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Management Board  
27 March 2008  
Pafos, Cyprus

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EXECUTIVE DIRECTORATE

PROGRESS REPORT

January 2008 – March 2008

Highlights

The first meeting between Focal Points and EFSA takes place in Parma in March. Focal Points agreement signed to date reached 21

The Executive Director visits the Slovenian Ministries of Agriculture and Health in Ljubljana on the 22/02. On the 28/02 the Executive Director visits the Swedish National Food Administration and National Veterinary Institute. The following day the visit continued with the European Centre for Disease Prevention and Control. A visit was also spent the Norwegian Royal Ministry of Health and Care Services.

New Zealand's Minister of Food Safety and Ambassador in Rome and the US Agriculture Attaché visit EFSA.

The outcome of the special Advisory Forum on GMO risk assessment in Europe is published.

Opinions adopted include: food additives, nutrient sources, flavourings, nutrient profiles, animal health, Salmonella in meat, antimicrobial resistance, contaminants, enzymes in feed, GMOs, nutrient profiles and an analysis of the Southampton study on the effects of certain food colours and benzoic acid on hyperactivity in children.

A special issue on Bluetongue – comprising 13 manuscripts and entitled "*The EFSA epidemiological study on the 2006 Bluetongue outbreak in Western Europe*" – is sent to publishers.

**SCIENCE**

**RISK ASSESSMENT**

1. AFC

The AFC Panel held its 27<sup>th</sup> and 28<sup>th</sup> plenary meetings in Parma on 29-31 January and in Brussels on 6-7 March, respectively. 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 food additives area, the opinion on lycopene was adopted in January and the opinions on Rosemary extracts and on the Study from the Southampton University on the effect of some colours and benzoic acid on hyperactivity were adopted in March. In the field of nutrient sources, the opinion on Vanadium sources was adopted at the January meeting. In the field of flavourings, two Flavouring group opinions and three opinions on revised Flavouring Group Evaluation (FGE), as well as eleven groups of substances evaluated by JEFCA and considered by the AFC Panel, were adopted at the 27th meeting. At the 28th meeting, the Panel adopted one FGE and agreed that three FGEs could be adopted by Written Procedure. In the field of food contact materials, a 18<sup>th</sup> list comprising six substances was approved. The deadline for submission of public comments on the guidelines

for evaluation of recycling processes of plastics expired on 6 March. The comments received will be addressed and a new draft will be prepared for adoption by the Panel.

Regulation 202/2008 of the 4<sup>th</sup> of March amending regulation 178/2002 with regards to the number and names of EFSA's scientific panels, and particularly with regards to the split of the AFC panel was published in the Official Journal.

The call for expressions of interest for the membership of the scientific panels ANS (Panel on Food additives and nutrients sources added to food) and CEF (Panel on Food Contact Materials, Enzymes, Flavouring and Processing Aids) will close on the 17<sup>th</sup> March. Up to the 13<sup>th</sup> of March, 107 candidates had applied.

A possible decision on the composition of the panel is scheduled for the 29<sup>th</sup> of April 2008

## 2. AHAW

Between 23 January and 12 March, the AHAW Panel held one plenary meeting (30-31 January). The opinion on "Tuberculosis testing in Deer" was adopted; this opinion included the last Commission request to add the sanitary requirements for trade between non-free herds/countries. The report on "Welfare of salmon" was discussed and acceptance was postponed for the plenary meeting on 13-14 March.

A new mandate was received from the Commission in February concerning the list and criteria for susceptible fish species.

In relation to the mandate on "Fish welfare", the WG held a meeting with experts from Members States under the umbrella of the Advisory Forum including the most relevant stakeholders in March 4, with the participation of more than 45 experts. All relevant scientific information provided by the Member States experts and stakeholders will be evaluated and considered for the scientific opinion.

During this period, the AHAW scientific staff organized 17 WG meetings on mandates related to CSF, BT, AI, Fish susceptible species, welfare of Dairy cows and Fish welfare (trout, carp eels and sea Bass) issues.

Representatives of the AHAW Unit gave presentations on the activities of the Panel at the following events: i) OIE Group on List of Aquatic disease, January 23-24-25, Paris ii) Veterinary Regulations Conference, March 4-5 in Dublin iii) Meeting with IFAH 12 March in Parma iv) Meeting with FAO experts on fish welfare and Bluetongue 20 February Roma

In addition ,AHAW scientific staff attended to the following meetings a, i) SCoFCAH WG meeting on 5-6 February and 4-5 March, ii) Training on Surveillance of Methods in Fish Diseases, February 7, Cesenatico, iii) Climate related transboundary pests and diseases including relevant aquatic species FAO, February 25-26-27, Rome, iv) Advisory Group for the Animal Health strategy, February 27, Brussels, v) Aquatic Animal Health Standards, March 3, Paris, vi) Wrapstun project under art 36, March 3-4, Brussels, vii) EU Environment & Health Action Plan EU Parliament, March 6, Brussels ix) Aquatic animal health standards committee, OIE, March 5-7, Paris and x) CVO meeting on Bluetongue on 12 March in Brussels,

