

Office of the Executive Director and the Management Board

## HIGHLIGHTS

### Risk Assessment

The ANS Panel adopted 7 opinions and 2 statements - including an opinion on taurine and D-glucuronolactone in “energy drinks”. AHAW Panel adopted an opinion on fish welfare, which supersedes 5 previous minority opinions, and a mandate on locomotion problems of dairy cattle was agreed. A self-mandate was accepted on good practice in scientific assessment in animal health. BIOHAZ Panel adopted three opinions and a working group on BES-related risk of bovine intestines is being formed on request of the Commission. The Unit participated in the DG-SANCO/EFSA Workshop on Salmonella Control in Pigs. CEF Panel completed the evaluation of FGE.19 flavouring substances and requested additional data for 270 substances. Guidelines for active and intelligent packaging were published for public consultation and 8 opinions were adopted as well as the 22<sup>nd</sup> list of substances used in food contact materials. The Panel issued a statement on the risk of 4-methylbenzophenone in cereals in response to an urgent request from the Commission. CONTAM Panel adopted opinions on saponins in feed and cadmium in food and received requests from the Commission on acceptance criteria for previous cargoes for fats and oils and the tolerable daily intake of melamine. FEEDAP Panel adopted 2 opinions on feed additives and endorsed a working document on ractopamine for consultation with EMEA. NDA adopted 3 Art 14 child health claims, 2 claims on risk reduction, an Article 13 (5) opinion and a claim related to a novel food application. A total of 43 opinions have been adopted covering 50 applications and opinions and approx. 1000 Art 13 claims are scheduled to be adopted in July 2009. PLH signed with the JRC, IPSC, Agriculture Unit, Agri4cast group a service level agreement for a “model framework for the assessment of EU climatic suitability for the establishment of organisms harmful to plants and plant products” to support the activities of the PLH Panel by comparing methodologies for modelling climatic suitability. PPR signed an Art 36 contract for an assessment of the impact of metabolic processes on the toxicology of pesticides and closed the public consultation on the Guidance Document on dermal absorption in mid-January.

### Scientific Cooperation and Assistance

The Scientific Cooperation Unit held the 4<sup>th</sup> Focal Points meeting and reached 20 Focal Point agreements signed so far. The expert database now counts 1300 experts. AMU Unit contributed to the DATEX report on  $\beta$ -casomorphins, to the PLH opinion on Citrus Black Spot Fungus, to the CONTAM opinion on Cadmium and has started a self-mandate on Isoflavons. The DATEX Unit has published the report on potential health impact of  $\beta$ -casomorphins and contributed to the EFSA statement on 4-methylbenzophenone in cereals. The expert group for chemical occurrence data with representatives from most EU MSs has met. The PRAPeR Unit finalised 10 reasoned opinions on MRLs and in collaboration with DATEX and AMU organised a meeting to promote common EFSA data collection strategy. The EMRISK Unit coordinated the report on “lessons learned” after the dioxin incident, revised the EFSA emergency manual and initiated testing of its functionalities. The ZOONOSES Unit published the Community Summary Report on Zoonoses in 2007 with a press briefing in collaboration ECDC and EC organised.

### Scientific Committee & Advisory Forum

The Scientific Committee held its 34<sup>th</sup> Plenary Meeting and adopted the opinion on Potential risks arising from Nanosciences and Nanotechnologies in food and feed safety. The Advisory Forum held its 30<sup>th</sup> plenary in Ljubljana and the meeting focused on the dioxin crisis with discussions of “lessons learned”.

## **Communications**

In cooperation with the Commission and ECDC, EFSA organised a press briefing on the Third EFSA-ECDC Annual Report on Infectious Diseases Transmissible from Animals to Humans. EFSA hosted a meeting of the Heads of Communication and Information Network (HCIN) of the EU agencies and the 22<sup>nd</sup> meeting of the Advisory Forum (AF) Working Group on Communications in Parma. A media dinner was organised in Milan where the Executive Director described EFSA's role and mission to Italian journalists. Prior to the AF meeting in Ljubljana, EFSA co-organised a half-day event with the Slovenian authorities entitled "EFSA and Slovenian risk assessment institutions – strengthening capacity in food safety" which was attended by more than 60 representatives of national food authorities, food industry, consumers and the scientific community. During the event EFSA and Slovenia signed the annual Focal Point agreement.

## **Administration**

The series of bilateral meetings between EFSA and DG-SANCO continued and the Executive Director met the new Director General of DG Environment, Mr. Falkenberg. Dossiers of interest to EFSA were monitored in the European Parliament including draft recommendations on statistics for plant protection products and residue limits of pharmacologically active substances in animal products. EFSA took over the coordination of the network of Heads of EU Agencies on March 1 for a 1-year term. Delegations were received from Kyung-pook National University of South Korea, the Spanish Agency for Food Safety and Nutrition (AESAN) and the Japanese Food Safety Commission. An EFSA delegation, led by the Executive Director, visited various US institutions, including CDC, USDA, and FDA and the Commission Delegation in Washington DC. Experts from the three Candidate Countries participated in several EFSA meetings and a seminar on the institutional framework of EFSA was held in Brussels.

## RISK ASSESSMENT

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

The ANS Panel held four working group meetings (two in January and two in March) and one Plenary (in January). One meeting was held with the Commission and scientific support was provided for Communications and Legal and Policy Affairs on 8 occasions. In addition, one request for public access to documents was received on the dossier on titanium dioxide.

The opinion on Taurine and D-glucuronolactone in "energy drinks" was adopted by written procedure on 15 January 2009 and published along with a press release. The ANS Panel adopted during its 4<sup>th</sup> Plenary from 27 to 29 January 2009 six opinions (Ferrous phosphate, Monomethylsilanetriol, Nicotines, Choline-stabilised orthosilicic acid, Taurates and the second ERF study on aspartame) and two statements (Selenium amino acid chelate and Ethanolamine phosphate). Two more opinions (High viscosity white mineral oils and Ascorbates) were forwarded to the Panel members for adoption by written procedure.

