

Management Board  
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Subject :	Executive Director's Progress Report			
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Office of the Executive Director and the Management Board

ED Progress Report  
01.06.2009 – 30.09.2009  
HIGHLIGHTS

**Risk Assessment**

The **ANS** Panel held 3 Working Group and 3 Plenary meetings and a total of 32 opinions was adopted. The **AHAW** Panel held 3 Plenary and various Working Group meetings and adopted 6 opinions and one statement. **BIOHAZ** held 3 Plenary and various Working Group meetings, 4 opinions were adopted and 2 reports published. The **CEF** Panel held 3 Plenary and 8 Working Group meetings during which twenty opinions and guidelines were adopted. **CONTAM** held 2 Plenary and 12 Working Group meetings - 3 opinions and one statement were adopted. **FEEDAP** held 3 Plenary and 17 Working Group meetings and 2 technical hearings. The Panel adopted 9 opinions. The **GMO** Panel held 2 Plenary and 26 Working Group Meetings, a total of 8 authorizations were adopted. The Panel provided technical assistance to DG Sanco during 2 SCFCAH meetings with Member States regarding 2 of the Panel's adopted opinions and the updated Food and Feed guidance. **NDA** held 2 Plenary and 10 Working Group Meetings as well as one technical meeting. A total of 101 opinions were adopted. The **PLH** Panel held 2 Plenary and 5 Working Group Meetings in the reference period. The **PPR** Panel held 3 Plenary Meetings and 24 Working Group Meetings during which 7 opinions were adopted and one report was published.

**Scientific Cooperation and Assistance**

**SCO** report that Focal Point Agreements were signed with all 27 Member States, various Focal Point meetings were organized and candidate country representatives were invited. The new web area for the EFSA Journal is being developed by IT and a prototype is expected in the autumn. **AMU** delivered 2 reports and contributed to an opinion of the GMO panel. **DATEX** completed the full exposure assessments for lead and arsenic, the results are now with the CONTAM Panel. **PRAPeR** organized 22 teleconferences with the European Commission (EC) and Member States and one meeting with experts from Member States. 26 reasoned opinions were adopted in this period. **EMRISK** established a network on Emerging Risk Identification and held meetings with the Discussion Group on Emerging Risks as well as other meetings with representatives from EU Agencies, the EC, FSA and FAO. One internal report was completed. **ZOONOS** held 8 Working Group Meetings and completed one scientific report during this period. The Annual Zoonoses Report of 2008 was received from Member States and is being analysed by EFSA and ECDC.

**Scientific Committee & Advisory Forum**

The Scientific Committee held one Plenary Meeting and adopted one guidance document. The Advisory Forum held 2 meetings during which ways forward for cooperation between EFSA and Member States were discussed.

**Communications**

Communications organized various joint events and interviews with the Executive Director and press in Member States highlighting EFSA's role in food safety. Many press releases and web stories were published and over 200 media requests answered. Various scientific and corporate publications are now available in different languages.

**Administration**

International visits were received and meetings, for example with the Swedish Presidency, attended. One Pre-accession seminar was organized and experts from Turkey, Croatia and the Former Yugoslav Republic of Macedonia participated in various EFSA meetings.

## RISK ASSESSMENT

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

The Panel held 3 Working Group meetings and 3 Plenaries. Two meetings were held with the European Commission and scientific support was provided for EFSA's Communications Directorate and Legal and Policy Affairs Unit on more than twenty occasions.

The Panel adopted 32 opinions (of which 23 are statements) corresponding to 82 applications during its Plenary. In addition it adopted 9 opinions referring to 23 dossiers: Calcium phosphinate, Humic acid/fulvic acid chelate; Caprylates; Potassium molybdate; Calcium silicate and silicon dioxide/silicic acid gel; Manganese ascorbate, manganese aspartate, manganese bisglycinate and manganese pidolate as sources; Picolinate; Chromium(III) lactate trihydrate; Chromium nitrate and 23 statements referring to 59 dossiers: Data requirements for the evaluation of food additive applications; Orotic acid salts; Vitamin D-enriched yeast; Riboflavin-enriched yeast; Biotin-enriched yeast; Vitamin C-enriched yeast; Magnesium-enriched yeast; Iron-enriched yeast; Zinc-enriched yeast; Copper-enriched yeast; Manganese-enriched yeast; Vitamin B12-enriched yeast; Pantothenic acid-enriched; Niacin-enriched yeast; Vitamin E-enriched yeast; Vitamin K-enriched yeast; Thiamine-enriched yeast; Vitamin B6-enriched yeast; Calcium-enriched yeast; Magnesium taurinate; Sodium hyaluronate; Tocopherol and tocotrienol; Manganese ethanolamine phosphate.

The calls for tender '*Preparation of pre-evaluation documents, including toxicological and non-toxicological data, to support the re-evaluation of food additives permitted in the European Union and belonging to the functional classes of preservatives, antioxidants and emulsifiers-stabilisers-gelling agents*' (service contract) and '*Data collection on metabolites, degradation products and other related compounds of food additives selected by EFSA from those currently permitted in the European Union*' (framework contract) were launched in August and September and are expected to be signed in November and December.

The Panel is now mainly dealing with food additives. The focus will be on the re-evaluation of food colours, the evaluation of new applications for food additives and the preparation of a new guidance document on food additives.

### Panel on animal health and welfare (AHAW)

The AHAW Panel held 3 Plenary meetings in this period. Working Group meetings have been held on the following mandates: i) epizootic hemorrhagic disease, ii) welfare impact of genetic selection of commercial broilers, iii) management and housing of grand-parent and parent stocks raised and kept for breeding purposes, iv) guidelines on scientific assessments on animal health using modeling, v) brucellosis in pigs, vi) African Swine Fever, and vii) ticks. A stakeholder meeting on Broilers took place in Brussels on September 23.