## 3. BIOHAZ

The following opinions were adopted at the BIOHAZ Plenary of 23-24 January:

- A quantitative microbiological risk assessment on *Salmonella* in meat: Source attribution for human salmonellosis from meat
- Biological Safety of a Process for the Hydrolysis on-Farm of Dead Pigs
- Biological Safety of a Process for the Hydrolysis on-Farm of Dead Rabbits

Furthermore, following a request from the EC, a scientific report was published on:

- Scientific and technical clarification in the interpretation and consideration of some facets of the conclusions of its Opinion of 8 March 2007 on certain aspects related to the risk of Transmissible Spongiform Encephalopathies (TSEs) in ovine and caprine animals

The following opinion was adopted at the BIOHAZ Plenary meeting of 5-6 March:

- Assessment of the possible effect of the four antimicrobial treatment substances on the emergence of antimicrobial resistance

At the same Plenary, the BIOHAZ Panel agreed to send the draft opinion on “Foodborne antimicrobial resistance as a biological hazard” to public consultation

Working Groups are being established for the following self-tasking mandates:

- Follow up on the QPS approach for assessing the safety of microorganisms intentionally added to the food chain
- Overview of source attribution methodology

Working Group meetings have been held for the following two new mandates which were requested by the EC:

- Assessment on the risk for human and animal health related to the Revision of the BSE monitoring regime in some member states (MS)
- Assessment on the risk related to TSEs from carcasses of ovine and caprine animals below 6 months of age intended for human Consumption

The first meeting of the consortium formed under the Article 36 grant on Quantitative Microbiological Risk Assessment on *Salmonella* in breeder and slaughter pigs was held. A call for data and related workshops, scheduled for 21-24 April, has been organised.

#### 4. CONTAM

In the period 24 January to 12 March 2008, the CONTAM Panel met once in plenary (19-21 February) and adopted five opinions and one statement:

- Perfluorooctane sulfonate (PFOS), perfluorooctanoic acid (PFOA) and their salts;
- Mercury as undesirable substance in animal feed;
- Cross-contamination of non-target feedingstuffs by decoquinate authorised for use as a feed additive;
- Cross-contamination of non-target feedingstuffs by robenidine authorised for use as a feed additive;
- Cross-contamination of non-target feedingstuffs by halofuginone hydrobromide authorised for use as a feed additive;
- Statement on fatty acid esters of 3-chloro-1,2 propanediol (3-MCPD esters).

In the above mentioned period, eight working group meetings were held related to request heavy metals in food (2 meetings), cross-contamination of coccidiostats (2 meetings), marine biotoxins (2 meetings), and polycyclic aromatic hydrocarbons (PAHs) (2 meetings).

CONTAM staff is actively involved with the scientific preparation of the colloquium on acrylamide (22-23 May 2008).

#### 5. FEEDAP

During the period February 2008 until 12<sup>th</sup> March 2008, the FEEDAP Panel held 11 working groups and one plenary meeting during which one opinion was adopted and one opinion was proposed for written adoption.

In addition, two technical hearings had taken place, to discuss a specific dossier with DSM and general issues, covering completeness check, confidentiality and administrative procedures with the representatives of IFAH.

After adoption by the Standing Committee on Food Chain and Animal Health (SCFCAH) of the 'Commission Regulation on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives', EFSA is implementing a series of Technical Guidance Documents that will contribute in the preparation and presentation of feed additives dossiers. In this framework, EFSA has met industry representatives of the Feed Additives Association – FEFANA – to identify their needs on this area.

In view of the re-evaluation of the feed additives currently available in the EU market and taking into account the important workload (approximately 2500 feed additives registered in the Community Registry of Feed Additives), EFSA had a meeting with the representatives of the EC and the CRL in order to discuss the work-plan and the possibility of setting a list of priorities and a calendar, according to the provisions of Article 10 of the Regulation (EC) 1831/2003.

## 6. GMO

In the period January to 12 March 2008, the GMO Panel had one plenary meeting, in Parma on 30-31 January 2008. At this meeting, the GMO Panel adopted i) a scientific opinion on the GM aspects of the microorganism used for the production of the feed additive L-Valine (this is a co-adoption between FEEDAP Panel and GMO Panel for an application submitted under Regulation (EC) 1831/2003); ii) a scientific opinion on the application for the placing on the market of GM T45 oilseed rape for food and feed uses, import and processing (EFSA-GMO-UK-2005-25); iii) a scientific opinion on the application for renewal of the authorisation of GM T45 oilseed rape used as existing food additives and feed materials produced from oilseed rape T45.