The ANS Panel is currently developing a call for tender on the development of preparatory documents for the re-evaluation of preservatives. This call for tender will be launched by mid 2009. The contracts on evaluation of natural colours and synthetic colours was finalized in February 2009.

At this moment the ANS Panel is dealing with 128 nutrient sources substances, which will have to be finalised by May 2009. Thereafter, the ANS Panel will focus on the re-evaluation of food colours, the evaluation of new applications for food additives, the establishment of the data requirements for the applications for food additives, the revision of the guidance document on food additives and the re-evaluation of preservatives.

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

The AHAW Panel held its 39<sup>th</sup> plenary meeting on January 28-29. Working Group meetings were held on the following mandates: stunning and killing of fish species, welfare of dairy cows, scientific assessments using modelling, and brucellosis in pigs.

Representatives of the AHAW Unit attended various meetings for example: SCOFCAH meetings on animal diseases; Task force for the eradication of animal diseases; AH standing committee Working Group expert meeting on Bluetongue; Kick-off meetings on grants on tuberculosis in wildlife and Crimean-Congo hemorrhagic disease and epizootic hemorrhagic disease; Annual meeting of Community and National Reference laboratories on foot-and-mouth disease and swine vesicular disease.

One opinion was adopted on the general approach to fish welfare. This opinion provides an overall approach regarding the welfare, biology and physiology of fish farming. It addresses and satisfies all the issues outlined in the 5 minority opinions recorded in relation to AHAW Panel opinions previously adopted on the welfare of farmed carp, farmed European sea bass and gilthead sea bream, farmed trout, European eel and Atlantic salmon. The 5 minority opinions are superseded in the light of the new opinion. Additionally, a scientific opinion on leg and locomotion problems of dairy cows was accepted by the Panel as one of the 4 risk assessments to be carried out, in order to provide a reply to the question on dairy cows welfare. As suggested by the Commission a deadline extension for the Dairy Cows mandate until June 2009 has been requested.

On Art 36 the activity concerned a kick off meeting of a new project on data collection for emerging fish diseases on 16 February

A new self-mandate was accepted February 5 by the ED on 'Good Practice in Conducting Scientific Assessments in animal health using modelling'. The aim of this mandate is to provide chairs and members of AHAW Working Groups with procedural guidelines for the use of mathematical and statistical models in conducting scientific assessments in animal health during their specific tasks and mandates. The goal is that models should be well-integrated into the scientific work and reflect the intention of the mandate.

### Panel on biological hazards (BIOHAZ)

The 45<sup>th</sup> Plenary of the BIOHAZ Panel was held on 21-22 January. The 46<sup>th</sup> Plenary was held on 4-5 March.

Working group meetings were held on the following mandates: Update Revision of BSE Monitoring regime, Technical Guide on Poultry Decontamination, Assessment of the equivalence of the Australian Monitoring programme, TSE Resistance in Goats, ABP FuelCal, ABP Bunker System, Salmonella in pigs, Salmonella criteria, Salmonella in Breeding Hens, Salmonella in Laying hens, Irradiation of Food, Campylobacter in broiler meat, Antimicrobial resistant marker (ARM) genes used as marker genes in GM Plants, Meticillin Resistant Staphylococcus aureus (MRSA), ABP Alternative method from EULA, Food safety aspects of Dairy Cows, Revision of Guidance on Carcass Decontamination.

Six working group meetings and one teleconference were held in January. Ten working group meetings were held in February and 2 working group meetings are foreseen in the 1<sup>st</sup> half of March.

BIOHAZ Unit representatives as well as members of the Working Group on Salmonella in pigs participated in the Sanco/EFSA Workshop on Salmonella Control in pigs on 26<sup>th</sup> February.

Public consultation on the draft opinion on the use and mode of action of bacteriophages in food production was published on 30<sup>th</sup> January.

At the Plenary of 21-22 January, the BIOHAZ Panel adopted three opinions. The following opinions are being tabled for possible adoption at the Plenary of 4-5 March: MRSA, Salmonella in Breeding Hens, Joint BIOHAZ and GMO opinion on the Use of ARM genes used as marker genes in GM Plants, Genetic TSE resistance in goats.

A working group on BSE-related risk of bovine intestines is being formed following a request from the European Commission. A new self-tasking mandate on updating the opinion on Maintenance of the list of QPS microorganism intentionally added to food or feed (2009 update) will be presented at the March Plenary.

A new self-tasking mandate on the Revision of the joint CEF/BIOHAZ guidance document on the submission of data for the evaluation of efficacy and potential occurrence of acquired reduced susceptibility of substances for the removal of microbial surface contamination of foods of animal origin intended for human consumption is being undertaken. Collaboration with SCHER and SCEBHIT, the SANCO non-food committees, is foreseen.

The BIOHAZ unit met with the EPFRA association to discuss issues related to the Animal-By-Products applications. Meetings with some Member States (Italy and France) on similar issues were held in the first half of March.

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

The CEF Panel held its 4<sup>th</sup> Plenary meeting in January. The following four working groups have met: Food Contact Materials, Flavourings 1, Flavourings 2.

Meetings organised by the Commission in the areas of flavourings, smoke flavourings and food contact materials were attended.

Guidelines for Active and Intelligent Packaging have been published for public consultation on 25 February, since the corresponding Regulation has been voted by the Standing Committee on the food chain and animal health on 12 February 2009.

The highest priority was given to the evaluation of the "FGE.19" flavouring substances, i.e. those which have structural alerts for genotoxicity. This evaluation has now been completed. No substance has been rejected, but data have been requested for 270 substances.