Representatives of the AHAW Unit attended the following meetings: SCOFCAH meetings on animal diseases; Eadgene and Sabre Industry Days in Rome; Annual meeting on CRL AI/ND in Pulawy, Poland; Brainstorming meeting on Influenza A in Brussels; visit FDA/US delegation in Washington; Cost 867 Annual Meeting in Isafjordur, Iceland; AH Advisory Committee Brussels; Pre-accession Seminar in Skopje; Induction week in Brussels; Working Group Aquatic Animal Health in Brussels; Working Group on Novel Influenza A in Brussels; XIV ISAH Congress in Vechta, Germany; ISVEE in Durban, South Africa; EEAP in Barcelona; One Health Conference in Brussels

Six opinions were adopted in this period. On dairy cow welfare 5 specific risk assessments were adopted, i) leg and locomotion problems, ii) udder problems, iii) metabolic and reproductive problems, iv) behaviour, fear and pain of dairy cows; v) a scientific opinion on the overall dairy cow welfare assessment. One opinion was adopted on brucella suis.

Additionally, in order to support the activities of DG RTD, DG MARE and DG SANCO in setting priorities for research, a statement on "fish welfare research needs" was adopted.

A call concerning the *Animal Welfare: Housing and Management Risk Assessment Guidelines* was published in June and proposals are being evaluated. A call on data collection and evaluation for the mandate on the impact of genetic selection on welfare of broiler chickens was also published in June and a grant will be signed shortly.

The self mandate on *Development of Animal Welfare Guidelines* will be delivered in 3 documents i) stunning and killing guidelines, July 2010; ii) Transport guideline, September 2010 and iii) housing and management, April 2011.

A new mandate is expected from the European Commission concerning broiler diseases linked with genetic selection. Topics for self-mandates are being considered as a follow-up to completed grant reports and potential self mandates on *Tuberculosis in Wildlife* and *African Horse Sickness* are being considered.

#### Panel on biological hazards (BIOHAZ)

The BIOHAZ Panel held 3 Plenary meetings; Working Group meetings were held on the Australian monitoring programme for carcasses, *Salmonella* in pigs, antimicrobial resistance, Qualified Presumption of Safety, *Campylobacter* source attribution, *Campylobacter* in broiler meat, bovine intestines, irradiation, protocol for resistance to scrapie in goats in Cyprus, fish parasites, *Salmonella* in broilers, *Salmonella* in laying hens, TSE transmission via semen and embryo, carcass decontamination, animal by-products in biogas, evaluation of rapid TSE tests, analytical TSE tests, and *Salmonella* criteria.

The Network on Microbiological Risk Assessment met in June.

The BIOHAZ Panel adopted 4 opinions during the reporting period: a) BSE risk in bovine intestines; b) Food safety considerations concerning the species-specific welfare aspects of the main systems of stunning and killing of farmed fish; c) Food safety aspects of dairy cow housing and husbandry systems; and d) Statement on a protocol for additional data collection based on the EFSA recommendations on resistance to scrapie in goats in Cyprus.

Furthermore, the following 2 outputs were published: *Joint scientific report of ECDC [European Centre for Disease Prevention and Control], EFSA and EMEA [European Medicines Agency] on meticillin resistant Staphylococcus aureus (MRSA) in livestock, companion animals and food* and *Consolidated presentation of the joint Scientific Opinion of the GMO and BIOHAZ Panels on the "Use of Antibiotic Resistance Genes as Marker Genes in Genetically Modified Plants"* and the *Scientific Opinion of the GMO Panel on "Consequences of the Opinion on the Use of Antibiotic Resistance Genes as Marker Genes in Genetically Modified Plants on Previous EFSA Assessments of Individual GM Plants"*.

The Call for Article 36 proposals on "Data harvesting on *Campylobacter* in broiler meat" was published in July and the deadline for submission of proposals was 15 September 2009. The tenders received following the procurement call on "Quantitative Microbiological Risk Assessment of *Campylobacter* in the broiler meat chain were evaluated and a contract has been awarded.

Three new mandates were received on: the risk profile of foodborne viruses (EFSA); risk based control of biogenic amines in fermented foods (EFSA); and possible epidemiological or molecular association between TSEs in animals and humans (EC), in collaboration with ECDC.

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

The CEF Panel held 3 Plenary meetings. In addition, 8 Working Group meetings were held: 2 on food contact materials, 2 on recycling of plastics, 2 on Flavourings, and one each on smoke flavourings and irradiation).

The CEF Panel adopted 20 opinions: 6 on flavouring substances with structural alerts for genotoxicity and 14 on food contact materials.

Ten more opinions were planned for the September Plenary, 6 on flavourings, 2 on food contact materials and 2 on smoke flavourings. A statement on the interpretation of the margin of safety (MoS) for smoke flavourings has also been planned for the September meeting.

Guidelines on submission of a dossier for safety evaluation by the EFSA of active or intelligent food packaging were adopted and published in August. Guidelines on evaluation of enzymes were adopted and published in August.

The evaluation of received offers for summarising toxicity studies of dossiers for food contact materials was finalised and the contract is expected to be signed by the end of September.

A draft opinion on data needed for risk assessment of flavourings was endorsed in July. A 2-step public consultation is planned: presentation of the draft opinion on the EFSA website in October and a workshop in January 2010, resulting in adoption of the final opinion in July 2010.

A new ad hoc Working Group on recycling of plastics was created. Around 40 applications are expected until the end of 2009/beginning of 2010. A new Working Group on irradiation of food was also created.