EFSA received two mandates from DG Environment, one regarding an update of EFSA guidance document for the environmental risk assessment of GMOs, the second one regarding the French Safeguard clause on MON810 maize under Directive 2001/18/EC and Emergency measures under Regulation (EC) 1829/2003.

Seven WG meetings were held on the molecular characterization, food/feed safety, and environmental risk assessment of applications for placing GMOs on the market within the framework of Regulation (EC) 1829/2003. Two 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). Three WG meetings were held in the context of the self-task activities, one for "Assessment of Allergenicity of GM foods", one for "Strategies for statistical analysis of data generated for the comparative food safety of GMOs" and one for "Guidance for the risk assessment of GM plants used as production platform for non-food products". Two special WG meetings were dedicated to the request of the European Commission to update the EFSA Guidance Document.

In addition,

- EFSA finalized and published, on 5 March 2008, the overall opinion of applications EFSA-GMO-UK-2005-25 (T45 oilseed rape) and EFSA-GMO-RX-T45 (T45 oilseed rape for renewal) submitted under Regulation (EC) 1829/2003.
- EFSA published the outcome of the special advisory Forum on GMO risk assessment in Europe (held 13 November 2007).
- EFSA published its report from the self-task activity on animal feeding trials in GM plant evaluation on the EFSA webpage and in the peer-reviewed scientific journal Food and Chemical Toxicology 46 (2008)S2-S70).

## 7. NDA

### *Nutrient profiles*

The NDA Panel has adopted on 31 January 2008 its Opinion on "The Setting of Nutrient Profiles for Foods bearing Nutrition and Health Claims pursuant to Article 4 of the Regulation (EC) No 1924/2006". The release of the Opinion was accompanied by an EFSA press release and press conference to explain the main outcomes and the scientific criteria that could be utilised by EU policy makers in assessing which foods may carry nutrition and health claims. The Panel advised that the main scientific consideration in establishing nutrient profiles is the potential of a food to adversely affect overall dietary balance, as defined by nutrient intake recommendations. In preparing its scientific advice to the Commission the Panel also considered views from stakeholders resulting from two consultation events, i.e. the EFSA Conference on Nutrition and Health Claims (EFSA, 2006), and the EFSA Scientific Colloquium on Nutrient Profiles (EFSA, 2007).

In addition to this Opinion, EFSA will continue to assist the European Commission in establishing a nutrient profile scheme, by developing a suitable food composition database and providing advice on its use in testing any proposed system.

### *Information meeting of external experts for the evaluation of health claims*

The NDA panel is currently increasing its pool of external experts to assist the Panel and its working groups related to the mandate of the NDA Panel under the framework of the Regulation (EC) No 1924/2006 on nutrition and health claims made on foods. On 6 and 7<sup>th</sup> March an information meeting with external experts was organised to explain the NDA work programme and working procedures with respect to health claim applications. By taking into account their declarations of interest and the expertise required, external experts may be called upon when a particular expertise/assistance is needed.

### Population Reference Intake

The working group on the PRI continues to proceed with the scientific advice on macronutrients.

### Novel Foods

A working group meeting was held in Parma on 18 February. The Working Group has agreed to forward two opinions (tomato oleoresin lycopene and synthetic lycopene) to the NDA Panel for written adoption.

### NDA Plenary meeting

The NDA Panel has held its 19<sup>th</sup> Plenary meeting on 30-31 January 08. Main topics on the agenda were "Nutrient Profiles" and the organisation of the Panel's tasks on claims.

## 8. PLH

One plenary meeting was held on 20-21 February. The Panel adopted 7 opinions out of the batch of 30 related to pest risk assessments (PRAs) on pests considered harmful for the four French Overseas Departments (FOD: Guadeloupe, French Guiana, Martinique and Reunion) in the context of Directive 2000/29/EC. Further 10 draft opinions were recommended for written adoption. Issues requiring harmonisation along the permanent working groups were tackled by a joint Working Group on FOD PRAs, which met the week preceding the plenary.

On 18<sup>th</sup> February a meeting with SANCO services took place to discuss the role of the Panel in the peer-review of pest risk assessments and to harmonise the understanding of the economic impact required by the international standards. A strategy paper on the role of the Panel will be drafted and discussed with the stakeholders to assure effectiveness of the available resources.

The Scientific Coordinator of the Panel attended on 19<sup>th</sup> February the meeting of the Panel on Phytosanitary Risk of the European and Mediterranean Plant Protection Organisation. EFSA's role and activities in risk assessment were presented with particular attention to Plant Health.

## 9. PPR

The PPR Panel held one plenary meeting on 12-13th February, and WGs.

The WGs on Toxicology and Residues discussed the draft opinion on cumulative risk assessment in human health (EFSA-Q-2006-160) scheduled for adoption in April 2008.

The work of the contract to outsource the preliminary work on the exposure component in the context of the self-tasked question on the risk assessment for cumulative exposure of triazoles pesticides is ongoing (6-month procurement) and was discussed in 2 parallel WGs on Residues and in Toxicology.

