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EXECUTIVE DIRECTORATE

HIGHLIGHTS

Risk Assessment

The AFC Panel adopted draft opinions on bisglycinates, dietary exposure to aluminium, and glycinate nicotinate, as well as a statement on the assessment of the safety of nutrient sources. Following a 2-month public consultation, guidelines for the evaluation of recycling processes for plastics were adopted. AHAW adopted an opinion on avian influenza and sent a letter to the Commission to split the question of Welfare on Dairy cows into 5 scientific opinions. An opinion on consumption of bovine tongue was adopted at the BIOHAZ plenary of 16-17 April and further opinions on the risk of TSEs from carcasses of ovine and caprine animals and on the microbiological risk assessment on feedingstuffs for food-producing animals were adopted at the plenary of 4-5 June. CONTAM adopted opinions on cross-contamination of non-target feedingstuffs by diclazuril and nicarbazin; tropane alkaloids in animal feed; and a risk/benefit assessment of nitrate in vegetables. FEEDAP held 22 Working Group meetings and two plenary meetings during which seven opinions were adopted. In addition, one technical hearing took place to discuss a specific dossier on a coccidiostat and two stakeholders meetings were organised. GMO held three plenary meetings and adopted five scientific opinions. Seven mandates were received from the Commission and nine meetings of the standing working groups were held. NDA adopted opinions on the safety of synthetic zeaxanthin, lycopene oleoresin from tomatoes and synthetic lycopene. It adopted draft opinions for public consultation on deriving and applying dietary reference values, dietary reference values for water and guidance for food-based dietary guidelines. PLH held 2 plenary meetings and one Working Group meeting. The mandate on 30 PRAs made by France on organisms considered harmful for plants and plant products in the French overseas departments was finalised and 30 opinions were published and presented at the Standing Committee of Plant Health. PPR held two plenary meetings and 23 Working Groups and an opinion on cumulative risk assessment in human health was adopted.

In Scientific Cooperation, 24 Focal Point agreements have been signed, the list of Article 36 organisations has been updated and, in 2008, 9 calls were launched under Article 36 and 8 under a procurement procedure on a budget of €1.1 and €0.3 million, respectively. The Scientific Colloquium on acrylamide, jointly organised with the CONTAM Panel unit, concluded that there is currently no need to revisit the risk assessment on acrylamide. The 2nd meetings of the ESCO Working Group on the risks and benefits of food fortification with folic acid and the ESCO Working Group on the expert database, which agreed on a final strategy to populate the expert database, took place.

The Scientific Committee had its 30th Plenary meeting and Scientific Committee Working Group meetings were held in the area of transparency in risk assessment – scientific aspects, animal cloning, welfare of experimental animals, nanotechnology, risk benefit assessment and benchmark dose approach in risk assessment. At the 26th Advisory Forum plenary meeting in Rome on 10-11 April 2008, the outcomes of the first focal point meeting and the status of the work of the AF Working Groups and the ESCO projects were discussed.

Communications carried out a number of activities aimed at raising EFSA's visibility in Europe including the CIBUS Fair and the "Festa dell'Europa" in Parma and the visit of the Executive Director to the Hungarian Food Safety Office. Press releases included the Southampton study on food additives and child behaviour, antimicrobial resistance and Salmonella in turkeys.

In Administration, the Legal and Policy Affairs Unit has been created and EFSA representatives had participated in nine EP Committee meetings. The Executive Director had met with Commissioner Vassiliou and the Director General of SANCO. EFSA had participated in meetings of the Chief Veterinary Officers (CVOs) and the 8th meeting of EFSA's Stakeholder Consultative Platform took place.

RISK ASSESSMENT

AFC

The AFC Panel held its 29th plenary meeting on 1-3 April 2008 and its 30th plenary meeting on 20-22 May 2008 in Parma. A significant number of draft opinions have been adopted by the Panel and some have been deferred to the next meeting because of lack of time. In the field of nutrient sources, at the April meeting a statement was adopted on the possibility of assessing the safety of nutrient sources added for nutritional purposes in food supplements and the bioavailability of the nutrients from these sources based on the supporting dossiers. At the May meeting, opinions on certain bisglycinates as sources of copper, zinc, calcium and magnesium and glycinate nicotinate as a source of chromium were adopted.

The opinion on the safety of the dietary exposure to aluminium was adopted in May 2008. It is an important opinion that has mobilised significant resources for more than one year. It covers multiple fields: food additives containing aluminium, food contact materials, water and contaminants. The CONTAM Panel has been associated with the preparation of this opinion through the participation of a Panel Member in the ad hoc Working Group.

In the field of flavourings, three opinions on Flavouring Group Evaluations (FGE) and one opinion on Revised FGEs, as well as seven opinions on FGEs of substances evaluated by JEFCA and considered by the AFC Panel, were adopted at the 29th meeting. At the 30th meeting, the Panel adopted a draft opinion on Camphor, six opinions on FGEs and three opinions on FGEs of substances evaluated by JEFCA and considered by the AFC Panel. In the field of food contact materials, opinions on 2 substances from the 19th list were adopted. Following a 2-month period of public consultation, guidelines for evaluation of recycling processes of plastics were adopted. An opinion on the treatment of Natural Mineral Waters with oxyhydroxides media has been scheduled for adoption by written procedure.

AHAW

Between 12 March and 09 June, the AHAW Panel held two plenary meetings (13-14 March and 07-08 May). The opinion on "Avian Influenza" was adopted. This opinion provides, as requested by the European Commission, a scientific update of the risk assessment on the highly pathogenic H5N2 strain, including a summary of the 5 previous scientific opinions.