Three opinions related to 39 substances of FGE.19 were adopted. One substance was concluded to be of no safety concern related to genotoxicity. Data were required for 38 substances, including important substances currently on the market. A supplement to the statement on List of alpha, beta-Unsaturated Aldehydes and Ketones Representative of FGE.19 Substances for Genotoxicity Testing will be published shortly.

Furthermore, three opinions for applications on smoke flavourings have been adopted and a generic opinion on dietary exposure assessment and one opinion on a processing aid has been adopted.

The Panel adopted the 22<sup>nd</sup> list of substances including 8 substances intended to be used to manufacture food contact materials. 7 substances could be used and one should not be used.

EFSA has been asked on 20 February by the Commission to evaluate if the substance 4-methylbenzophenone would be covered by the TDI on benzophenone and hydroxybenzophenone and evaluate the risk of the presence of 4-methylbenzophenone found in cereals. A statement has been issued in collaboration with DATEX.

A tender has been launched for the examination and drafting of a report on non-toxicity data related to the evaluation of substances intended to be used in food contact material. Offers have been evaluated by EFSA and commencement of activities is expected in April 2009.

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.

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

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)

Within the reference period the CONTAM Panel held its 30<sup>th</sup> plenary meeting. Ten working group and audio conference meetings were held during this period related to requests on undesirable substances in animal feed – section nitrite (3 meetings), arsenic in food (1 meeting), marine biotoxins (3 meetings), cadmium in food (2 meetings), and lead in food (1 meeting). In addition, a first planning audio conference meeting was held related to the work of the new established working group on previous cargoes.

The following opinions were adopted at the 30<sup>th</sup> CONTAM plenary meeting: Saponins as undesirable substances in animal feed and Cadmium in food.

EFSA has received two requests for scientific advice from the European Commission which fall within the remit of the CONTAM Panel. One request is related to the assessment of the appropriateness of the criteria for acceptable previous cargoes for fats and oils proposed by the FAO/WHO in collaboration with the National Institute for Public Health and the Environment (RIVM) in the Netherlands compared to the criteria proposed by the Scientific Committee on Food (SCF). The second request is related to the tolerable daily intake of melamine established by the SCF in 1989 in the light of the outcome of the recent WHO expert consultation on melamine. This request will be addressed jointly by CONTAM and CEF. However, further clarification on the mandate was asked by EFSA to the European Commission.

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

In the reference period the FEEDAP Panel held its 55<sup>th</sup> plenary meeting and twelve working group meetings on micro-organisms, enzymes, coccidiostats, amino acids, organic acids related dossiers, trace elements and Ractopamine.

The Panel adopted two scientific opinions on applications for authorisation of a feed additive. The working document on Ractopamine has been endorsed by the FEEDAP Panel and has been sent to EMEA according to the terms of reference sent by the European Commission.

There are currently two calls for proposals under progress, one on trace elements, for which the kick off meeting with the beneficiary of the grant agreement on trace elements took place in January, and the other on the environmental impact of zinc and copper used in animal nutrition. A call for proposals has been published on 23<sup>rd</sup> February regarding mycotoxin detoxifying agents.

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

The GMO Panel held two plenary sessions. 18 working group meetings were held: Four days with the food/feed Working Group, two days with the environmental risk assessment Working Group and four days with the molecular characterisations Working Group, two days with the Working Group for GMM. For self tasks and mandate Working Groups two days of meeting were held with the joint GMO-BIOHAZ Working Group for the antibiotic resistance marker genes mandate, four days of meetings were held with the non-target organisms Working Group and the Working Group for updating the environmental guidance. The Working Group for development of guidance for GM

animals met during one day, the statistics Working Group met two days and the Working Group for assessment of allergenicity of GMOs worked during two days.

GMO panel members met experts from Norway in the spirit of the article 30 procedure concerning general issues on allergenicity and GM food. Technical assistance was provided to DG SANCO during a SCFCAH meeting with Member States regarding the panels' opinions on the data package submitted in support of French and Greek national respective safeguard clauses to ban GM maize MON810. EFSA organised a one day technical meeting for applicants where both general issues concerning application risk assessment procedure as well as questions pertaining to individual application dossiers were discussed.

Two GMO application opinions were adopted: one opinion on renewal of Bt11 maize and feed containing and or consisting of Bt11; one on application GHB614-glyphosate tolerant cotton, both under regulation (EC) No 1829/2003. In February several offers received in connection with a call for tender on data collection of methodology and hazards relevant for environmental risk assessment of GM fish were evaluated. A high quality offer was identified. Expected starting date of contract is beginning of April 2009. Similar calls for tender with respect to GM insects, birds and mammals are under development.

Application for authorisation of the enzyme preparation FINASE EC (6-phytase) for chickens for fattening, chickens reared for laying, laying hens, turkeys for fattening, turkeys reared for breeding, piglets (weaned), fattening pigs, sows, ducks and other minor species. A request for a scientific opinion on supplementary information about the enzyme preparation of trade name ECONASE XT L and ECONASE XT P was received from the EC. Both applications were submitted under Regulation (EC) No 1831/2003. An application for authorisation of genetically modified H7-1 Roundup Ready® Sugar beet for food and feed uses and cultivation submitted under Regulation (EC) No 1829/2003 was received. A new Working Group on GM animals was implemented to elaborate guidelines on the food/feed safety of GM animals.

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

The NDA Panel held fifteen Working Group meetings and two Plenary meetings. A meeting with three European organisations representing food supplements manufacturers and suppliers in Europe was organised to discuss recent developments with health claims applications and the Article 13 health claims community list.

In its January Plenary meeting the NDA Panel adopted three Article 14 health claims referring to children's health and development, two opinions referring to risk reduction and one Article 13 (5) claim opinion (claims based on newly developed scientific evidence and/or for which protection of proprietary data is requested). In addition one opinion related to a novel food application was adopted.