A steering committee is following the work of the contract (9-month call under Article 36) to outsource the preparatory work for the development of a new Guidance Document on exposure of operators, workers, bystanders, and residents to pesticides.

The revised draft of the Guidance Document on risk assessment for birds and mammals was on the EFSA website for public consultation until 27<sup>th</sup> January 2008. The core WG met on 17-18th March to analyse the 127 pages of comments. The adoption is foreseen before summer.

The first public consultation on the revision of the Guidance Document on persistence in soil will close on 25<sup>th</sup> March, the Fate WG discussed the work-plan. An Ecotoxicology WG will treat the issues on soil organisms in parallel.

The work for the development of a new Guidance Document on environmental exposure in greenhouses was started by the relevant WG, the outsourcing of preliminary work is under discussion.

## SCIENTIFIC COOPERATION AND ASSISTANCE

### 1. Scientific Cooperation

The Scientific Cooperation Unit has nearly completed the recruitment. The unit continued its work in facilitating cooperation between EFSA and Member States:

- i. The first meeting between Focal Points and EFSA took place on 5/6 March in Parma. 25 Member States plus Norway, Switzerland and the Commission participated. Focal Points exchanged first experiences with regard to setting up the Focal Point network in their countries and discussed how to intensify the cooperation between EFSA and Member States. To facilitate the exchange of views, meetings of Focal Points and EFSA were considered extremely useful and are planned to take place regularly from now on.
- ii. Contacts with all Member States regarding Focal Point agreements took place. To date, 21 agreements have been signed and several agreements have been sent to the respective Member States for signature. The remaining agreements will follow as soon as administrative issues in the respective Member States have been solved.
- iii. Following the first working group meeting on the expert database, the project plan has been revised and sent out again for consultation to WG members and internally within EFSA. The project plan is expected / prepared to be submitted for discussion and possible endorsement to Members of the AF at the coming meeting in April. Following this, the pilot phase can start immediately.
- iv. Article 36 list: The updating of the contact details for electronic mail of the Article 36 database has been finalised. The further development and migration of the database to the CRM platform is ongoing. A procedure to monitor the launching of calls under Article 36 is about to be established.
- v. The planning of the Colloquium on acrylamide has started in cooperation with the CONTAM Panel Unit and the Communications Directorate. It will take place in Tabbiano (Italy).

- vi. An EFSA internal steering group on the strategy to raise awareness of EFSA's scientific work has been established and met for the first time. The strategy has also been presented to the Scientific Committee and was well received. Member States have been contacted to nominate delegates for a small task force to discuss the structure of a platform to exchange scientific data between Member States and with EFSA;
- vii. The 2nd meeting of the ESCO Working Group on folic acid food fortification is scheduled to take place in May in Dublin. The Member State summary reports on the situation regarding folic acid are in the process of being submitted by the WG members, and the compilation of these documents by EFSA is under development.
- viii. 13 manuscripts for the Bluetongue special issue entitled "*The EFSA epidemiological study on the 2006 bluetongue outbreak in Western Europe*" have been received and forwarded to the editor (ELSEVIER). Publication of that special issue is planned for the first half of 2008. An article on the EFSA's 5th anniversary for the news section of *Trends in Food Science & Technology* has been accepted by the publisher and will be published shortly.
- ix. ECDC Stockholm (29/02) : a number of issues were presented and discussed during the visit. T. A MoU will be signed very soon. Best practices on crisis preparedness will be shared with ECDC and they have asked to share EFSA's expertise on the organisation of the work of the panels and experts.
- x. EFSA visited the Swedish Food Administration and the Swedish Veterinary institute. A first agreement was taken for the organisation of a joint workshop (EFSA-ECDC-Swedish Veterinary Institute) on anti-microbial resistance during the Swedish presidency. This will be organised in Stockholm in November 2009.

## 2. Assessment Methodology

The Assessment Methodology Unit is part of the WG evaluating the UK publication on the effects of certain food additives on child behavior. After an initial review of the Lancet paper and the Food Standards Agency report, the Assessment Methodology Unit proceeded with the re-analysis of the raw data and issued a statistical report to the working group. Results from that report were used in the opinion prepared by the WG and the opinion together with the statistical report in annex was adopted during the AFC plenary of March 6 and 7.

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.

EFSA started a self-task to assess the relevance and robustness of the claim that a specific protein fragment (BCM7) resulting from human digestion of A1  $\beta$ -casein in cows' milk is associated with a wide range of non- infectious diseases. An internal working group was set up and the Assessment Methodology unit will provide a technical review of the available epidemiological studies.

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 member of that ad hoc WG and is preparing an inventory of the available scientific literature or other relevant data on aspartame.