#### Panel on contaminants in the food chain (CONTAM)

The CONTAM Panel held 2 Plenary meetings and 12 Working Group and audio conference meetings related to requests on marine biotoxins (2 meetings), lead in food (2 meetings), arsenic in food (4 meetings), evaluation of previous cargoes (2 phone conferences), melamine in food and feed (one meeting) and ambrosia in feed (one meeting).

During the 33rd and 34th CONTAM Plenary meeting and by written procedure, 3 opinions (2 marine biotoxins - pectenotoxins and domoic acid and one summary opinion on 6 regulated marine biotoxins) and one statement (effects on public health of an increase of the levels for aflatoxin total from 4 µg/kg to 10 µg/kg for tree nuts other than almonds, hazelnuts and pistachios) were adopted.

One Art. 36 call related to a toxicological study on 3-MCPD esters was published with a deadline for submission of proposal for 15 September 2009. A negotiated procedure related to editorial revision of scientific outputs was successfully carried out.

A request for a scientific opinion on brominated flame retardants was received.

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

In the reference period the FEEDAP Panel held 3 Plenary meetings and 17 Working Group meetings on micro-organisms, enzymes, coccidiostats, amino acids, trace elements, technological additives, colouring agents and flavourings. Two technical hearings were held in order to provide support to the applicants for the preparation of dossiers for the evaluation of feed additives.

The Panel adopted 9 scientific opinions for the authorisation of a feed additive.

The grant on mycotoxin detoxifying agents was signed on 8 June

#### Panel on Genetically Modified Organisms (GMO)

The GMO Panel held 2 Plenary and 26 Working Group Meetings on the following issues: food/feed safety, environmental risk assessment, molecular characterisations and GM microorganisms. For self tasks and generic mandates, meetings were held for non-target organisms, for updating the environmental guidance and for statistics related to updating the environmental guidance. Furthermore meetings on the development of guidance for GM animals, for comparators for risk assessment, for the update of GM microorganisms guidance and for assessment of allergenicity of GMOs were held.

Technical assistance was provided to DG SANCO during 2 SCFCAH meetings with Member States regarding 2 of the panels' adopted opinions and the updated Food and Feed guidance. EFSA organised a one day technical meeting for GM microorganisms applicants to discuss general issues as well as aspects regarding individual application dossiers. GMO Panel members met experts from Member States, environmental NGOs and applicants one day respectively for consultation regarding the work to update of the environmental risk assessment guidance. EFSA arranged a

European Conference “EFSA and GMO risk assessment for Human and Animal Health and the Environment” 14-15 September to present current risk assessment principles and exchange views with stakeholders and Member States.

Eight opinions for authorisation for food and feed use under Reg. (EC) No 1829/2003 were adopted: 3 renewals of Maize MON810 (3 different scopes in separate applications including cultivation); Maize MON88017 x MON810 ; Maize MIR604; Maize MON89034 x NK603; Maize Bt11xGA21 and renewal for oilseed rape MS8/Rf3. One opinion under regulation (EC) No 1831/2003 on feed additive Ronozyme ProAct was adopted. Four opinions on generic mandates were adopted: one clarification regarding the feed additive Danisco Xylanase G/L and 3 opinions on Safeguard Clauses from Austria.

In July a call for risk assessment criteria related to GM birds and mammals was published.

One application for authorisation of food and feed use under Reg. (EC) No 1829/2003 was received, soybean MON87701 x MON89788. Two applications were received under the same regulation under the scope cultivation (maize MON89034 x NK603 and maize MON89034 x MON88017). One new Working Group on guidance for GM animals environmental risk assessment was implemented.

#### Panel on dietetic products, nutrition and allergies (NDA)

The NDA Panel held 10 Working Group and 2 Plenary meetings, one technical meeting with applicants on recent developments on health claims applications and one National Expert meeting on Dietary Reference values.

The NDA panel launched a public consultation on Dietary Reference Values for carbohydrates, dietary fibre, and fat. These documents were also discussed at the national expert meeting in September 2009.

The draft *Frequently-asked Questions* document in relation to health claims application which was released for public consultation and discussed at a NDA technical meeting with applicants in June 2009, has been revised according to the comments received and is published together with a summary report on the comments received during the consultation.

The NDA Panel adopted 3 opinions related to Article 14 health claims referring to disease risk reduction, 2 opinions related to Article 13 (5) claims (claims based on newly developed scientific evidence and/or for which protection of proprietary data is requested), 94 opinions covering 523 items related to Article 13 (1) claim. One opinion on plant stanols and plant sterols and blood LDL-cholesterol and one opinion on labelling reference intake values for n-3 and n-6 polyunsaturated fatty acids

With respect to an overview of health claim applications, to date EFSA has received 260 children and risk reduction claims. 70% of applications received have not been validated yet as EFSA is seeking more information from the applicants or clarification from Member States. The EFSA NDA Panel has adopted 54 opinions covering 62 applications; 21 applications have been withdrawn; 10 applications are in progress. For Art. 13(5) claims (based on new science and/or proprietary data) EFSA has received 21 applications, 6 applications have been withdrawn, 13 opinions have been adopted, and one application is in progress.

In the context of novel foods, the NDA has received new mandates on conjugated linoleic acid, on sardine peptide products, on fermented black bean extract and on chitin-glucan.

It is foreseen that the NDA panel will adopt in its Plenary meetings of 13-15 October 2009 and 2-4 December 2009 additional Article 13 opinions.

In the light of experience gained with the evaluation of Article 13.1 health claims, EFSA is planning a meeting on 6 October to exchange views between experts from Member States, Commission Services and EFSA panel experts. To this end, a briefing document will be prepared and distributed to the participants prior to the meeting.