With respect to an overview of health claim applications, to date EFSA has received 241 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. By now the EFSA NDA Panel has adopted 43 opinions covering 50 applications; thirteen applications have been withdrawn; ten applications are in progress For Art. 13(5) claims (based on new science and/or proprietary data) EFSA has received eighteen applications, three applications have been withdrawn, six opinions have been adopted, and nine applications are in progress.

The NDA Panel is making progress with the evaluation of Article 13 health claims and it is targeted to adopt opinions for around 1000 claims in July 2009. It is targeted to endorse for public consultation 2 opinions on dietary reference values (carbohydrates, fats) at the NDA March Plenary meeting.

A draft opinion for labelling reference values for selected nutritional elements will be discussed at the March Plenary meeting.

A stakeholder meeting including all key players is foreseen for 15 June 2009 to discuss recent development with respect to health claims. NDA received two new mandates related to energy conversion factors and one new application for labelling exemption (barley beta amylase). A special Advisory Meeting on Dietary Reference Values for macronutrients is foreseen for September 2009 and a Science colloquium related to the revision of an EFSA Guidance for Novel Food applications is planned for October 2009.

### Panel on Plant health (PLH)

Since the previous report, the Panel has held one plenary meeting and four working group meetings. In March a further 2 working group meetings are scheduled to address accepted mandates.

The Commission agreed to a time extension of one month for the delivery of the opinion on the Oak Processionary Moth to enable sufficient time for data collection and the identification of additional scientific expertise. The deadline for delivery of the opinion is the end of May 2009.

The working group on the harmonised framework for the assessment of risks of organisms posing a threat to the Community's plant health held its inaugural meeting on in January. The public consultation on the guidance document for the evaluation of pest risk assessment documents made by third parties for phytosanitary purposes was launched in January 2009 with a closing date for comments of 2<sup>nd</sup> March 2009.

A significant development for the Panel's future work concerns the clarification received from the Commission at the meeting in January in Brussels that the Panel would not be required to assess economic impacts. Responsibility for this matter will remain exclusively within the jurisdiction of the risk manager.

A service level agreement for a "model framework for the assessment of EU climatic suitability for the establishment of organisms harmful to plants and plant products" was signed between the JRC, IPSC, Agriculture Unit, Agri4cast group. The objectives of the collaboration are to support the activities of the PLH Panel by comparing methodologies for modelling climatic suitability.

It is anticipated that a new mandate will be requested by the Commission and accepted by EFSA to produce a scientific opinion on the Pine Wood Nematode. The mandate relates to the reliability and effectiveness of an alternative heat treatment of wood shavings infested by the pinewood nematode. The time frame for delivering the opinion is expected to be short so work has already commenced on data collection and identifying appropriate experts.

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

The PPR Panel held one plenary meeting in February. Ten working group meetings took place: A kick-off meeting for the revision of the Guidance Documents "Aquatic Ecotoxicology" and the GD "Terrestrial Ecotoxicology", a Working Group Fate GD Persistence in Soil, a Working Group Toxicology, a Joint Working Group Toxicology & Residues, a Working Group Fate GD greenhouses (protected crops), a Working Group Revision of the Persistence in Soil GD Ecotox (Bugs), a Working Group Ecoregions, and three Working Groups Residues (Triazole Mandate and Probabilistic Mandate).

Further, a meeting with JRC on QSARs, a Steering Committee meeting on greenhouse data collection, and an Expert Consultative Group Meeting Project on Threshold of Toxicological Concern took place. In addition, a telephone conference on the OECD ecoregion crosswalk project and a web conference on Ecotoxicological effects took place.

Two representatives of the PPR Unit participated in the Pesticide Steering Committee meeting and gave a presentation on 3 Feb on the activities of the Panel.

An Article 36 grant contract has been signed for a project aimed at examining the impact of metabolic processes on the toxicological properties of pesticides.

The public consultation on the GD for dermal absorption closed on 15th January. The outcome of the public consultation will also be an important background document for the contractor selected for the negotiated procedure whose work should start at the beginning of April. The final report is expected for submission in Oct/Nov.

## **SCIENTIFIC COOPERATION AND ASSISTANCE**

### Scientific Cooperation (SCO)

New Focal Point (FP) Agreements have been signed with 20 Member States and those for the remaining Member States (MS) are underway. These agreements will allow consolidating the cooperation between MS and EFSA, after the first year of FP activities. On 3-4 February the 4<sup>th</sup> FP Meeting was held assessing the past and discussing future work priorities. The FPs were also updated on the outcome of the 2<sup>nd</sup> FP-Working Group meeting on the evaluation of

the pilot phase on the Information Exchange Platform (IEP). FPs considered the IEP a useful tool to keep MS and EFSA informed about upcoming and ongoing risk assessments on food and feed safety. EFSA's expert database continues to grow. By the end of February 2009, over 1300 experts have applied. The validation of all these applications should be finalised by mid March. The database is now routinely used by EFSA staff and Panels and can also be accessed by Member States.

Following the adoption of the updated Article 36 list by the EFSA Management Board in December 2008, the updated Article 36 list is now published on the EFSA website. 128 newly designated organisations were added to the 243 organisations previously on the list. This increase of more than 50 percent substantially broadens and strengthens the available scientific expertise.

With the ESCO Working Group on risks and benefits of folic acid, the SCO unit organised a scientific event in Uppsala on 21-22 January. 60 experts discussed recent scientific developments in this area. The outcome of the meeting supports the work of the ESCO Working Group. The report will be available on the EFSA website in spring 2009.

The project of developing the current EFSA Journal into an online Journal that is recognised and complies with best practices in the field of academic publishing made further progress. A new web area for the EFSA Journal on the EFSA corporate Website is being created. Changes, including modified templates for EFSA's scientific outputs, were necessary to meet minimum requirements of bibliographic databases to which EFSA intends to apply for indexation.