In order to better structure the final outcome of these mandates, on 30 April a letter was sent to the Commission to split the question of Welfare on Dairy cows in 5 scientific opinions corresponding to the following areas i) lameness, ii) mastitis, iii) metabolic disorders, iv) fertility problems and 5) a combined general opinion including the physiological aspects. This distribution of tasks will allow specific risk assessments for each one of the identified problems in order to provide better support to the EU Commission.

In relation to fish, mandates on salmon welfare and trout were discussed at the March and May plenaries. According to the outcome, it was confirmed to the Commission that adoption of both these opinions was possible in June while, for the remaining 3 species, adoption will be postponed to September.

On 27-28 May AHAW contributed to the special Advisory meeting on Animal Health organized by the EFSA Advisory Forum with representatives from Member States. On the first day representatives from EFSA and the Commission gave presentations; AHAW presented its work program, the team composition and the process of developing Scientific Opinions. EFSA launched a questionnaire before the meeting in order to prepare the main issues for possible collaboration. On the second day there was room for questions and answers to the MS related to the Questionnaire. It was agreed that a document of possible procedures between EFSA and MS should be shared in September.

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

- Biological aspects in intensive rearing of the Farming Animals March 13-14
- FDM Labs in Zürich 14 March
- IFREMER – Nantes 18-19 March
- Joint Annual Meeting of the National Reference Laboratories for Avian Influenza and Newcastle disease Brussels 09-11 April

- DGRTD project COST 867 Krakow 15-16 April
- Farm Animal Welfare and the interface with disease Bristol 16-17 April
- QualyPig conference, Cremona 19 April
- International Forum on Global Aspects of Farm Animal Welfare Brussels 22-23 April
- Meeting on Wrapstun , Art. 36 Uppsala 23-24 April
- Systematic Review course Nottingham 06-09 May
- Advanced Methods for Validation of Diagnostic tests, Berlin 14-16 May
- Animal Transportation Conference, Dresden 18-21 May
- Global Animal Health Bologna, 29 May
- EPG Symposium Brussels 06 June
- Epizone Bluetongue Symposium Brescia 07 June
- Animal Welfare and Research Quality Gargnano del Garda 09-10 June

BIOHAZ

The opinion on “Consumption of bovine tongue” was adopted at the BIOHAZ Plenary of 16-17 April and the opinions on “Assessment on the risk related to TSEs from carcasses of ovine and caprine animals below 6 months of age intended for human consumption” and on “Microbiological risk assessment on feedingstuffs for food-producing animals” were adopted at the BIOHAZ Plenary of 4-5 June.

The public consultation on “Foodborne antimicrobial resistance as a biological hazard” and the call for data on the same issue was closed on 27 May. A call for data on *Salmonella* in pigs was published on EFSA's website. The deadline for the submission of data was 9 June. Data has been received from various countries and will be used by the Article 36 grant consortium for the Quantitative Microbiological Risk Assessment on *Salmonella* in pigs.

Ad hoc Working Groups were established for the following mandates:

- The assessment of the public health significance of methicillin resistant *Staphylococcus aureus* (MRSA) (self mandate)
- TSE infectivity in milk products from small ruminants
- Examination and selection of applications for TSE tests suitable to enter into a formal evaluation programme
- Technical guide for the scientific data collection on antimicrobial resistance within the framework on decontamination of poultry carcasses.

CONTAM

In the period 13 March to 8 June 2008, the CONTAM Panel met once in plenary (9-11 April) and adopted the following four opinions, one of which by written procedure:

- Cross-contamination of non-target feedingstuffs by diclazuril authorised for use as a feed additive;
- Cross-contamination of non-target feedingstuffs by nicarbazin authorised for use as a feed additive;
- Tropane alkaloids as undesirable substance in animal feed;
- Nitrate in vegetables – risk/benefit assessment

In the above mentioned period, 13 Working Group meetings were held related to the request on heavy metals in food (4 meetings), cross-contamination of coccidiostats (1 meetings) , marine biotoxins (2 meetings), undesirable substances in animal feed –section natural plant products (2 meetings) and polycyclic aromatic hydrocarbons (PAHs) (3 meetings). A new Working Group on nitrite as undesirable substance in animal feed was started and met already once.

CONTAM staff was actively involved in the scientific preparation of the colloquium on acrylamide which was successfully held on 22-23 May 2008 in Tabiano, Parma.

FEEDAP

During the period 13th March 2008 until 9th June 2008, the FEEDAP Panel held 22 Working Group meetings and two plenary meetings during which seven opinions were adopted. In addition, one technical hearing took place to discuss a specific dossier on a coccidiostat.

Two Stakeholders meetings were organised during this period. The first one was held on 23rd of April in Ghent with the EMFEMA members on “The assessment of minerals and trace elements as feed additives in the EU” and the second one on the 25th April in London, organised jointly with the FSA on “The assessment of silage additives in the EU”. The aim of these meetings was to explain the general procedure for the authorisation process of trace elements and silage additives in the framework of Regulation (EC) No 1831/2003, as well as to give information on how to perform the assessment of safety and efficacy of these types of additives.

In view of the re-evaluation of the feed additives currently available in the EU market and taking into account the important workload (more than 2500 feed additives registered in the Community Registry of Feed Additives), EFSA has invited the representatives of the European Commission (SANCO D2) to the FEEDAP Plenary Meeting in April in order to discuss several aspects which need consideration within the re-evaluation process as for example the organisation, coordination and use of available resources, potential criteria for prioritisation and a timetable.

On 6th June, EFSA was invited to the Working Group Meeting of the Standing Committee on Food Chain and Animal Health (SCFAH), in order to continue the discussion on the work-plan and the general implications of the re-evaluation in the framework of the provisions set in Article 10 of the Regulation (EC) 1831/2003.