The Panel will finalise by end of 2009 the draft opinions on dietary reference values for macronutrients and on food based dietary guidelines, taking into account the comments received during the public consultation and at the national expert meeting.

#### Panel on Plant health (PLH)

The renewed Panel on Plant Health (PLH) held its inaugural meeting in June followed by a second Plenary in September. Work has commenced on 3 new mandates requested by the Commission: requiring Pest Risk Assessments for the EU territory for the organisms *Gibberella circinata*, and *Dryocosmus kuriphilus* and a quantitative pathway analysis on US (United States) wheat with respect to the likelihood of Karnal Bunt introduction. To address these new mandates, 5 Working Group meetings have been held. A presentation to the Standing Committee on Plant Health (SCPH) on the Oak Processionary Moth took place on 22<sup>nd</sup> September 2009. Preparations are underway for the PLH Special Advisory Forum meeting to be held on 20 and 21 October 2009.

The guidance document for a harmonised framework for pest risk assessments was endorsed by the Panel and launched for public consultation in May 2009 with a deadline for comments of 2<sup>nd</sup> October 2009.

The Article 36 call for *Pest risk assessment for the European Community Plant Health – A comparative approach with case studies* was launched on 14 July 2009 with a deadline for submissions of 30 September 2009.

The terms of reference for a new self task for the Panel are currently being finalised to address environmental risk assessment and the effect of management options on the level of risk.

#### Panel on plant protection products and their residues (PPR)

The PPR Panel held 3 Plenary Meetings during the reference period. A total of 24 Working Group Meetings in the area of toxicology, residues, ecotoxicology and fate/behaviour took place during the reference period. The Head of Unit of the PPR Unit participated in 2 Pesticide Steering Committee meetings. A Panel member and a representative from the PPR Unit visited the US-EPA and Health Canada to update on EFSA guidance work and to exchange information on scientific methodologies in Europe, USA and Canada.

During the June Plenary meeting, 7 opinions were adopted: 6 on the Annexes II & III and one on triazoles. A Report on the PPR Stakeholder Workshop: *Improved Realism In Soil Risk Assessment (IRIS) - How will pesticide risk assessment in soil be tackled tomorrow?* has been published.

Two calls for tender (persistence in soil, protected crops) were launched on 25 July with a deadline of 1 September. Final reports and databases on greenhouse structures should be delivered by the contractors by September 2009. A call for a grant agreement regarding the *"Identification of cumulative assessment groups of pesticide residues and proposals for prioritization according to the criteria proposed by the PPR Panel"* was launched on 12 June with a deadline of 15 September 2009.

Five new mandates will probably be requested by the Commission, following the outcome of the Joint Working Group on the GD birds & mammals. The *FOCUS Groundwater* report has been finalised, and will be forwarded to EFSA PPR for an opinion. However, due to the recent developments regarding staff transfer from PPR to PRAPeR, the possibility to accept new mandates will have to be carefully considered.

Terms of Reference were agreed for the WG Ecoregions for developing further the concept, and for the WG on Ecotoxicological Effects for the preparation on a draft opinion on protection goal. These concept proposals will be available for consultation by the end of 2009.

The PPR Panel will run a workshop on the development of a new Guidance Document (GD) on Emissions of Plant Protection Products (PPPs) from Protected Crop Systems (e.g. greenhouses and crops grown under cover) in Nov 2009. A competition to award a specific contract on "Data entry of pesticide ecotoxicology Tier 1 study endpoints in a XML schema-database" under a multiple framework contract will be launched in the coming weeks.

## SCIENTIFIC COOPERATION AND ASSISTANCE

#### Scientific Cooperation (SCO)

Focal Point (FP) Agreements have now been signed with all 27 Member States. National meetings were organised by FPs with the participation and support of EFSA in Luxembourg, Bulgaria and Slovenia. For the first time, candidate country representatives were invited to attend the 6<sup>th</sup> FP Meeting (9-10 September in Parma). Linked to the FP meeting a dedicated training session was organised to train FPs on operational matters of Article 36 grants.

The Information Exchange Platform was further developed; access to it has been broadened and an advanced search tool was released.

The expert database includes to date nearly 1500 experts. Cooperation with 11 international organisations has started to explore possibilities to contact experts of their networks. With the support of FP, possibilities for cooperation and data sharing with national expert databases and networks of experts operating within EFSA's remit were explored in the Member States and EEA/EFTA countries.

Following consultations with the Advisory Forum and Scientific Committee (SC), the draft 2010 Work Programme on grants and contracts was finalised. Two IT tools are currently being developed: one to manage the Article 36 list of competent organisations and a second one to provide an extranet space for the Article 36 network.

The final report of the ESCO Working Group on risks and benefits of folic acid, which also includes the outcome of the scientific event in Uppsala in January 2009, was finalised, following intensive consultations with experts involved, and submitted to EFSA's Executive Director.

IT started constructing the new web area for the EFSA Journal; a prototype is expected in autumn. An Editorial Board was established, composed of the 6 non-chairs of the SC and the 2 EFSA Science Directors. Vittorio Silano was appointed Editor-in-Chief of the EFSA Journal. To comply with requirements of bibliographic databases the templates for EFSA scientific outputs were revised and harmonised. Training sessions on the use of these templates were organised for EFSA staff; EFSA Scientific Panels were updated at their plenary meetings.

The 12<sup>th</sup> booklet in the EFSA Scientific Colloquium Report Series on assessing health benefits of controlling *Campylobacter* in the food chain has been printed and disseminated.