#### Assessment Methodology Unit (AMU)

The assessment methodology unit held the first Working Group meeting in March 2009 on the application of systematic review methodology into the food and feed risk assessment process and contributed to the DATEX report "Review of the potential health impact of  $\beta$ -casomorphins and related peptides" and the PLH opinion on "Citrus black spot fungus".

A significant methodological contribution was made to the CONTAM opinion on Cadmium and a scientific article has been submitted publication to the 'Environmental Health Perspectives' journal while two others are in preparation. The AMU Technical report for dose-effect modelling is also being finalised. Subsequent to the work on cadmium benchmark doses (BMD), a request has come from the SCAF WORKING GROUP on BMD to collaborate on their opinion regarding the use of BMD with human data.

AMU started a self mandate for the ESCO Working Group on the Hazard characterisation of use of dietary isoflavones and isolated isoflavones from soy or red clover in food supplements and collaborated closely with the AHAW panel on a self mandate on "Good Practice in Conducting Scientific Assessments in Animal Health Using Modelling".

The Head of Unit of AMU was part of the EFSA delegation visiting the CDC in Atlanta and the CEAH and gave two presentations on modelling approaches used in EFSA.

A multiple framework contract on toxicology was drafted in order to provide a back-up support to the panels. This framework contract was launched beginning of March.

Further support was given to Working Groups of BIOHAZ, ZOOSES and PLH.

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

In February the DATEX Unit published the report "Review of the potential health impact of  $\beta$ -casomorphins and related peptides". The report was produced by a Working Group coordinated by DATEX and contains a detailed review of the available scientific literature that addresses possible health effects of  $\beta$ -casomorphins and related peptides, and in particular  $\beta$ -casomorphin-7 (BCM7), a peptide sequence present in the milk protein  $\beta$ -casein. A few studies have suggested that BCM7 may contribute to increased risk of certain non-communicable diseases, such as autism, cardiovascular diseases and type I diabetes. EFSA undertook this work as part of its regular monitoring and assessment of possible emerging risks associated with the food chain. Based on this review, EFSA concluded that a



cause and effect relationship is not established between the dietary intake of BCM7, related peptides or their possible protein precursors and non-communicable diseases.

The Expert Group for Chemical Occurrence Data consisting of representatives from most EU Member States met on 19 February 2009. The group agreed to explore harmonisation of the total diet study approach recommended by the WHO for chemical contaminant analyses. The group also discussed improvements to electronic data transfer as a means of facilitating the submissions of contaminant results to EFSA. Food classification is an issue of common interest. A new approach was presented that will be further developed during the coming months.

DATEX contributed the exposure assessment part and participated in the general development of the recently published "EFSA statement on the presence of 4-methylbenzophenone found in breakfast cereals".

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

The PRAPeR Unit in collaboration with DATEX and AMU organised a meeting to promote common EFSA data collection strategy. The second part of the meeting focussed on the future data submission of pesticide monitoring results as required in Article 31 of Regulation 396/2005.

PRAPeR was represented in one Standing Committee on the Food Chain and Animal Health (Residues) meeting and in a Working group dealing with the monitoring Regulation for 2010. PRAPeR was also represented in one Standing Committee

Ten reasoned opinions regarding the modification of existing MRLs or the possible exemption of an active substance for MRL setting were finalised.

#### Emerging Risks Unit (EMRISK)

The unit provided scientific and administrative support to the ESCO Working Group on Emerging Risks in the completion of their mandate. The final report was revised and presented to the EFSA Executive Director.

During the dioxin emergency, which affected pork from Ireland, the Emerging Risks Unit supported the activities of EFSA and consequently coordinated a report on "lessons learned". This report was revised on the basis of comments from members of the MT and submitted for final adoption.

A strategy paper for the medium term planning of the Emerging Risks unit, describing its mission, mandate and activities, was completed. Comments from Heads of Units and Directors within EFSA were integrated and the document was submitted for final adoption.

The EFSA Emergency Manual was revised on the basis of additional internal and external comments and submitted for final adoption. The implementation of the document and the testing of its functionality in a "crisis simulation exercise" were initiated. A working group on simulation exercises with representatives from Member States started.

The EFSA Emergency/Crisis cards were updated, printed and distributed.

Five project plans, as parts of formal applications for self-mandates, were formulated and submitted for adoption. Two projects, following calls for tender, (Development of a SAS Macro to import, analyse and visualize data from the DG-SANCO Rapid Alert System for Food and Feed Safety (RASFF) 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; and Delivery of a database on bioactive constituents of food plant) were started with Kick-off meetings.

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)

During the period one network meeting was organised on 17-18 February and that meeting specifically focussed on IT issues related to the zoonoses web-based reporting system. It was also the first partly shared IT data collection meeting organised in collaboration with the DATEX and PRAPeR units and their experts. In addition, seven working group meetings were held during the period.

The Community Summary Report on Zoonoses in 2007 was published on 20 January and a press briefing was organised in Brussels in collaboration with ECDC and the Commission. As a consequence, all together over 100 articles were published around Europe about the report.

In the beginning of the year, a series of kick-off meetings were organised with the new contractors and Article 36 grant collaborators. This covered the grant collaborators for the food survey project and project on harmonisation of monitoring and reporting of rabies and Q fever. The contractors involved were two statistical analyses contractors and four contractors to support the baseline survey analyses as well as a contractor for antimicrobial resistance data analyses and a contractor for Salmonella serovar source attribution analysis.

Three new working groups started their activities, and they were the working groups to support the analyses of Campylobacter and Salmonella in broilers and broiler meat baseline survey, the analyses of Salmonella in breeding pigs baseline survey and the analyses of MRSA in pigs baseline survey.