GMO

In the period 12 March to 9 June 2008, the GMO Panel had three plenary meetings in Parma. During this period the GMO Panel adopted five scientific opinions

- a scientific opinion on the application for the placing on the market of Carnation Moonagua 123.8.12 (notification C/NL/06/01) under Directive 2001/18/EC
- a scientific opinion on the application for the placing on the market of Econase XT (FAD-2007-0020 under Regulation (EC) No 1831/2003; GMO/FEEDAP co-opinion)
- an updated version of the Guidance document of the GMO Panel for the risk assessment of genetically modified plants and derived food and feed
- an opinion on the possible safety concerns of admixture in food and feed of non-authorised GM maize event DAS 59132
- a scientific opinion on the application for the placing on the market of Danisco Xylanase G/L (endo-1,4-beta-xylanase) – request for an updated opinion

EFSA received seven mandates from the Commission requesting

- an update of scientific opinion on the application for the placing on the market of Danisco Xylanase G/L (endo-1,4-beta-xylanase),
- assessment of possible safety concerns of admixture of non-authorised GM maize event DAS 59132 in food and feed
- assessment of the scientific studies supporting safeguard measures and the suspension of cultivation of MON810 in Greece
- assessment of new information submitted by Austria in the context of its safeguard measures on MON810 and T25 invoked under Article 23 of Directive 2001/18/EC
- assessment of new information submitted by Hungary in the context of its safeguard measure on MON810 invoked under Article 23 of Directive 2001/18/EC
- assessment of new information submitted by Austria in the context of a safeguard measure adopted under Article 23 of Directive 2001/18/EC on oilseed rape GT73

- a consolidated opinion on use of antibiotic resistant marker genes (ARM) used as marker genes in genetically modified plants

Nine meetings were held with the standing WG:s on molecular characterization, food/feed safety, and environmental risk assessment of applications for placing GMO:s on the market within the framework of Regulation (EC) 1829/2003. Two additional WG meetings discussed the risk assessment of applications submitted under Regulations (EC) 1829/2003 and (EC) 1831/2003 for co-opinion by the FEEDAP and the GMO Panels (feed additives and biomass for feed purposes). Lastly, three WG meetings were held in the context of the self-task activities, one for “Assessment of Allergenicity of GM foods”, two for “Strategies for statistical analysis of data generated for the comparative food safety of GMOs”.

NDA

In the period of 20 March to 9 June 2008 the NDA Panel had one Plenary meeting on 22-24 April 2008 where the following opinions were adopted:

- Safety of synthetic zeaxanthin as an ingredient in food supplements: The Panel concluded that the safety of zeaxanthin as an ingredient in food supplements at the proposed use level of 20 mg/person/day has not been established.
- Safety of lycopene oleoresin from tomatoes
- Safety of synthetic lycopene

In the context of providing scientific advice on nutrient intakes, the Panel adopted the following draft opinions for public consultation:

- the principles for deriving and applying dietary reference values
- dietary reference values for water
- guidance for food-based dietary guidelines.

Public consultation will be launched before the summer. The remaining opinions on dietary reference values for macronutrients will be adopted and released for public consultation before the end of 2008.

Related to health claims, over 200 Article 14 applications (90% referring to children claims and 10% referring to risk reduction claims) have been received up to now. Some claims applications will be adopted in the July Plenary meeting. The consolidated Member States list on functional claims (Article 13 claims) is expected before the summer break (around 1500 claims). In order to prepare for the workload, some general principles for the scientific substantiation of claims are currently being elaborated. In addition 6 sub Working Groups on claims are currently being set up.

PLH

In the reference period the PLH Panel held 2 plenary meetings and one Working Group meeting. It was a period of intensive finalisation of the Panel's mandate on 30 PRAs made by France on organisms considered harmful for plants and plant products in the French overseas departments. Thirty opinions were published and presented at the Standing Committee of Plant Health on two occasions, on 31 March and 27 May.

The Panel has discussed two new mandates: (1) on request from the EC on citrus black spot and (2) a self-task on guidance document on evaluation of PRAs submitted for EFSA scientific opinion. The related Working Groups have been initiated.

The Panel has also started discussion on the EFSA role in scientific support for the decision making in plant health at the EU level. A preparatory meeting with the COPHS PRA Group took place in Ljubljana on 6 May.

PPR

The PPR Panel held two plenary meetings on 15-16th April and 17-18th June, and twenty three Working Groups took place since 27th March.

The opinion on cumulative risk assessment in human health (EFSA-Q-2006-160) was adopted by the Panel on 15th April 2008, a web story was published, this work was triggered by the 7th EFSA Colloquium on 28-29th November 2006 in Parma. The work on the opinion on the risk assessment for cumulative exposure of triazoles pesticides (EFSA-Q-2007-183), as an example illustrating the generic opinion adopted) is ongoing and was discussed in two parallel Working Groups in Residues and in Toxicology. The steering committee analysed the half-way report from the contractor (9-month procurement) on the exposure component.

The opinion on the Guidance Document on risk assessment for birds and mammals (EFSA-Q-2006-064) is foreseen for adoption on 17-18th June. A collaboration with Commission and Member States in autumn will allow to prepare a "ready to use" Guidance Document with management recommendation, as requested by MS in the final public consultation. A steering committee analysed the half-way report from the contractor (9-month contract under Article 36) regarding the development of a new Guidance Document on exposure of operators, workers, bystanders, and residents to pesticides (EFSA-Q-2008-261).