#### Assessment Methodology Unit (AMU)

The assessment methodology unit (AMU) organized and chaired a 3-day meeting for the Working Group (WG) on the use of systematic literature review in June and a teleconference in July. The ESCO WG on isoflavones which is chaired by AMU held a 3-day teleconference in July and a 2-day working group in September. In addition, in August the first meeting took place of the WG on modelling the link between the EU microbiological criteria to poultry meat prevalence at retail. AMU staff participated and contributed to various WGs of SCAF, BIOHAZ, ZOONOSSES, PRAPeR, PPR, DATEX, PLH and ITOP.

AMU delivered one internal report on the statistical evaluation of monitoring data on *Salmonella* in Poultry meat (July) and the final report on the art 36 on colony collapse disorder syndrome in bees will be delivered by the applicant in September (draft final report delivered in August). The AMU contribution to the GMO opinion on new methodologies on bio-equivalence assessment was integrated into the opinion and the opinion was published in July.

AMU published one Art 36 call - "Data sources and models to identify the emergence of infectious diseases in fish" - in July and the Toxicology multiple framework contract (10 contractors) was signed in September and is now available for EFSA.

AMU will start the Art 36 project on data sources and models to identify the emergence of infectious diseases in fish and will give a significant contribution to PRAPeR. Numerous assistance requests from PLH, AHAW and PPR.

#### Data Collection and Exposure Unit (DATEX)

The DATEX unit completed full exposure assessments for lead and arsenic and passed the results to the CONTAM Panel. Both substances are ubiquitous and found in many food groups.

For the first time exposure was also calculated for the full age range of children using consumption data from the Art 36 project called EXPOCHI. The report on default assumptions used within EFSA was finalised and submitted to the Scientific Committee for adoption. Results on comprehensive food consumption information for adults has been already received from some collaborating Member States and a database containing more detailed food consumption information has been initiated.

A final report on furan analyses from the Art 36 project with the Danish Technical University was approved.

#### Pesticide Risk Assessment Peer Review (PRAPeR)

The PRAPeR Unit organised 2 further meetings of the Pesticide Steering Committee to discuss the management and scheduling of the pesticide peer review programme, and held 8 bilateral teleconferences with the Commission to monitor progress. In addition, PRAPeR held 7 teleconferences with the Commission and the relevant rapporteur Member States (RMS) to agree on the scope of the peer review for several active substances, and held 7 teleconferences with experts from the Member States to discuss scientific issues for specific active substances. PRAPeR also organised a specialised meeting with experts from the Member States to discuss micro-organisms used as active substances in plant protection products.

The PRAPeR Unit was represented in 2 meetings of the Standing Committee on the Food Chain and Animal Health (one meeting of the Legislation group and one meeting of the Pesticide Residues group). In addition, the Unit was also represented in a Joint conference organised by EFSA and the Slovenian Ministry of Agriculture, Forestry and Food on "The Role of the EFSA in Assessing Risk from Farm to Fork". PRAPeR experts attended a meeting organised by JRC to coordinate the activities of EFSA and JRC in the field of biocide and pesticide assessments.

Twelve conclusion reports were issued concerning the pesticide peer review of the risk assessment of 12 active substances. Public consultations on the assessment reports submitted by the RMS for 11 active substances were launched.

A total of 26 reasoned opinions on MRL applications were adopted, one of them combined a MRL application with a MRL review according to Article 12(2).

The 2007 Annual Report on Pesticide Residues was published on 09/07/2009. This report contains a comprehensive overview of the national monitoring activities and an analysis of the actual consumer exposure to pesticides. Two calls for contracts were launched in the reference period, one on the data collection of CXLs (Codex maximum residue levels) and related scientific information, the second regarding contribution to the drafting of the 2008 Annual Report on Pesticide Residues.

In the second half of 2009 and early 2010, the PRAPeR Unit will receive a further 75 assessment reports from the Reporting Member States (RMS) concerning active substances that have been resubmitted according to Commission Regulation (EC) No. 33/2008, of which approximately 80% are expected to be submitted in the period September–December. In addition, PRAPeR has received 4 assessment reports for Annex I renewal of active substances, and expects to receive a further 2 such assessment reports in 2009. Draft Assessment Reports for 3 further new active substances have also been received.

In the reference period the European Commission forwarded twenty new requests regarding the assessment of MRL applications.

Except for the 164 active substances for which the MRL review under Article 12(2) of Regulation 396/2005 is currently ongoing and the 189 active substances which have been included in the review programme according to the provisions of Article 12(1) of Regulation 396/2005, an additional 22 active substances have to be added to the work programme because a decision on the inclusion of the active substances in Annex I of Directive 91/414/EEC has entered into force.

#### Emerging Risks Unit (EMRISK)

Further to establishing a network on Emerging Risk Identification, the Unit has participated in the Discussion Group on Emerging Issues, chaired by the EC and comprising representatives from other EU Agencies and EC services. Meetings have also been held with the FSA and the FAO.

The beta version of the Bioactive Compounds Database was presented by Institute of Food Research (contractor) to EFSA's Units. The database is now under evaluation. The final report on the RASFF mandate was completed and the IT tools developed are now used to monitor RASFF notifications.

An Art 36 call on the predicted impact of climate change and the development of aflatoxin B1 in EU was published in June 2009 and the proposals are being evaluated with a view to awarding the contract in October 2009. The Working Group "Crisis simulation exercise 2009" met 3 times to review an in-house training exercise being prepared by an external contractor. The exercise, held on 7 July, was facilitated by the contractor who also provided a report including recommendations for further developing the EFSA Emergency Manual. Preparation for an exercise to be held jointly with MS and EC in November is underway.

