

European Commission

Within the framework of DG SANCO high level conference "Delivering for Tomorrow's European Consumers", the Executive Director was invited as a panellist to speak in connection with uncertainties around safety issues related to emerging technologies on 29 October.

SANCO also organised an international conference on Global Risk Assessment in November, to which EFSA Director of Risk Assessment participated as a panellist.

The Executive Director and the Director of DG SANCO continued with their regular schedule of bilateral meetings on 11 December 2008. The close cooperation and numerous operational contacts between EFSA and the Interface Unit of DG SANCO continued. In addition to the participation of Commission colleagues to scientific meetings at EFSA, the Advisory Forum and Stakeholder events, the EFSA representatives participated in:

- two meetings of the European Commission's Advisory Group on the Food Chain, Animal Health and Plant Health. Topics respectively concerned the implementation of the EU Animal Health Strategy and animal cloning.
- Meetings of DG SANCO SCoFCAH are regularly attended by EFSA representatives, mainly in the area of Plant Protection, Animal Health and Welfare and Microbiological Hazards.
- 1st EU Veterinary Week 2008 in Brussels on 10th November.

On 10th of November the Joint Research Centre (JRC) and the EFSA signed a Memorandum of Understanding to facilitate technical cooperation.

European Parliament

EFSA representatives followed parliamentary developments on a series of dossiers to EFSA interest while participating in several EP Committee meetings including ENVI, AGRI, BUDG. This activity concerned inter alia the new package of legislative proposals on the use of pesticides, the revision of the novel food Regulation that includes a common authorisation procedure; the proposed future legislation on food information for consumers (labelling rules) and questions in relation to EFSA's 2009 draft preliminary Budget. On the latter an EFSA delegation, led by the Executive Director, met with key MEPs to discuss EFSA dedicated budgetary lines.

A working breakfast on the legal developments with regard to the future new legislation on plant protection products, involving an EFSA delegation and MEPs, was organized at the European Parliament on Tuesday 7th of October. This meeting allowed the representatives of the European Parliament to have a better understanding on the functioning of the EFSA Pesticide Risk Assessment Peer Review and on the need for EFSA to have sufficient time at its disposal for proper experts' consultation in order to deliver quality scientific output in the peer review process.

On 6 November, the Executive Director met with the ENVI Committee for an exchange of views on operational activities of EFSA.

Council of the European Union

Besides the regular contacts held between EFSA and the Presidency, a series of conferences and seminars involving EFSA senior representatives were organised under the leadership of the French Presidency. This mainly concerned health risk assessment in the context of food, animal and plant imports, biotechnologies, sustainable agriculture and pesticides.

At the invitation of the French Presidency, the Executive Director together with senior managers presented EFSA's Draft Strategic Plan 2009-2013 at a joint meeting of EU Chief Veterinary Officers and Chief Officers on Plant Health on November 7th. The Council position on EFSA Strategic Plan has been adopted by the Ministers on 21st of November and will be officially transmit to EFSA's Executive Director shortly.

At the invitation of the French Presidency, EFSA participated at a Conference on Sustainable agriculture and pesticides that took place in Paris on 25-26 November.

In view of the preparation of the upcoming Presidency of the European Union, EFSA's Executive Director met representatives from the Ministry of Agriculture on 5th December in Prague. Mr Jiri Ruprich, member of the Management Board, joined EFSA's Executive Director for this visit.

Relations with Stakeholders

On the 20th-21st October EFSA organized the 9th Stakeholders Platform meeting in Brussels. During that meeting the new Chair of the Platform Dr Andreas Varlamos, from EKPIZO, the Greek Consumers Organisation and member of BEUC, was elected. The new Chair of the Platform has been invited to attend the next Management Board meeting in Parma, on the 18th December. It was agreed that in 2009 three meetings of the Platform will be organized, the first one been at the end of February.

On 21st of October the series of technical meetings on important issues of interest to stakeholders was continued and a technical meeting on the draft opinion on nanotechnologies was held in Brussels.

International Relations

On 14 October a joint seminar on the health effects of climate change on food and water safety and nutrition was organised by the WHO, the FAO and EFSA, with the support of the Italian Ministry of Labour, Health and Social Affairs and the participation of DG SANCO. This was the first event where the WHO Regional Office for Europe, FAO and EFSA joint forces in setting up a seminar to address an issue of common concern. In view of the good cooperation and beneficial exchanges established in the context of this event it was agreed to continue in future with further cooperation along such lines.