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

The Assessment Methodology Unit Multiple Framework Contract is used to outsource statistical tasks. Technical support was provided to the Zoonoses unit for the first call under this Framework contract on baseline study analyses. The Assessment Methodology Unit is, together with the Zoonoses unit, guiding the analysis of these baseline study results and checking the input provided by the consultants.

The unit is part of a working group on trend analysis modeling (set up by the Zoonoses unit). During a first meeting, tasks were distributed and the unit will explore Bayesian approaches in trend modeling.

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 directorates. This is an ongoing task.

Workload-tracking databases were developed and implemented for different units in EFSA.

Data management assistance was provided to the Praper unit in preparation for the collection of pesticide residue monitoring data by EFSA.

Short term consultancy was provided to the Scientific Committee and Advisory Forum unit, the NDA unit, the FEEDAP unit and the GMO unit.

### 3. Datex

The DATEX Unit published the review of dietary intakes of plant sterols from fortified foods in the European Union Member States requested by the European Commission. Food products with added plant sterols are widely available in the EU, such as yellow fat spreads and dairy products. Consuming plant sterols has been shown to help reduce blood cholesterol as part of a healthy diet. However, high doses can also reduce levels of carotenoids in the blood and thus a plant sterol intake of a maximum of 3 g per day is recommended. The report highlights that while there seems to be little over-consumption of such products in the EU, a small established subgroup appears to be consuming in excess of recommended amounts. It also reveals low consumer awareness of labelling and dietary guidelines for such products and of the need to consume sufficient fruit and vegetables to ensure robust blood carotenoid levels.

As part of the implementation of the nutrient and health claims legislation, the DATEX Unit has been developing databases of food composition across EU Member States. A national food composition database was compiled from information accessed from Denmark, Germany, Italy, Ireland, Norway, Sweden and the United Kingdom. This database now contains information on 35 macro- and micronutrients in approximately 18,000 food products. Using mathematical selection criteria a subset of the database containing a representative sample of about 700 products was produced and circulated to EU Member States for their work on nutrient profiling systems. Work is still continuing on a similar commercial database containing a limited range of nutrients in about 4,000 food products to measure the market impact of the new rules.

The work initiated by the Scientific Committee to develop a concise food consumption database has reached its first milestone. Summary consumption data from 14 Member States have been submitted to the EFSA web team for immediate publication. A further three countries are currently checking their final data and their results will be submitted as soon as cleared. Data from another five countries are being prepared with the help of BfR in the EFSA sponsored Article 36 project and are expected to be published well before the end of this year.

The DATEX Unit is coordinating the EFSA self mandate to assess the relevance and robustness of the claim that a specific protein fragment (BCM7) resulting from human digestion of A1  $\beta$ -casein in cows' milk is associated with a wide range of non-infectious diseases. As a first step, an internal working group was set up with participants from the Scientific Cooperation and Assistance Directorate to provide a technical review of putative mechanistic modes of action, toxicology and epidemiological results. An external working group to guide the work will be set up shortly.

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

The pesticide peer review process continued with the distribution of draft assessment reports for 3 new active substances and 6 existing active substances of the fourth stage to the respective applicant(s) and Member States. For the new substances, the public versions of the reports were produced and made available on the EFSA website, initiating a 40-day public consultation period. This will follow also for the 6 existing substances. For 71 substances of the fourth stage, the initial risk assessment provided by a designated rapporteur Member State was made available to the Commission and Member States. For three substances of the third stage, the conclusion on the risk assessment was finalized and submitted to the Commission. Conclusions of the risk assessment for another 11 substances are in

the process of being finalized prior to end of March while another 36 substances are at different stages of the peer review.

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, which entered into force on 28 Sept. 2007.

The European Commission requested an update of the risk assessment in the framework of the setting of temporary MRLs. In reply to this request, EFSA presented an addendum to the opinion on the safety of proposed temporary MRLs on 15 February 2008 covering 102 active substances. In the course of the temporary MRL exercise, EFSA developed a database on toxicological reference values which was presented to the Member States in January 2008.

## 5. Zoonoses

The Zoonoses Task Force held one meeting on 11-12 March. The main focus of the meeting was in the starting reporting period for 2007 zoonoses data. The new version of the Zoonoses Web Reporting Application was introduced and the reporting manual and specific guidelines for the 2007 reporting were adopted together with a document on a new format of the Community Summary Report. Also, the guidance for the reporting and monitoring provided by the BIOHAZ and AHAW panels opinions were considered and greatly appreciated.

In addition, the Task Force adopted a report on specifications for harmonised monitoring and reporting of antimicrobial resistance in *E.coli* and *Enterococcus*, which are the two indicator organisms for the general occurrence of resistance in animals.

Three Working Group meetings were organised during the period and two of them addressed the development of statistical trend analyses of the zoonotic agents in the Community Reports and one concerned *Salmonella* baseline survey analyses.