#### Animal Diseases Transmissible to Humans Unit (ZOO NOSES)

Together 8 working group meetings were organised and 5 of them were related to the on-going analyses of the EU-wide baseline surveys on *Salmonella* and methicillin resistant *Staphylococcus aureus* (MRSA) in breeding pigs and *Salmonella* and *Campylobacter* in broiler meat. Two meetings concerned the revision of reporting rules for food-borne outbreaks and one meeting was about harmonisation of monitoring and reporting of *Yersinia enterocolitica* in animals. Furthermore, a coordination meeting with EFSA's contractor for zoonoses data analyses and the European Centre for Disease Prevention and Control (ECDC) was organised for the end of October.

A scientific report on technical assistance on the statistical evaluation of monitoring data on *Salmonella* in fresh poultry meat was issued at the end of June and sent to the Commission.

A call for tenders was published in July on an inventory of available data sources and proposal for data collection on vector-borne zoonoses in animals.

In addition, a competition under the statistical framework contract was launched in September regarding assistance in statistical evaluation of the achievement by Member States of EU *Salmonella* reduction targets in animal populations.

The annual zoonoses reports of 2008 were received from the Member States in June and the data is being analysed by EFSA and ECDC. The Summary report will be published in January 2010.

The process of revising the Community rules for reporting of food-borne outbreaks was started in June in order to address the difficulties encountered in this annual reporting by the Member States. The revised reporting rules should be finalised by the end of 2009.

### SCIENTIFIC COMMITTEE & ADVISORY FORUM

#### Scientific Committee

The renewed Scientific Committee held its inaugural plenary meeting (37<sup>th</sup> plenary meeting) on 21-22 July 2009 during which Prof. Vittorio Silano was re-elected as Chair, while Drs. Ada Knaap and Dr. David Lovell were elected as Co-Chairs.

The Scientific Committee adopted during its Plenary Meeting the guidance document for the safety assessment of botanicals and botanical preparations intended to be used as ingredients in food supplements. A workshop will be organised on 24 November 2009 to present the work done by EFSA to the Stakeholders and the European Member States, and to discuss the possible way forward on this issue. An Art 36 call was launched to prepare a report on the applicability of physicochemical data in threshold-of-toxicological-concern assessments. A negotiated procedure for a procurement has been launched for the preparation of a report on Terminology in Risk Assessments.

A request has been received for a new mandate from the European Commission to in relation to providing guidance on risk assessment on nanoscience and nanotechnologies. The mandate is related to the recommendations in the published EFSA nanotechnology opinion (of February 2009) on the need to revise current guidance documents and asks for detailed guidance for safety assessment including requirements directly usable in the elaboration of applications.

A new working group on genotoxicity testing strategies has been established

#### Advisory Forum (AF)

The 32<sup>nd</sup> AF meeting was held in Prague in June. The AF discussed EFSA's preliminary Management Plan for 2010, the cooperation between EFSA and the Member States both in general and specifically in the area of genetically modified organisms, the follow up on the recommendations of the ESCO working group on botanicals, priorities for further work on harmonisation, import-related risks, and the SC opinion on the use of benchmark dose approach in risk assessments.

The 33<sup>rd</sup> AF meeting was held in Stockholm in September. The AF discussed the cooperation in the field of dietetic products, nutrition and allergies, non-plastic packaging materials and genetically modified organisms as well as legal aspects of data collection and sharing. The AF also continued its reflections on the way forward for the cooperation between EFSA and the Member States and concrete actions for further harmonisation.

### COMMUNICATIONS

A joint event EFSA-AGES with the title 'Relevance of EFSA for Austrian Food Safety' was organized in Vienna, Austria. A joint conference was organized with the Greek food safety agency EFET during which EFSA's Executive Director was interviewed by local and national media.

During a media lunch in Brussels EFSA's Executive Director met with journalists from the mainstream European press. During a media lunch in Paris in September, EFSA's Executive Director met a selection of French journalists covering food safety issues.

On occasion of a NDA technical meeting on health claims in Brussels the Chair of the NDA Panel was interviewed by the press agencies *DPA*, *AFP* and *EFE* and specialized publications such as *EU Food Law* and *Nutraingredients*.

Furthermore, Communications organized interviews by *EFE* (Spanish press agency), *Agroesfera* (TV programme on agriculture of TVE) and the *Newsletter of the Universidad Complutense Madrid* with EFSA's Executive Director on the occasion of the opening of AESAN summer courses in Madrid. During the international Gornja Radgona Agricultural Fair in Slovenia, EFSA's Executive Director was interviewed by national TV and radio.

In September EFSA organized a GMO conference with Member States and Communications organized the presence of media on-site and interview requests. A total of 140 participants attended the conference: national risk assessment experts, stakeholders, Advisory Forum members, GMO panel members, and international food safety bodies.

During the reporting period over 200 media queries were received and 13 media interviews organized.

#### Science/Corporate Press releases / Web news stories:

The Press Office issued 5 press releases and 19 web news stories:

##### Press Releases:

- EFSA's Scientific Committee promotes alternatives to animal testing
- European public health agencies evaluate antibiotic resistance of *Staphylococcus aureus*
- EFSA advises on welfare of dairy cows
- EFSA publishes its first report on pesticide residues in food
- EFSA completes first EU-wide assessment of vitamin and mineral sources used in food supplements

Web News Stories:

- GMOs (eg. ARMG, MON810)
- Corporate issues (eg. Call for MB members, renewal of Stakeholder platform)
- Nutrition and health claims
- Contaminants in food (eg. marine biotoxins)
- Food contact materials
- Food additives and enzymes
- Oak processionary moth
- Pesticides

Web

Three principal online communications projects have been launched since the last MB meeting:

- The online subscription for electronic newsletters has been upgraded to include a wider range of products and to allow each user to tailor his/her subscription.
- The scientific documents search has been improved to allow users to search *all* scientific outputs from a *single* interface.
- The web statistics now includes figures on website traffic for content related to specific Panels and Units.