A new question was received from the Commission on toxicological effects of deltamethrin (EFSA-Q-2008-373), a Working Group started working. The Fate Working Group analysed the comments from the public consultation (close on 25th March) on the revision of the Guidance Document on persistence in soil (EFSA-Q-2007-184) and work-plan. Collaboration with JRC (Ispra) was developed on specific aspects. The Ecotoxicology Working Group is treating in parallel the issues on soil organisms, from their discussion emerged the need for a new self-task opinion regarding the usefulness of total concentrations and pore water concentrations as metrics for the assessment of ecotoxicological effects in soil, a Working Group will start in June. The work for the development of a new Guidance Document on emission from protected crop systems-greenhouses and cultivations grown under cover (EFSA-Q-2008-260) is ongoing; the outsourcing of some work via procurement is in preparation.

SCIENTIFIC COOPERATION AND ASSISTANCE

Scientific Cooperation

To date, 24 Focal Point agreements have been signed and two further agreements are ready to be signed. The last pending formal Focal Point nomination was received. The agreement with Norway can be signed as soon as the legal situation permits.

The second meeting between Focal Points and EFSA took place on 4-5 June 2008 in Parma. 26 Member States plus Norway and Switzerland attended. The discussion included the establishment of a list of scientific topics of common interest, the exchange of scientific information on the new Information Exchange Platform, communication activities, in particular regarding the launch of the expert database, Focal Point events at national level, and workshops to be held mainly in the newer MS to encourage experts to apply for EFSA's Scientific Panels and Scientific Committee.

Questionnaires were distributed to Focal Points to collect information on (a) risk assessment procedures in MS; and (b) surveillance data on the colony mortality in bees.

The list of Article 36 organisations has been updated and is fully operational. In 2008, 9 calls were launched under Article 36 and 8 under a procurement procedure on a budget of 1.1 and 0.3 million €, respectively.

The Scientific Colloquium on acrylamide, jointly organised with the CONTAM Panel unit, concluded that there is currently no need to revisit the risk assessment on acrylamide. The next colloquium on *Campylobacter* will take place in December 2008 in Rome.

The strategy to raise awareness of EFSA's scientific work is progressing well. The Scientific Committee and EFSA are currently discussing the development of the EFSA Journal to an online referenced journal. The first Working Group meeting to establish a platform to exchange scientific information took place on 23 May 2008. The terms of

reference were agreed on and actions were presented to Focal Points at the 2nd Focal Point meeting for consideration.

The 2nd meeting of the ESCO Working Group on the risks and benefits of food fortification with folic acid took place on 29 May in Dublin. An interim report on the situation in the different MS will be prepared by August 2008. An international scientific event is planned for 22-23 January 2009 in Sweden.

The second meeting of the ESCO Working Group on the expert database agreed i.a. on a final strategy to populate the expert database.

The unit has participated actively in meetings organised by Focal Points in Finland and Germany, and is invited to similar events in Norway, Portugal, Slovak Republic, Cyprus and Spain.

Assessment Methodology

EFSA started a self tasking to assess the relevance and robustness of the claim that a specific protein fragment (BCM7) resulting from human digestion of A1 β -casein in cows' milk is associated with a wide range of non-infectious diseases. A Working Group lead by DATEX will meet for a first time on the June 12. AMU provides the epidemiological expertise to this Working Group.

AMU provided together with the Zoonoses unit epidemiological support to the BIOHAZ mandate on the treatment of poultry carcasses with antimicrobials.

After some EFSA staff took a course in systematic literature review the AMU started a project on the adaptation and implementation of that approach in EFSA.

As a follow-up to the special Advisory Forum on GMO risk assessment, the Assessment Methodology Unit is providing, as needed, support for literature search and review regarding the related methodological aspects.

Help is provided to the Scientific Committee in the review of literature on cloning.

An ad hoc internal task force on aspartame has been set up in preparation of a special Advisory Forum meeting later this year. The Assessment Methodology Unit is a member of that ad hoc Working Group and is preparing an inventory of the available scientific literature or other relevant data on aspartame.

In addition AMU provides statistical support to the AFC Working Group assessing the 2nd Ramazzini study.

Based on a demand for the executive director the AMU prepared a review and overview of the scientific literature comparing efficacy of Sodium hydroxide with other compounds in biocidal products.

The Assessment Methodology Unit is responsible for the collection and analysis of progress indicators derived from the 2008 work plan for all units in the risk assessment and scientific cooperation and assistance directorate. This is an ongoing task.

DATEX

The DATEX Unit completed the initial assessment of more than 140,000 analytical results for cadmium in foods submitted by 20 Member States. The assessment is part of the CONTAM response to a Commission mandate requesting updated information on cadmium levels in food. The data collection set a new record for the Unit in relation to the number of analytical results handled.

As part of the authorisation process for several smoke flavouring applications, DATEX was asked by the AFC Panel to calculate potential exposure. A draft report was provided to the AFC during the period. Evaluation of occurrence data on polycyclic aromatic hydrocarbons and a full exposure assessment was completed as part of the CONTAM Working Group covering the topic.

Work for the CONTAM Working Group on marine biotoxins continued with completion of the exposure assessment section of the Opinion on Azaspiracids, a marine biotoxin occurring in shellfish. The evaluation included more than

12 000 data from some European countries where this contamination has been detected and monitored. Seasonal trends and geographical distribution was investigated.

Pesticide Risk Assessment Peer Review (PRAPeR)

For 2008 a new working programme was developed for the third and fourth stage of existing active substances on the basis of the Commission Regulation (EC) No. 1095/2007. According to the Regulation EFSA is to deliver some 60 conclusions within the first 9 months of 2008, i.e. by the deadline of 30 September laid down in the Regulation. To assist coordination of this work EFSA holds bi-weekly videoconferences with Commission services, and monthly telephone conferences with Member States to track progress and identify potential concerns. With regard to the completion of the Stage 3 review, in the year to the end of May, 14 conclusions were finalised and delivered to the Commission, with a further 5 anticipated to be delivered before the end of July. Five expert meetings were held in April, while 30 of the final 31 Stage 3 active substances are scheduled for discussion in two back-to-back rounds of expert meetings (with two meetings in parallel for each specialist section) in May - July.