## SCIENTIFIC COMMITTEE & ADVISORY FORUM

### Scientific Committee (SC)

The Scientific Committee had its 34<sup>th</sup> Plenary Meeting during which it discussed the progress on the consideration of cross-cutting issues in the various Scientific Panels, SC Working Groups and the Scientific Cooperation and Assistance Directorate. EFSA updated the SC about the outcome of meetings of the Management Board and the Advisory Forum. Working group meetings were held in the area of welfare of experimental animals, risk-benefit assessment, and ESCO botanicals. The kick off meeting of the newly established Working Group on a mandate "Exploring options for providing preliminary advice about possible human health risks bases on the concept of threshold of toxicological concern (TTC)" was held on 13<sup>th</sup> January. Another Working Group meeting is scheduled for the 10<sup>th</sup> March. It is foreseen to finalise the mandate by summer 2010.

The public consultation for the draft opinion on transparency on EFSA's risk assessment closed on 15 February. The opinion will be proposed for adoption at the next SC plenary in April.

At the plenary the Scientific Committee adopted its scientific opinion on the Potential Risks Arising from Nanoscience and Nanotechnologies on Food and Feed Safety. The opinion will be published at the beginning of March together with a report on the outcome of the public consultation and the public comments received.

EFSA has received 99 comments on the public consultation on the draft opinion "Transparency in the scientific aspects of risk assessment carried out by EFSA: general principles" which ended on 15<sup>th</sup> February. The SC working group will now finalise the opinion, taking into account the comments received, and submit it to the Scientific Committee for adoption at its plenary meeting in April 2009.

The EFSA Scientific Panels will be consulted until mid-March 2009 on the draft opinion on Benchmark Dose. Adoption is expected before the end of the mandate of the current Scientific Committee.

The kick-off meeting of the article 36 contract signed with the Central Science Laboratory for the development of a framework for the risk assessment of chemical mixtures took place on 21 January 2009. The purpose of this one-year project is to build a toxicological database on relevant chemical mixtures to food safety.

### ADVISORY FORUM (AF)

The 30<sup>th</sup> AF plenary meeting was held in Ljubljana on 18-19 February, 2009. Ireland presented a comprehensive overview of the dioxin in pork incident which contributed to the discussion on 'lessons learned' from EFSA's involvement in providing urgent scientific advice, particularly in the context of communications during such incidents.

Agreement was also reached on a means of progressing the work on Harmonisation of Risk Assessment which will be developed further for discussion at the 31<sup>st</sup> AF plenary on 22 and 23 April, 2009. In addition, the AF agreed to the proposal to disband the existing AFITWG and to provide new mandates to create specific data collection Working Group/Networks as needed. The AF agreed to a new mandate on Isoflavones and received updates on the ESCO on folic acid and the proposal for an emergency simulation exercise to be held later in 2009.

## COMMUNICATIONS DIRECTORATE

On 20 January, EFSA organised in cooperation with ECDC and the European Commission an informal press briefing to discuss the 3rd EFSA-ECDC annual Community Report on Infectious Diseases Transmissible from Animals to Humans. 11 Brussels press correspondents, mostly from national press agencies, attended the briefing which was followed by a number of short interviews with EFSA's Director of Scientific Co-operation and Assistance, Hubert Deluyker; Head of Unit for Surveillance and Communication at ECDC, Andrea Ammon; and Head of EFSA's Zoonoses Unit, Pia Makela. The Zoonoses Report was covered widely by media across the EU and beyond, with nearly 100 articles in major newspapers, regional media, specialised publications and web portals.

On 4-5 February, the Agencies' Heads of Communications and Information Network (HCIN) came to Parma. It brought together those responsible for the communication from all EU Agencies. 41 representatives attended the Agencies' Heads of Communications meeting and 22 attended the Webmasters Information Network meeting. The network aims to increase the visibility and strengthen communication and information about the activities and results of the agencies through joint activities (i.e. publications, internet, and events) and by knowledge-sharing and exchanges of good practice. The HCIN network is coordinated and chaired by EFSA in 2009. The communication Troika for EU agencies is EU-Osha (EU Agency for Safety and Health at Work), EFSA and EMCDDA (European Monitoring Centre for Drugs and Drug Addiction).

On 5 February, the Press Office organised a media dinner in Milan. The Executive Director met a number of Italian journalists, including one or two who had written negative articles about EFSA in the past. The aim of the event was to explain EFSA's role and mission and its current and future activities. A few questions focused on GMOs, BSE/TSE, health claims (including botanicals), pesticides and Zoonoses. There were also a couple of questions about how EFSA is integrating in Parma; and on the Expo 2015 in Milan. Before the dinner, Catherine was interviewed by Sergio Nava of *Radio 24*. All those who took part welcomed the approach and said it added great value to their understanding of the Authority. The journalists from *Il Sole 24 Ore* and *Italia Oggi* wrote balanced articles covering all the aspects mentioned at the dinner.

On 13 February, the 22<sup>nd</sup> meeting of the Advisory Forum Working Group on Communications took place in Parma. The meeting was opened by EFSA's Executive Director, Catherine Geslain-Lanéelle. The objective of meetings with the national communications experts is to exchange information and experiences and strengthen the coherence and co-ordination of communications activities between the national authorities and EFSA. Key issues on the agenda of this meeting included the future development of risk communications guidelines, an overview of communication on upcoming scientific issues, an update on cooperation in communication, a presentation of EFSA's Emerging Risk unit and lessons learnt in 2008 from the urgent requests for scientific advice focusing on the Irish dioxins incident.

Prior to the Advisory Forum meeting in Ljubljana, on 18 February, EFSA together with the National Institute of Public Health and the Ministry of Agriculture, Forestry and Food held the half day event "EFSA and Slovenian Risk Assessment Institutions - Strengthening Capacity in Food Safety". 60 participants from national food authorities, industry, consumers, and scientists attended where they heard about cooperation between EFSA and Member States, the challenges and opportunities in risk communication, and the work of the Slovenian National Focal Point and Advisory Forum. During the meeting, EFSA and Slovenia's Ministry for Agriculture, Forestry and Food signed the annual Focal Point agreement.