New content includes a new A-Z Topic on Food Contact Materials, following the publication of the guidelines on active and intelligent substances in food contact materials. Existing topics sections were updated to reflect on-going scientific work on animal health, pesticides, food supplements, GMOs, and dietary reference guidelines. Other content initiatives were the online support of the stakeholder platform call and the Management Board members call.

Publications

Since the last MB meeting, various scientific and corporate publications have been produced, with a significant increase in multilingual content. These include:

- Since July the 2008 annual report summary has been available electronically in all 23 EU languages and printed in all 4 EFSA working languages.
- Issue 4 of EFSA's thematic newsletters, *EFSA in focus* (Animals, Plants, Food), in English was published and distributed in July. The other 3 EFSA working language versions are in production.
- *EFSA News* no. 20 and *Moving Together* no. 3 were published in all 4 EFSA working languages in July.
- The foodborne outbreaks report was printed and delivered in September.
- The Scientific Colloquium report 11 (Acrylamide carcinogenicity) was printed and distributed in June and report 12 (Assessing the health benefits of controlling *Campylobacter* in the food chain) in July.
- Greek and Slovenian versions of the corporate brochure were printed to mark joint events in both of these countries.

## ADMINISTRATION

Legal and Policy Affairs Unit (LPA):

*Cooperation with EU Institutions*

European Commission

The sequence of bilateral meetings between the EFSA Executive Director and the SANCO Director General was continued and 2 meetings were held in July and September with important issues discussed such as Health Claims, Pesticides, EFSA/FDA Liaison Officer exchange, Mid-term planning, and the Roadmap.

Five EFSA staff members attended for the first time the SANCO induction week exercise held in Brussels in June.

EFSA staff members participated in numerous meetings of the European Commission's Standing Committee on the Food Chain and Animal Health on invitation of the Commission's services, notably on issues concerning GMOs, Phytopharmaceuticals, Animal Health and Welfare and Microbiological Hazards.

On 17 July EFSA also attended the SANCO Advisory Group meetings respectively on the evaluation of the GM Food and Feed Legislation and on the possible review of the dietetic food legislation.

#### EU Presidency

On 1<sup>st</sup> July, Sweden took over the EU's 6-month rotating presidency from the Czech Republic.

On 24 September, EFSA's Executive Director met representatives from the Swedish Presidency in Stockholm. This meeting, as part of the regular meetings that EFSA holds with the EU Presidency, aimed at exchanging views on activities carried out by EFSA and that are in the agenda of the Presidency. At this occasion, EFSA met representatives from the Ministry of Agriculture, National Food Administration, Environmental Protection Agency, Swedish Board of Agriculture, the National Veterinary Institute and the Swedish Chemical Agency.

#### Bilateral EU Member States visits

On 13 July, EFSA's Executive Director opened in Madrid the 1<sup>st</sup> Course on Food Safety and Nutrition organized by the Spanish Agency of Food Safety and Nutrition (AESAN) and the University Complutense of Madrid. This one-week course is part of the on-going cooperation between AESAN and EFSA to further explain the Agency's role and activities.

#### Relations with Stakeholders

At its June meeting, the Management Board took the decision to renew the EFSA Stakeholders Consultative Platform on the expiry of its 3-year mandate, through the launching of a call for expressions of interest for full membership and associated membership. The Call for expressions of interest together with the renewed approved Terms of Reference was published on EFSA's website on 26 June and the deadline for submitting the applications was the 31<sup>st</sup> August. An evaluation committee for the assessment of the applications was set up and the evaluation meetings took place at the beginning of September. The Management Board will be invited to consider the list for membership and for associate membership on October 8.

#### International Relations

On 25 June, EFSA welcomed the visit of a delegation from the German Bundestag, comprising 5 members of the Parliamentary Group for Food, Agriculture and Consumer Protection. The delegation was joined by the German Consul in Milano. They were particularly interested in EFSA's system of declaration of interest. The participants concluded that cooperation must be strengthened between EFSA and the German Bundestag.

On 26 June, EFSA received the visit of the Chief Executive of New Zealand Food Safety Authority (NZFSA), accompanied by his Director of Science. In the morning session, both participated in the Science Strategy Taskforce meeting. The bilateral meetings focused on subjects of common interest like zoonoses and biohazards.

On 22 September a delegation of the Australian Trade Commission visited EFSA. They were interested in knowing what the current areas of major focus/concern are for food safety in the EU.

On 29 September, a delegation from the Republic of Colombia, comprising 10 representatives of "Centro de Productividad del Tolima", visited EFSA. The meeting focused on subjects of common interest as animal health and feed additives.

Pre-Accession Programme and European Neighbourhood Policy (ENP)

On 14/15 September, a Pre-Accession Seminar on Risk Assessment Methodology was organised in Dubrovnik, Croatia where the work of EFSA Assessment Methodology Unit (AMU) in providing technical support in the field of statistics, modeling, data management and risk assessment was presented. Experts from Member States shared their views and experiences in the area of consumption data collection and cooperation between EFSA and the Member States on Zoonoses data collection. Representatives from the competent authorities in Croatia and the Former Yugoslav Republic of Macedonia presented the state-of-the-art of data collection in their countries. The European Commission gave information on the development of the Pre-Accession Programmes. A total of 40 experts from the different authorities in Croatia and the Former Yugoslav Republic of Macedonia participated.

Experts from Turkey, Croatia and the Former Yugoslav Republic of Macedonia also participated in various EFSA meetings such as the AF Plenary meeting, the Pesticide Steering Committee and the Focal Points meeting.