With regard to Stage 4 of the review programme, the list of active substances to be peer reviewed has been subject to change. Currently there are 7 active substances of stage 4 scheduled for peer review. For 82 of the 100 substances of the fourth stage, the draft assessment report provided by the rapporteur Member State has been made available to the Commission and Member States. For 47 of these substances the draft assessment report has been distributed to the respective applicant(s).

On the 2nd of September 2008, EFSA will take over the responsibility for pesticide MRL risk assessment at EU level as stipulated in Regulation (EC) No. 396/2005. In order to prepare the implementation of that Regulation, EFSA already developed in close collaboration with Member States some templates for submission of data as well as the PRAPeR MRL workspace.

Zoonoses

The period of March to May was the reporting period provided for the Member States to submit their data on zoonoses from the year 2007, and by June all Member States except one had sent their reports. A special training day on the new reporting format for food-borne outbreaks was held in April to support the reporters. Also a meeting with the Community Reference Laboratories on zoonoses and the Commission was organised in April to discuss the activities of the parties and to enhance collaboration.

The unit organised nine Working Group meetings during the period and two of them addressed new mandates: harmonisation of the monitoring of verotoxigenic E.coli and revision of Salmonella/ Campylobacter baseline survey protocol.

All together 8 reports were issued, and 3 of them were reporting manuals to aid the annual reporting and two reports were on the analyses of EU-wide baseline surveys in turkeys and slaughter pigs providing the Salmonella prevalence estimates through out the Community.

Two new Article 36 grant calls were launched, one on harmonisation of monitoring of rabies and Q fever and one on survey methods for food-borne pathogens in foods.

In addition two country visits to France and United Kingdom were carried out to enhance the national reporting.

SCIENTIFIC COMMITTEE

The Scientific Committee had its 30th Plenary meeting on 21-22 April in Parma. The Committee 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, the Advisory Forum and the hearing of the Executive Director in the European Parliament. In

addition a discussion was started on possible subjects for inclusion in the SC's multi-annual work programme. Discussions will continue at the next plenary meetings before a final proposal will be provided to the Executive Director.

Scientific Committee Working Group meetings were held in the area of transparency in risk assessment – scientific aspects, animal cloning, welfare of experimental animals, nanotechnology, risk benefit assessment and benchmark dose approach in risk assessment.

As regards the SC activities, the following progress can be noted:

- At the April plenary the Scientific Committee endorsed a draft guidance document for the safety assessment of botanicals and botanical preparations. It will be published on EFSA's website together with a compendium of botanicals that have been reported to contain toxic, addictive, psychotropic or other substances that may be of concern, the comments received during the public consultation and a report summarising how these comments were addressed. A recently created ESCO Working Group on Botanicals has started testing the proposed safety assessment approach with real cases and will continue to work on the compendia of botanicals that have been reported to contain toxic, addictive, psychotropic or other substances that may be of concern.
- The Scientific Committee discussed also a draft opinion on animal cloning which had been updated taking into consideration the comments received during the public consultation. The Scientific Committee provided several comments that will be further considered by a drafting group. The aim is to submit a final draft to the Scientific Committee for adoption at its July plenary.
- The Scientific Committee discussed a draft opinion on transparency in risk assessment - scientific aspects at its April plenary. It has now been sent to the different EFSA panels for consultation. It is planned to submit a final draft of the opinion to the Scientific Committee for adoption at its plenary meeting in September.
- At the April plenary, the Scientific Committee considered the outcome of the working group on Nanotechnology. It is planned to have a draft opinion discussed at the July plenary.

ADVISORY FORUM

At the 26th AF plenary meeting in Rome on 10-11 April 2008, the AF discussed the outcomes of the first focal point meeting in Parma on 5-6 March 2008 and the status of the work of the AF Working Groups and the ESCO projects.

The draft EFSA decision on the selection of experts, the related expert database project plan and the proposed revised AF Extranet structure were commented and endorsed by the AF.

The AF members and EFSA staff also joined a crisis exercise aiming at testing and suggesting improvements to EFSA's draft crisis handling manual.

At the first special AF meeting on animal health in Parma on 27-28 May 2008, the AF representatives on animal health discussed EFSA's role in animal health, the EC animal health strategy and other issues of common interest, e.g. data collection.