On this occasion, the Press Office arranged media interviews with the Executive Director with *Dnevnik* (a leading daily newspaper), *Mladina* (an influential weekly publication) and *Radio Slovenia*. The main Slovenian news agency, *STA*, also published a wire on the signing of the Focal Point agreement with Slovenia before the joint event.

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

The Press Office issued the following press releases and web news (period 20 January – 6 March):

#### Press Releases:

- EFSA-ECDC report shows *Campylobacter* cases in humans on the rise, while salmonellosis is in decline; listeriosis remains of concern (20 January 2009)
- EFSA recommends revised maximum vitamin A levels in feed for main food producing animals (2 February 2009)
- EFSA adopts opinion on two ingredients commonly used in some energy drinks (12 February 2009)
- EFSA issues statement on 4-methylbenzophenone in some breakfast cereals (4 March 2009)
- EFSA publishes opinion on the potential risks arising from nanotechnologies on food and feed safety (5 March 2009)

Following the request from the European Commission for urgent advice on the migration of 4-methylbenzophenone, the Press Office prepared internal media lines and a reactive Question and Answer document which was also circulated to the Advisory Forum and its Working Group on Communications. A press release was subsequently published along with the EFSA statement. A number of media queries on the subject were dealt with both by phone and e-mail. Early coverage included newswires from several major European press agencies.

#### Web News Stories:

- EFSA evaluates citrus black spot (20 January 2009)
- Folic acid: an update on scientific developments (23 January 2009)
- Management Board meeting in Rome (2 February 2009)
- EFSA meets Italian government on school and transport links (9 February 2009)
- EFSA to provide advice on the risks of 4-methylbenzophenone in food (20 February 2009)
- EFSA launches public consultation on active and intelligent food contact materials (25 February 2009)

### Web

The most significant developments on the website during the period have been in the areas of content, usability, outreach and content management system development.

Content initiatives included the publication of a new topic section on food supplements, new information on EFSA's work on active and intelligent packaging, 4-methylbenzophenone and new developments in areas such as nanotechnology and fish welfare. On the corporate side, the colour edition of EFSA's Strategic Plan was published and highlighted on the homepage, while other developments were presented including the joint event in Ljubljana, the Stakeholder Platform meeting and EFSA's coordination of the EU agencies network.

A key usability upgrade was made through the launch of a new "Topics A-Z" area, offering an alphabetical index of key scientific topics covered by EFSA. It includes an "In the spotlight" feature to highlight specific topics and users can sort through topics by Panels/Unit. The main topics page is located in the global site navigation while each Panel and Unit section now contains a link to relevant topics. Another usability upgrade involved the main Events and meetings section, which now enables users to search all forthcoming and past events from one page using a single search interface.

In the outreach field, the live webcast of the January Management Board meeting attracted over 1,300 views, maintaining an encouraging trend following a steep increase in recent viewing figures achieved through an email promotion campaign directed to subscribers to the EFSA highlights email newsletter. An online user survey was also implemented to gather key quantitative data on user profiles, by asking users one question: "In what role are you visiting the EFSA website today?" This was achieved through exploiting a feature of the content management system. Over 39,000 responses were gathered during the 1 month survey period. The data obtained will help inform future website developments and communications activities.

A key content management system development was implemented through configuring a new file upload and linking feature. This allows greater flexibility in the way key files such as pdf documents are presented on the website, particularly where a large number of files are published on a single web page together with other content. It allows content such as Management Board agendas and associated documents to be presented in a more user friendly format.

### Publications

Since the last MB meeting, various scientific and corporate publications have been produced. These include:

#### Scientific:

- The third edition of EFSA's thematic newsletters, EFSA in focus (Animals, Plants, Food), is in production.
- The CD-ROM of all EFSA scientific outputs is being printed in March.

#### Corporate:

- EFSA news 19 in all EFSA working languages has been sent to print and will be distributed in March.
- The final version of 2009 Work Plan in all EFSA working languages has been delivered.
- The English version of the Strategic Plan 2009-2013 has been laid out, and made available electronically on the EFSA website, and is being printed. Proofreading of all translations of the other EU official languages will begin in March with the emphasis on EFSA's other working languages, French, German and Italian, with production finishing in April. All other linguistic versions will then follow.

## 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 General Director was continued and a meeting was held on 13 February. The agenda comprised issues such as Plant Health and the approach to socioeconomic assessments, the GMO and the ARM (Antibiotic Resistance Marker) mandate, Cloning, Nano, the MoU with Japan.

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 5 March, the EFSA Executive Director met with the new Director General of DG Environment, Mr Falkenberg and discussed the work programme of EFSA in areas of relevance to DG Environment, the mandates that EFSA has received from DG Environment, i.e. general mandate on environmental risk assessment of GMOs and GMO safeguard clauses.

##### European Parliament

In the Environment, Public Health and Food Safety (ENVI) Committee a series of dossiers of EFSA's interest were monitored. This concerned a draft recommendation on statistics for plant protection products (to be adopted in the ENVI Committee on 30/03/2009) and the adoption of a draft recommendation on the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin.

LPA staff also participated to the ENVI meeting where MEPs considered a series of non-legislative work. It notably concerned:

- A draft own report on regulatory aspects of nanomaterials, where MEPs generally recognised the opportunities offered by nanotechnologies, whilst underlining that risk should be addressed and assessed in all cases.
- The adoption of draft opinions on:
  - the 2007 Budget Discharge, which grants EFSA ED the discharge for 2007;
  - the harmonization/mutual recognition of food quality standards, where among others it was now suggested to set an EU Agency for Product Quality, which would work closely with EFSA .
  - The consideration of draft opinions respectively concerning:
    - a proposed Directive on the protection of animals used for scientific purposes, which developed a more animal welfare friendly approach to the issue of the use of animals in scientific experimentation, while introducing measures based on the three "R" principle of replacing, reducing and refining the use of animals in experiments;
    - the marketing standards for poultry meat, including the ban on chlorinated agents to be used as antimicrobial treatment.