On 1 and 2 July, EFSA hosted the first EU seminar on food safety for ENP countries together with SANCO, RELEX and ENLARG. The 2-day meeting, held in Brussels, was a first step in building closer cooperation in this area with Mediterranean and Eastern European countries bordering the European Union. The seminar provided a valuable platform to outline EFSA's role in the EU food system and to gain insight into the priorities of the ENP countries.

Data Protection

In response to an opinion of the European Data Protection Supervisor (EDPS) concerning the handling of annual and specific Declarations of Interest at EFSA, the recommendations of EDPS are being followed up in relevant DoI guidance and in the IT tool. Furthermore, a notification for checking by EDPS was submitted regarding the EFSA leave management.

Some follow-up actions on specific data processing operations were implemented, namely the personal data processing in the context of the EFSA journalist database and EFSA newsletters, the handling of personal data in the context of mission management and vis-à-vis the new travel agency of EFSA, personal data handling in the context of meeting and events organisation by EFSA.

Human Resources

## HR - Staffing Progress Report until 30 September 2009

FINANCIAL STATEMENT												
					RECRUITMENT (+)				END OF CONTRACT (-)			
Staff Categories	2009 Upper ceilings		September 2009 situation	End 2008 situation	Number of New Contracts issued since year start	New comers	Change in contract, Cat. or Grade	Offer letters sent (contract not yet started)	Departures	Change in Cat. or Grade	Contract expiry	"Net" Result
	EP	in line with budget reserve										
Temporary Agents and Officials												
- Executives, Managers & Officers (AD)	197	197	180	177	13	9	4	4	7	2	1	3
- Assistants functions (AST)	158	158	141	141	23	5	18	6	10	13	0	0
Total	355	355	321	318	36	14	22	10	17	15	1	3
Contract Agents												
- Officers functions (CA FG IV)	41	36	35	30	7	6	1	0	1	1	0	5
- Assistants functions (CA FG I, II, III)	44	40	28	34	7	6	1	8	4	9	0	-6
Total	85	76	63	64	14	12	2	8	5	10	0	-1
Seconded National Experts (executives functions)												
	20	12	11	13	4	4	0	1	5	1	0	-2
Total all staff categories	460	443	395	395	54	30	24	19	27	26	1	0

The execution rate of the staff plan in line with the 2009 budget reserve ceilings at the end of September 2009 is 89.2%. Execution rate including 19 pending offers is 93.5%.

Finance

Budget execution:

The budget execution in August was 89% of the target execution for that month. This is mainly due to planning difficulties met in the area of scientific cooperation with delays incurred in the tendering of contracts and grants. Whereas these delays were absorbed in August, award and ensuing budgetary commitments are expected to be made over the period September – October. A specific document on the budget execution, forecast and partial release of the reserve is presented to the Management Board.

## Glossary

**AF** – Advisory Forum

**AFC Panel** – Panel on food additives, flavourings, processing aids and materials in contact with food

**AGES** – Austrian Agency for Health and Food Safety

**AHAW Panel** – Panel on animal health and welfare

**AMRGs** – Antimicrobial resistance marker genes

**AMU** – Assessment Methodology Unit

**ANS** – Panel on Food Additives and Nutrient Sources Added to Food

**ARM** – Antimicrobial resistant marker

**BIOHAZ Panel** – Panel on biological hazards

**BMD** – Benchmark dose

**CDC** – Centres for Disease Control and Prevention (US)

**CEF** – Panel on Contact Materials, Enzymes, Flavourings and Processing Aids

**CONT** – Control committee

**CONTAM Panel** – Panel on contaminants in the food chain

**COPA** - European agricultural union

**COPHS** - Chief Officers of Plant Health Services

**DATEX** – Data Collection and Exposure Unit

**DG ENV** – Directorate General Environment

**DG RTD**- Research Directorate General

**DG SANCO** – Directorate General for Health and Consumers

**DOI** – Declaration of Interest

**EC** – European Commission

**ECDC** – European Centre for Disease Prevention and Control

**EDPS** – European Data Protection Supervisor

**EEA** – European Environment Agency

**EMA** – European Medicines Agency

**EMIDA** - Coordination of European Research on Emerging and Major Infectious Diseases of Livestock

**ENP** – European Neighbourhood Policy

**EP** – European Parliament

**EPA** – Environmental Protection Agency

**EPPO** - European and Mediterranean Plant Protection Organization

**ESCO** – EFSA Scientific Cooperation projects

**EUFMD** - European Commission for the control of Foot-and-Mouth disease

**ENP** – European neighbourhood policy

**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

**FP** – Focal Point

**GD** – Guidance Document

**GMO Panel** – Panel on Genetically Modified Organisms

**HoU** – Head of Unit

**HR** – Human resources

**IPA** - Pre-accession Assistance

**ITOP** – IT& Operations Unit, EFSA

**JECFA** – Joint FAO/WHO Expert Committee on Food Additives

**JRC** – Joint Research Centre of the European Commission

**LPA** – Legal and Policy Affairs (EFSA)

**MRSA** – Meticillin-resistant *Staphylococcus aureus*

**MRL** – Maximum residue levels

MEP – member of Parliament  
MS – EU Member States  
NDA Panel – Panel on Dietetic Products, Nutrition and Allergies  
OIE – Office International des Epizooties  
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  
RASFF – Rapid Alert System for Food and Feed  
RMS – Reporting Member States  
SC – Scientific Committee  
SCA – EFSA Scientific Cooperation & Assistance Directorate  
SCAR – standing committee on agricultural research  
SCO – EFSA Scientific Cooperation Unit  
SCOFAH / SCFAH– Standing Committee on Food Chain and Animal Health  
TDI – Tolerable daily intake  
TSE – Transmissible spongiform encephalopathy  
TTC – Threshold of toxicological concern  
WTO – World Trade Organization