COMMUNICATIONS DIRECTORATE

Communications activities

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

- On 5 May 2008, Catherine attended CIBUS Fair in Parma and gave interviews to local journalists. EFSA also had a stand throughout the fair (5-8 May). Around 800 visitors came to the EFSA stand where food industry professionals could learn about EFSA's role and what it does in the EU food safety system.
- On 6 May 2008, a joint press conference to launch the "Festa dell'Europa" was organised by EFSA in cooperation with the Commune of Parma, the Province of Parma and Europass. EFSA's Executive Director together with the Mayor of Parma and the President of the Province met local media to present and promote activities organised during the week to commemorate 9 May - Schuman Day. The EFSA organised activities and exhibition stand throughout the event attracted around 2,000 visitors from and around Parma.
- On 21 – 22 May 2008, Catherine visited the Hungarian Food Safety Office (HFSO) in Budapest and attended a joint conference on "Food Safety Challenges in Europe" organised jointly by EFSA's press office and the HFSO. The press office organised a meeting including Catherine & Mária Szeitzné Szabó, Director General of the Hungarian Food Safety Office and a number of Hungarian journalists. The media present included the Hungarian news agency, the key national daily, the most important business daily; the most widely read agriculture monthly and the HFSO in-house scientific journal. Catherine also explained how EFSA recruits its scientists and staff and she expressed the wish to have more Hungarian experts at EFSA, a message which was widely reported. The meeting was mentioned in the national press and in TV and radio bulletins.
- On 22-23 May 2008, in Tabiano, Parma, 80 scientists from 22 countries mainly from Europe, and including the United States, gathered for a Scientific Colloquium to debate the current state and future challenges regarding the potential toxicity and cancer risk associated with dietary exposure to acrylamide.
- On 5 June 2008, the Communications department "kicked off" a comprehensive promotion campaign in order to support EFSA's population strategy of the Expert Database. A special web feature (including a specific web banner) was prepared; an announcement was made to 445 specialist magazines and media; and the Focal Points and the Advisory Forum Communications Working Group were asked to support the promotion campaign. Other activities will follow shortly, including seminars mainly in some of the newer Member States to promote participation in EFSA's scientific activities, the preparation of a special information leaflet and targeted promotion letters to key national, European and International organisations involved in the scientific areas covered by EFSA.
- On 7 June 2008, EFSA had a stand at the DG SANCO village during the European Institution's open doors event in Brussels.
- On 9 June 2008, the Press office organised a joint event with the Dutch Food and Consumer Products Safety Authority (VWA) entitled "Future challenges to microbial food safety". Hubert Deluyker and Marta Hugas were interviewed by specialised media.

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

Press Releases:

- I. EFSA evaluates Southampton study on food additives and child behaviour (14/03/2008)
- II. The role of food in human exposure to antimicrobial resistant bacteria (17/04/2008)
- III. EFSA publishes EU-wide survey on Salmonella levels in turkeys (13/05/2008)
- IV. EFSA balances the consumer risks from nitrate in vegetables with the benefits of a balanced diet high in vegetables and fruit (05/06/2008)
- V. EFSA publishes EU-wide survey on Salmonella levels in slaughtered pigs (09/06/2008)

Southampton study on food additives and child behaviour:

As expected, there was a wide reaction to the Southampton study opinion in the UK (*Channel 4 News*, in *Reuters*, *Sunday Times*, *Financial Times* and *Daily Mail*) media, but it also generated interest in Spain (*El País*), Germany (*Süddeutsche Zeitung*), Ireland (*The Irish Examiner*), Finland (*Turun Sanomat*) and Sweden (*Svenska Dagbladet*).

The coverage was factual, though some media misunderstood EFSA's role headlining their articles: "EU watchdog won't ban 'problem' colours" or "EU rejects plea to outlaw 'dangerous' food colours that lead to hyperactive children". Others added some background on the number of studies on the subject carried out over the past 30 years and the

inability among researchers to find hard and fast evidence to link the additives with hyperactivity. All in all, much of the coverage did not stray too far from what we said in our press release and opinion. Even publications hostile to food additives had little more to say than the colours stay, the ADIs remain and no ban had been imposed.

Antimicrobial resistance:

EFSA press release on food as a source of antimicrobial resistance generated significant coverage in key UK media (*Reuters, Daily Mail*) and some coverage in the Netherlands, France, Germany and Finland. Many publications ran headlines saying EFSA was warning, or even sounding an alarm that antimicrobial resistance through food was on the rise. The *Daily Mail* reported that concern was rising over “superbug forms of common food poisoning bacteria such as campylobacter and salmonella”. Most media reported that EFSA recommended a review of the food safety regime across Europe as common antibiotics were becoming less effective in fighting human infections.

Salmonella in turkeys:

EFSA press release on Salmonella in turkeys generated extensive coverage in the UK (*Reuters, Guardian, Times, Farmers Weekly*) and mainstream media in the Netherlands, France, Spain, Sweden and Finland. The articles published were factual and explained that on average one third of commercial turkey farms in Europe were infected with salmonella but the two bacteria types that caused disease in humans were only found in 4 % of flocks reared for human consumption, and 2 % of breeding flocks. Although all articles were balanced, some headlines, such as “Salmonella rife among EU turkey flocks” (*Reuters*) or “One-third of turkeys for food chain had salmonella” (*Farmers Guardian*) may have given the impression that salmonella in turkeys was a more serious problem in Europe than it is. Many journalists looked at the detailed country data in the survey and reported on the results accordingly.

Web News Stories:

- I. EFSA report on animal feeding trials in GM plant evaluation published in a scientific journal (10/03/2008)
- II. EFSA says pests could pose risk to French overseas banana growers (31/03/2008)
- III. EFSA opinion on four substances used to decontaminate poultry carcasses: Assessment of effects on bacterial tolerance and antimicrobial resistance (02/04/2008)
- IV. EFSA assesses safety of lycopene in foods (14/04/2008)
- V. Update on bisphenol A (25/04/2008)
- VI. Further update on EFSA’s work on the evaluation of nutrient sources in food supplements (28/04/2008)
- VII. Sunflower oil: contamination with mineral oil from Ukraine - Update (28/04/2008)
- VIII. EFSA evaluates new proposed uses of the red food colour lycopene (30/04/2008)
- IX. EFSA gives advice on citrus pests in French overseas departments (21/05/2008)
- X. EFSA invites leading scientists to sign up to its new expert database (05/06/2008)

Articles following web news stories appeared mainly in the specialised media across Europe, such as *EU Food Law, NutraIngredients, FoodNavigator, NewsFood.com, Just Food, etc.*

EFSA opinion on four substances used to decontaminate poultry carcasses:

The opinion generated considerable media interest in France and Belgium and in specialised press and radio & TV channels across Europe. Most articles explained that there was a trade ban on American poultry imports since 1997 and that EFSA’s opinion was to help the European Commission make a decision whether to lift the ban. The reporting on the EFSA scientific findings was factual and although many journalists called EFSA’s conclusions mixed, they also added -- often quoting EFSA web story -- that a lack of scientific data on antimicrobial resistance of the substances examined did not allow EFSA to give the European Commission more guidance.