On November 13, EFSA received the visit of a group from the European Institute of Public Administration, in the framework of the EuroMed Public Administrations Programme

Pre-Accession Programme for Turkey, Croatia and Former Yugoslav Republic of Macedonia

EFSA meetings: In the reporting period experts from the three Candidate countries took part in the following EFSA meetings: 1) Advisory Forum plenary meeting, 18-19 September, Paris 2) Task Force on Zoonoses Data Collection, 16 October, Brussels 3) Advisory Forum Communication WG, 23 October, London 4) 3rd meeting of the EFSA Expert Group on Food Consumption Data, 30 October, Parma 5) Advisory Forum plenary meeting, 20-21 November, Copenhagen 6) Scientific Colloquium on Assessing Health benefits of Controlling *Campylobacter* in the Food Chain, 4-5 December, Rome

Training seminars: In the reporting period 2 seminars were organised: 1) Seminar on *GMO risk assessment* on 25/26 September 2008 in Ohrid, the Former Yugoslav Republic of Macedonia, 25 experts from the Former Yugoslav Republic of Macedonia took part in the training with speeches from EFSA, 2 Member States and the Former Yugoslav Republic of Macedonia 2) Seminar on *Microbial risk assessment* on 26/27 November in Zagreb with the participation of the management Board Member Milan Pogačnik, Croatia. 40 experts from Croatia, Turkey and the

Former Yugoslav Republic of Macedonia took part in the training with speeches from EFSA, 3 Member States and the 3 Candidate countries.

In addition EFSA organised the 3rd European agencies meeting on network building with focus on the Pre-Accession Programmes and Neighbourhood Policy. Nine EU agencies and two representatives for the European Commission came to Parma to exchange information and best practices on the Pre-accession Programmes and Neighbourhood Policy.

Human Resources

Activity	Titles	Initial Appropriations	Current Appropriations	%	Commitments 2008 M€	%
Activity 1	PERSONNEL	16.2	15,1	23%	13,3	88%
	INFRASTRUCTURE	3.4	4,6	7%	3,7	80%
	OPERATIONS	13.1	12,8	19%	11,3	88%
A1 Scientific opinions & advices		32,7	32,6	49%	28,3	87%
Activity 2	PERSONNEL	5.7	5,3	8%	4,6	87%
	INFRASTRUCTURE	1.6	2,3	3%	1,8	77%
	OPERATIONS	6.2	6,9	10%	6,0	88%
A2 Methodologies & scientific cooperation		13.5	14,5	22%	12,4	86%
Activity 3	PERSONNEL	3.9	2,7	4%	2,3	85%
	INFRASTRUCTURE	1.4	1,7	3%	1,3	76%
	OPERATIONS	4.2	3,9	6%	3,0	77%
A3 Risk communication & relationships		9.5	8,3	12%	6,6	79%
Activity 4	PERSONNEL	8.3	7,8	12%	7,0	89%
	INFRASTRUCTURE	2.4	3,2	5%	2,5	78%
	OPERATIONS	0,0	0,0	0%	0,0	0%
A4 Administration		10.7	11,0	17%	9,5	86%
GRAND TOTAL		66,4	66,4	100%	56,8	86%

HR – Numbers of recruitment		
	Staff foreseen 2008 (establishment plan)	Total
AD	185	
AST	150	
Total	335	
HR – Numbers of recruitment procedure		

	Total staff number end Dec 06	Total number
AT+Officials	173	
AUX ¹	24	
CA	24	
END	7	
Total	228	
(P) = EFSA's staff recruited to TA posts (including AUX, CA) (R) = Resignations, termination of contract after probation (***) = EFSA's staff leaving their TA post in order to be recruited elsewhere ¹ Auxiliary Contract types ended at 31/12/2006		

Budget execution

As of 01 December 2008,

- EUR 56.8 million or **86 %** of the EUR 66.4 million budget including the Pre-accession program was committed. The commitment level stands EUR 1.5 million (2,5%) below the forecast made at the beginning of the year. This is mainly due to delays in recruitment (as most of the new recruits arrived in the third and last quarter of the year) and to delays in concluding significant grants and contracts for the scientific support.
- EUR 43.1 million or **65 %** of the total appropriations were paid. This payment level stands as the commitments, below the forecast made at the beginning of the year as major subcontracting scientific or IT projects have started during the last quarter of 2008.
- The following table and chart represent the budget execution along with the four activities identified by EFSA (Activity Based Budgeting)