In February, the intensive analyses of the *Salmonella* baseline surveys in turkeys and slaughter pigs were started in close collaboration with two contractors for the statistical and serovar analyses implementing weekly teleconferences. Also the Article 36 grant project on preparing proposals for harmonised monitoring and reporting schemes for zoonotic parasites began with a coordination meeting in February and consultation of the Zoonoses Task Force.

## SCIENTIFIC COMMITTEE

The Scientific Committee had its 29<sup>th</sup> Plenary meeting on 14-15 February 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 outcome of meetings of the Management Board, the Advisory Forum and a visit to EMEA. 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.
- The Scientific Committee discussed concerns raised by its members that the assessment of claims submitted by Member States under Article 13 of Regulation (EC) 1924/2006 foresees that EFSA will be looking at efficacy aspects whereas the safety of products with an associated claim will not be addressed. Concern was raised that providing an opinion on efficacy aspects only could be misunderstood as an approval of the safety. It was agreed that these concerns will be further described and shared with DG SANCO in order to identify possible solutions, e.g. a legal disclaimer on EFSA's opinions.
- The Scientific Committee was informed that EFSA will launch a call for external experts of the Scientific Committee.

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

In February, the second meeting of the ESCO WG emerging risks took place. The WG agreed to create three subgroups, each with specific tasks to fulfil. The three subgroups will work independently and meet to exchange views and share achievements. The next plenary meeting of the ESCO WG emerging risks is foreseen in December 2008.

The public consultation on the draft guidance for the safety assessment of botanicals and botanical preparations was really successful with 55 pages of comments submitted by 60 contributors from the industry and producers associations, national food safety authorities (Sweden, Hungary, Swiss, UK) and EMEA. The working group of the Scientific Committee will review mid-march the comments for a possible update of the draft guidance document. The updated approach will then be tested with real cases by the recently-created ESCO WG on Botanicals.

The public consultation on the draft opinion on animal cloning ended on February 25<sup>th</sup>. The WG met in early March to consider the comments received during the public consultation (about 80 scientifically relevant comments from about 20 industry organisations, NGOs, private persons and national authorities) as well as at a dedicated meeting of the Stakeholder Consultative Platform with members of the Scientific Committee and its working group on the 7<sup>th</sup> of February. It is planned that the final opinion will be submitted to the April plenary of the Scientific Committee for adoption.

#### ADVISORY FORUM

At the 25th AF plenary meeting in Parma on 31 January – 1 February 2008, the AF discussed the progress in the various ESCO working groups and networks, a strategy paper on data collection as prepared by the SCA Directorate, the scientific cooperation activities in the Article 36 network and the outcomes of the meeting with national experts in GMO risk assessment which was held in November 2007. Besides the various fruitful discussions, the following issues can be mentioned:

- The Advisory Forum endorsed the recommendations and conclusions of the report of the meeting with national experts in GMO risk assessment that took place in November 2007.
- Two special AF meetings have been proposed in the area of animal health and plant health. These meetings will probably take place in May and October, respectively.
- The AF also agreed to organise a meeting of national experts on aspartame.

Table 1 Number of plenary and working group meetings, as well as the number of opinions, reports and statements confirmed adopted in the period January-February 2008

|             | Plenary Meetings | Working Group Meetings | Number of opinions / reports |
|-------------|------------------|------------------------|------------------------------|
| AFC         | 1                | 7                      | 12                           |
| AHAW        | 1                | 15                     | 1                            |
| BIOHAZ      | 1                | 12                     | 4                            |
| CONTAM      | 1                | 9                      | 5                            |
| FEEDAP      | 0                | 16                     | 1                            |
| GMO         | 1                | 10                     | 0                            |
| NDA         | 1                | 3                      | 1                            |
| PLH         | 2                | 12                     | 7                            |
| PPR         | 1                | 8                      | 0                            |
| SC          | 1                | 8                      | 0                            |
| PRAPeR      | 0                | 0                      | 0                            |
| TF Zoonoses | 0                | 3                      | 28                           |
| Total       | 10               | 103                    | 59                           |

## EXTERNAL RELATIONS

### 1. Cooperation with the European Institutions

#### European Parliament

EFSA representatives participated in the following EP Committee meetings: the Slovenian Presidency work programme in food safety, agriculture and of health; the EU Animal Health Strategy; the proposed Regulations concerning residues of veterinary medicinal products in foods of animal origin; and the prohibition on the use in stock-farming of certain hormonal substances. EFSA also participated in the meeting where the EP's reports on the White Paper on nutrition, overweight and obesity were presented.

On January 29, the Executive Director gave a presentation on EFSA's activities to the EP Budgetary Control Committee. At the invitation of the Executive Director in her capacity as Chair of the Advisory Forum, a representative of the EP participated in the EFSA Advisory Forum meeting on 31 January – 1 February in Parma.

On 13 February, MEP Avril Doyle, member of the EP Environment, Public Health and Food Safety Committee, hosted a public hearing on the new Community Animal Health Strategy and Vaccine Technologies. EFSA's Director of Risk Assessment was invited to speak and she outlined EFSA's activities in animal health and welfare.