Bisphenol A update:

In the week of 16-20 April -- news from Canada and the United States dominated food-safety related news which impacted on EFSA. *Environment Canada* issued a draft screening assessment report on bisphenol A and *Health Canada* said it would be soon publishing a health risk assessment of bisphenol A from food packaging applications. This coincided with a draft U.S. NTP (National Toxicology Program) brief on bisphenol A, which raised fresh health concerns. Italian daily *Corriere della Sera*, in its report on the moves in Canada and the United States, referred to EFSA and said the Authority had already set the TDI and added that, therefore, Italian authorities were playing

down the scare stories. It quoted the ISS as saying that people's exposure was well below the levels set in Europe but if there was any new information on the effects of bisphenol it might have to be re-assessed. Further to publication of the web news story, EFSA's key topic section on Bisphenol A was updated.

Sunflower oil contamination:

The discovery that several shipments of Ukrainian sunflower that arrived in the EU were contaminated with mineral oil was extensively covered by the European media. Most articles referred to the EFSA's analysis of the oil samples that concluded that the mineral oil found in the Ukrainian shipments was not toxic due to its high viscosity. The sunflower oil crisis was most extensively covered by Greek and Spanish media, the two countries that received most of the Ukrainian oil shipments.

Web developments

The website has seen many improvements in terms of content, usability, site management, outreach and system administration. New content of particular weight include a new area dedicated to core management documents; the Experts Database, the Datex Concise European Food Consumption Database; new Key topic sections on Bisphenol A and Animal feed; and an update Key topics page on GMOs. Local awareness was highlighted through a new Europass page, and promotion of activities during Europe Week.

Core initiatives which improve web usability include better PDF file accessibility, achieved through file size reductions and up-front size indications; improved presentation of vacancies, notices, and speeches; less duplication of content; and better deep-linking from the homepage to a wider range of content. On-going site management projects include translation policy quality assurance, and continued focus on web SOPs to help ensure best practice online presence for EFSA. The Communications Directorate has also continued to work closely with the IT unit to resolve considerable and persistent problems related to Web Content Management System performance.

A significant outreach initiative was the Focal Points web toolkit designed to assist the national Focal Points as they build web pages/websites. The toolkit aims to establish a Europe-wide coherent message on the Focal Points' role in relation to EFSA and the national AF member; correct use of EFSA logo; and accurate cross linking between the EFSA website and national Focal Point websites.

Publications

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

Scientific:

- Two EFSA supplements in scientific journals. One on foot-and-mouth in 'Transboundary and Emerging Diseases' (Vol.55(1) 2008), and the other on EFSA's report on animal feeding trials play in the safety and nutritional assessment of GM plants, in 'Food and Chemical Toxicology' (Vol.46(1)2008).
- A scientific poster on additives in animal nutrition for the WPSA conference in Chalkidiki, Greece on 7-10 May was also produced.
- The 2006 Zoonoses report is currently being printed and will be ready for distribution soon.

Corporate:

- For the Festa dell'Europa and Cibus events 10 posters were produced explaining EFSA's work and its position in the EU food safety system.
- The Annual report and its summary, are currently being printed and will be ready for distribution at the Management Board meeting in Ljubljana.

ADMINISTRATION

Creation of Legal and Policy Affairs Unit

As of 16 April the Legal and Policy Affairs Unit was implemented joining legal staff and external relations staff in one Unit. The Unit liaises with EU Institutions, other bodies of the EU and other stakeholders that have a direct or indirect impact on the work of the EFSA. The objectives include the monitoring and compliance of all operations within the legislation applicable to EFSA: the sectoral legislation applicable to specific scientific areas and the general horizontal legislation.

Cooperation with the European Institutions

European Parliament

During the reporting period EFSA representatives participated in nine EP Committee meetings to monitor parliamentary developments on a series of items. This activity concerned inter alia the EU Animal Health Strategy; the proposed Regulations concerning residues limits of pharmacologically active substances in foods of animal origin; the White Paper on nutrition, overweight and obesity; the future legislation on the food improvement package (additives, enzymes and flavourings) that includes a common authorisation procedure; the proposal on a revision of the novel food Regulation; the EU existing ban on the use of chlorinated baths as antimicrobial agents in poultry production; financial questions covering the discharge for 2006 EFSA Budget and the Commission 2009 Budget.

EFSA appearances in Committees

On March 31, at the meeting of the EP Agriculture and Rural Affairs Committee, an EFSA representative was invited to present EFSA's work with regard to certain aspects related to the feeding of animal proteins to farm animals.

On April 2nd, the Executive Director gave a presentation on EFSA's achievements and the progress in planning for the future to the EP Environment Committee.

EFSA liaison MEP Kartika Liotard led an EP ENVI delegation who visited EFSA on 14 April 2008. The delegation was composed of MEP Magor Imre Csibi, Vice-chair of the ENVI, Committee and MEP Erna Hennicot-Schoepges, officials of the EP ENVI Committee, the Secretariat and Political Group, MEP assistants, the Dutch Senator Paul Peters as well as the Chair of EFSA's Management Board and the Chair of EFSA's Scientific Committee. The Executive Director and the EFSA Directors evolved into a constructive exchange of views with the delegation. Ms Liotard also kindly accepted the invitation to attend the Advisory Forum meeting in Oslo on 12 and 13 June.

Meeting Commissioner Androulla Vassilou

EFSA's Executive Director met the new Commissioner for Health Androulla Vassiliou on 3rd April in Brussels. Several issues were discussed and in particular the priorities for 2008, the challenges that the Authority is facing and in particular the workload and the mechanisms to address it.