An interesting debate on trans fatty acids (TFAs) took place, further to a question raising the need/relevance to introduce a European ban on industrially produced TFAs. EFSA previous opinions on this issue were referred to highlighting that there was no scientific evidence to distinguish partially hydrogenated oils (industrially produced TFAs) from naturally occurring TFAs in terms of health effects.

Finally, to be noted that the European Parliament also adopted in first reading a proposed Regulation to replace the current legislation on marketing and use of feed, which notably aims at simplifying existing procedures while promoting innovation in that field.

##### EU Presidency

EFSA participated at a Conference organized by the Czech Presidency on Quality Policy on 13<sup>th</sup> March in Prague.

##### EU Agencies

As from 1<sup>st</sup> March and until 28<sup>th</sup> February 2010, EFSA is coordinating the network of the Head of EU Agencies. This role entails chairing meetings of the network, coordinating activities between meetings and heading a troika involving the previous and future chairs, the European Monitoring Centre for Drugs and Drug Addiction and the European Centre for Disease Prevention and Control. The first meeting of this network under EFSA coordination will take place on 10<sup>th</sup> June in Brussels.

#### Relations with Stakeholders

The Stakeholders Platform meeting on 5 and 6 February in Brussels covered *inter alia* a discussion on the EFSA draft on Public consultations on scientific outputs. The ongoing exchange with the stakeholders was maintained by processing regular pre-notifications.

#### International Relations

At the end of January, EFSA received at service's level a delegation from the Kyung-pook National University, Daegu South Korea who was visiting Europe to study the European system of risk assessment.

On 12 February, R. Sabrido and A. Troncoso, respectively President and Executive Director of AESAN (the Spanish Agency for Food Safety and Nutrition) visited EFSA and exchanged views on joint activities in 2009 and 2010 as part of the term of Spain as EU Presidency country. The EFSA Executive Director was invited to open jointly with the Spanish Minister of Health the 4<sup>th</sup> Congress on food safety and nutrition to be organized by AESAN in July 2009.

On 5 and 6 March, EFSA received the visit of the Japanese delegation from Food Safety Commission, led by Dr. Toshio Ohtani, Deputy Director General. The EFSA Executive Director and the Deputy Director General exchanged letters stating the intention to sign in the near future a Memorandum of Understanding. On the week of 9<sup>th</sup> March, an EFSA Delegation, lead by EFSA's Executive Director and the Chair of EFSA's Scientific Committee, went to US to visit the US Centres for Disease Control and Prevention in Atlanta, the USDA APHIS Centre in Colorado, the USDA FSIS and ARS, the EPA and FDA in Washington as well the European Commission Delegation in Washington. This visit is part of the on-going implementation of EFSA's strategic approach re international activities that was adopted by EFSA's Management Board in January 2009.

#### Pre-Accession Programme

The LPA Unit coordinated and managed the attendance of experts from the three Candidate countries at the following EFSA's meetings (1) Pesticide Steering Committee on 2-4 February in Parma (2) AF Communication WORKING GROUP on 13 February in Parma (3) Task Force on Zoonoses Data Collection IT on 17-18 February in Parma (3) 2nd Expert Group on Chemical Occurrence Data on 19 February in Parma (4) Advisory Forum plenary meeting on 18 and 19 February in Ljubljana. In addition, the LPA Unit organized a Pre-Accession Seminar Training on the Institutional Framework of EFSA on 11/12 March in Brussels where the European Commission, the European Parliament, Slovenia from Member State's point of view and EFSA explained their respective role in the area of Food Safety in the EU. Risk Analysis framework with an accent on dividing the risk management from the risk assessment was presented and 27 experts from Croatia, Turkey and the Former Yugoslav Republic of Macedonia participated.



## Legal

The LPA Unit continued to ensure legal support to all operations of EFSA, especially regarding the legal framework of the Genetically Modified Organisms, Health and Nutrition Claims and for several recent regulations impacting on the pesticides sector.

## Data Protection

Following the inspection in December 2008 carried out by the European Data Protection Supervisor (EDPS) which was focusing on the CDAC system (staff appraisal) and the staff training policy, EFSA submitted since then, notifications for prior checking to the EDPS on a couple of important personal data processing operations at EFSA namely: the Declarations of Interest handling, the EFSA staff recruitment and the probationary staff appraisal.

## Human Resources

	Total staff number 31/12/2008	RECRUITMENT (+)					END OF CONTRACT (-)			Total staff number 31/03/2009
		Number of New Contracts	New comers	Change in contract, Cat. or Grade (*)	Departures (**)	Change in contract, Cat. or Grade (***)	Contract Expiry	"Net" Result		
AT + Officials	318	10	5	5	6	6		-2	316	
CA	64	7	6	1	2	1		4	68	
END	13	1	1		2			-1	12	
<b>Total</b>	<b>395</b>	<b>18</b>	<b>12</b>	<b>6</b>	<b>10</b>	<b>7</b>	<b>0</b>	<b>1</b>	<b>396</b>	
<small>(*) = EFSA's staff recruited to TA posts (including AUX, CA, END) at EFSA.</small>										
<small>(**) = Resignations, termination of contract after probationary period, termination of contract.</small>										
<small>(***) = EFSA's staff leaving their TA post in order to be recruited to a new post at EFSA.</small>										

## Finance

### Budget execution:

The budget execution in January stood at 131 % of the target execution for the month. This is mainly due to important commitments already been made in Infrastructure and Personnel.

This indicator has however discrete relevance at the very beginning of the year. Adjustments for the inflating effect observed in the commitment related to infrastructure will be brought next month.