The second edition of "EFSA Information to the European Parliament" was sent to the ENVI Committee in January 2008 and the third edition will be sent shortly.

#### European Commission

On 5 February, the Executive Director met with the Director General for DG SANCO for a bilateral meeting. EFSA 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 that were held in February. In addition, EFSA representatives attended meetings of the standing committee on invitation of the Commission's services.

### 2. Relations with EU Presidencies

The Executive Director visited the Slovenian Minister of Agriculture, Iztok Jarc and the Minister of Health, Mrs Mazej Kukovic on 22 February in Ljubljana. EFSA and representatives from the Slovenian Presidency discussed collaboration and exchanged ideas on the work programmes of the Authority and the Ministries of Agriculture and of Health. EFSA was invited by the Slovenian Presidency to participate in events in Ljubljana in August 2008. Milan Poganic joined the meeting with the Slovenian authorities. On the kind invitation of the Minister of Agriculture, EFSA Management Board will meet on 25<sup>th</sup> June in Ljubljana.

Preparations have already started with France, the Czech Republic and Sweden, which will hold the EU Presidency during the latter half of 2008 and in 2009, respectively. During the French Presidency, EFSA will hold its Advisory Forum meeting in September in Paris. On the kind invitation of the French Presidency, the Management Board will meet in Paris in early October. A joint event with the French authorities is planned on that occasion. EFSA will also be associated with several conferences that the Presidencies are planning in 2008 and 2009.

### 3. Relations with Stakeholders

#### Animal cloning

On 7 February, EFSA held a technical meeting in Brussels with its Stakeholder Consultative Platform to discuss the draft opinion on animal cloning. Publication of the final opinion of the Scientific Committee is anticipated in May.

#### Welfare aspects of farmed fish

On 4 March, EFSA held a consultation meeting with stakeholders and Member States experts to discuss its work on preparing a Scientific Opinion on Animal Welfare aspects of Husbandry Systems for Farmed Fish. Discussions focused on EFSA's draft Scientific Report on Farmed Salmon and on general issues relevant to all finfish species. EFSA is preparing separate Scientific Reports on other species including trout, carp, sea bass, sea bream and European eel.

#### Conferences

In March, EFSA announced a forthcoming conference with stakeholders on the assessment of silage additives in the EU, to take place in London on 25 April. The meeting will provide an opportunity to explain the basis for the procedures associated with the assessment of silage additives and for discussion between applicants, silage additive producers and associations involved in the preparation of dossiers and the experts who evaluate them.

### 4. International Relations

#### Visit of NZ Minister for Food Safety and NZ Ambassador in Rome

The Minister of Food Safety from New Zealand, Mrs Hon Lianne Dalziel, and the New Zealand Ambassador in Rome, visited EFSA on 3<sup>rd</sup> March. During the visit, EFSA's Executive Director and NZ authorities exchanged views on their respective work programmes and on the challenges in the food safety area.

#### Visit of officials from the US Embassy in Rome

EFSA welcomed the US Agriculture Attaché and Agriculture specialist from the US Embassy in Rome on 11<sup>th</sup> March. EFSA presented the work of the Authority for 2008, the achievements in 2007 and future challenges.

### 5. Pre-Accession Programme for Turkey, Croatia and Macedonia 2008

Under the new Instrument for Pre-accession Assistance (IPA), the European Commission has budgeted €500.000 for EFSA for the implementation of the action entitled: Preparatory Measures for the Participation of the Former Yugoslav Republic of Macedonia, Croatia and Turkey in EFSA.

The 200 programme will comprise a series of workshops and seminars, the topics of which were chosen in consultation with the Turkish, Croatian and Macedonian authorities and stakeholders. The Pre-Accession Programme

Steering Committee meeting took place on 20<sup>th</sup> February; discussions included project activities in 2008 and EFSA participation in the 2009-2011 Pre-accession Programme.

The first 2008 seminar on BSE and other TSEs will take place in Zagreb, Croatia on 26-27 March. EFSA's activities in BSE, other TSEs and ABPs (Animal By-Products) will be presented and the BIOHAZ Unit will describe the future role of EFSA in this field.