European Commission

On 4 April 2008 and on 18 June 2008, the Executive Director met with the Director General of DG SANCO. EFSA also participated in the plenary meeting of the European Commission's Advisory Group on the Food Chain, Animal Health and Plant Health in March and its working groups on animal health and animal welfare aspects. In addition, EFSA representatives attended meetings of the Standing Committee on the Food Chain and Animal Health on invitation of the Commission's services.

EU Presidencies

At the invitation of the Slovenian Presidency EFSA participated at meetings of the Chief Veterinary Officers (CVOs) and the Chief Plant Protection Officers (COPHs) that took place in Brussels on 10th and 12th June respectively. At those meetings the Director of Risk Assessment and the relevant Units contributed with presentations on the current work of EFSA on animal health and in the context of the EU Animal Health Strategy, and on EFSA's role on pest risk analysis system.

EFSA already started its liaison with the EU Presidency Troika, France, Czech Republic and Sweden, in view of the preparation of their Presidency term. Arrangements are on-going for EFSA's Executive Director to meet representatives from the French Presidency in Paris in July.

Relations with Stakeholders

The 7th meeting of EFSA's Stakeholder Consultative Platform took place on 24-25 April in Parma. Discussion points included the modus operandi of EFSA's Scientific Committee and Panels and the assistance provided to them by EFSA's Scientific Co-operation and Assistance Department including data collection. The Platform also exchanged views on risk communication and on the external evaluation of EFSA's stakeholder activities. The next meeting of the Platform will take place on 17-18 October in Brussels and preparations are already on-going for dedicated meetings with the Platform on particular topics.

On 4 June 2008, EFSA was invited to present its stakeholder's strategy and activities to IFAH members, representing the EU industry of Animal Health.

On 9 and 10 June EFSA hosted the bi-annual BEUC meeting of Food officers of consumer organisations across Europe. EFSA's Executive Director welcomed the representatives of BEUC and national consumer organisations and had an exchange of views with them. Technical presentations were given by the NDA and the Biohaz panel secretariat

International Relations

The USDA delegation led by Dr. Larry Granger, Director of the Centers of Epidemiology and Animal Health visited EFSA on 5th of May 2008. On 23rd of April 2008 a delegation from Beijing Food Safety Administration, led by Mr. Zhang Zhikuan, Director General, Beijing Administration for Industry and Commerce, visited EFSA in Parma. On 28-29 April 2008 a delegation from the Chinese Academy of Agricultural Sciences visited EFSA and presented the latest legislation on Food Safety in China. On 7-8 May EFSA hosted a meeting with MERCOSUR representatives from Brazil, Argentina, Uruguay and Paraguay.

On 3-4 June 2008, the Chief Scientific Officer of NZFSA, Dr. Scott Crerar, visited Parma and shared information with EFSA colleagues.

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

In the reporting period three training seminars were held, involving 114 experts from the three candidate countries (41 Turkish, 26 Croatian and 47 experts from the Former Yugoslav Republic of Macedonia) The subjects covered by the seminars were a) BSE and other TSEs, Zagreb, 26-27 March 2008, b) EFSA Management Board and Advisory Forum, Izmir 24 – 25 April 2008 (c) Crises handling seminar, Skopje, 27/28 May 2008. Experts from the three Candidate countries also took part in the following EFSA meetings during this period.

Human Resources*Contracts for Temporary Agents and officials (until 31st May 2008)*

			RECRUITMENT (+)			END OF CONTRACT (-)				
	Staff foreseen 2008 (Establishment plan)	Total TA & Officials end Dec 07	Number of New Contracts	Newcomers	Change in contract, Cat. or Grade (*)	Departures (**)	Change in Cat. or Grade (***)	Contract expiry	"Net" Result	Total TA & Officials end May 08
AD	185	144	22	15	7	6	5	4	7	151
AST	150	129	9	5	4	7	1	0	1	130
Total	335	273	31	20	11	13	6	4	8	281

Contracts for all staff (until 31st May 2008)

			RECRUITMENT (+)			END OF CONTRACT (-)				
	Total staff number end Dec 06	Total staff number end Dec 07	Number of New Contracts	New comers	Change in contract, Cat. or Grade (*)	Departures (**)	Change in contract, Cat. or Grade (***)	Contract Expiry	"Net" Result	Total staff number end May 08
AT + Officials	173	273	31	20	11	13	6	4	8	281
AUX ¹	24	4	0	0	0	3	1	0	-4	0
CA	24	24	18	17	1	1	4	0	13	37
END	7	9	0	0	0	0	0	0	0	9
Total	228	310	49	37	12	17	11	4	17	327

(*) = EFSA's staff recruited to TA posts (including AUX, CA, END) at EFSA.

(**) = Resignations, termination of contract after probationary period.

(***) = EFSA's staff leaving their TA post in order to be recruited to a new TA post at EFSA (AUX, CA, END not included)

¹ Auxiliary Contract types ended at 31/12/2007

Budget execution

EUR 28.3 million or 43 % of the EUR 66.4 million budget including the Pre-accession program was committed. The commitment level is in line with the forecast made at the beginning of the year (EUR 28.1 million).

EUR 16.1 million or 24 % of the total appropriations were paid. This payment level is fairly in line with the forecast made at the beginning of the year (EUR 16.5 million).

The transfers from one chapter to another or from one title to another executed until 10/06/2008 represent 2.42 % of the 2008 appropriations.

The budget Forecast indicates a 96 % budget execution at year end with a 100 % execution rate under the operational and infrastructure component of the scientific activities

The Management Board will appreciate the detailed information on the budget execution, forecast and budget transfers provided in separate documents.