## COMMUNICATIONS DIRECTORATE

### 1. Communications activities: on- and offline

Since the last MB meeting the Communications Directorate has carried out a number of on- and off line communications activities aimed at raising EFSA's visibility in Europe:

- On the 7 February 2008 Catherine Geslain-Lanéelle was invited by the Norwegian Royal Ministry of Health and Care Services to speak at the "Seminar on Food Law and Regulations on Hygiene and Control" in Oslo. Besides meeting the Minister of Health and Care Services, EFSA's Executive Director had the opportunity to speak to a selection of Norwegian journalists covering food and feed safety related issues in the following publications: *Nasjonen*, *ANB* and *Dagligvarehandelen*. The "breakfast with media" was an occasion to give Norwegian journalists a direct overview of EFSA's work in the field of GMOs, health claims, animal health and welfare, colours and biological hazards.
- On the 22 February 2008, Catherine Geslain-Lanéelle visited the Slovenian Ministry of Agriculture, Forestry and Food in Ljubljana. The visit included meetings with the Minister of Agriculture and the Minister of Health. On this occasion the Press Office organised a short meeting over coffee with Slovenian journalists who report on food safety and health-related issues. The journalists represented the following media: Radio Slovenia, one of Slovenia's most important newspapers, *Dnevnik*, and the Slovenian state news agency, STA. The encounter was relaxed and focused mainly on EFSA's work on nutrient profiling and health claims as it was a few days ahead of publication of our press release on nutrient profiles.
- On 26 February, EFSA organised a press briefing on Nutrient Profiles in Brussels following the publication of the NDA Panel's opinion providing scientific advice on the setting of nutrient profiles for foods bearing nutrition and/or health claims. In total 15 Brussels-based journalists attended the briefing. Among them were 8 press agencies, 5 dailies, 1 TV station and 1 specialised food publication. The media present covered 9 EU countries (Austria, Belgium, the Czech Republic, France, Germany, Italy, Slovenia, Spain, the UK) and 1 was a pan-European outlet. The coverage to date is neutral and factual, with an industry slant in some specialised press. Further communications activities included revision of the health claims key focus page on EFSA's website, preparation of the FAQ on claims and on Nutrient profiles as well as a reactive Q&A.
- On 28 February 2008, Catherine Geslain- Lanéelle's visited the Swedish National Veterinary Institute, the Swedish National Food Administration and the European Centre for Disease Prevention and Control to discuss food safety topics and enhanced cooperation with EFSA. Our colleagues at the National Food Administration invited local/regional media to a short but colourful ceremony to mark the appointment of a representative of the Swedish National Food Administration as National Focal Point. Catherine also gave an exclusive interview to Henrik Ennart from Swedish influential newspaper *Svenska Dagbladet* on topics ranging food additives, food labelling and omega 3. Catherine's address to the National Food Administration was carried on its website and on EFSA's website with links to each other's home pages.

#### 1.1 Other events

An award ceremony celebrating the winners of the school competition “Comunica l’importanza di mangiare sano: sicurezza, qualità e corretta nutrizione” took place on 20th February. The competition was organised by Europass, Regione Emilia-Romagna and EFSA and launched in September 2007, within the context of EFSA 5 Year celebrations. This competition, intended for Emilia-Romagna region high schools, was aimed at communicating the importance of a healthy diet through the production of three possible communication tools: magazine, advertisement and multimedia product.

Participants to the ceremony - about 120 people among which: local authorities, students and teachers of the awarded classes. Local media (TV and newspapers such as TV Parma, Gazzetta di Parma, etc.) were also present.

## 2. Corporate / Science Press material: Press releases / Statements / News alerts / Web news stories:

### Press Releases / Statements:

- I. EFSA launches its draft opinion on animal cloning for public consultation (11 January 2008)
- II. EFSA statement on the publication of the opinion of the European Group on Ethics and New Technologies on ethical aspects of animal cloning for the food supply (17 January 2008)
- III. EFSA updates EU scientific advice on listeria risk in ready-to-eat foods (22 January 2008)
- IV. Which foods may carry nutrition and health claims? EFSA provides scientific advice to assist policy makers (26 February)

### Cloning:

The publication of the draft opinion on cloning received considerable publicity over a relatively long period of time. This relates to a number of factors: the close proximity of the draft with the FDA's final report on cloning; and the close follow-up of the EGE opinion.

Overall EFSA's draft opinion generated much interest and saw coverage in top media from the *Washington Post* to *Le Monde* and *The Financial Times*. News agencies and syndicated copy (e.g. from the *New York Times/International Herald Tribune* group of publications and agencies such as *Reuters*), also meant that the reach of the coverage was very wide with stories reproduced globally at national and local level.

A challenge with this media interest has been to clarify the positioning of EFSA and its risk assessment remit, compared to the role of risk managers. Most stories however were fairly accurate about the conclusions, despite often misleading headlines, stating conclusions as final rather than draft views.

There was a significant broadcast element to the story with Prof. Vittorio Silano giving interviews to a number of international radio (Italian, French and Slovak) and TV stations (e.g. Swedish National television).

Although interest in the EFSA opinion on cloning has declined in February and March the press office still receives a steady number of questions and interview requests on this topic.

### Listeria:

EFSA's listeria press release also generated good coverage considering it was fairly uncontroversial, triggering reports in France, Germany, Spain, Italy and the UK. Articles reported on the recommendations given by EFSA's BIOHAZ panel on packaging and preservation of ready to eat foods. EFSA was pictured in a positive light, issuing its assessments on listeria and recommendations aimed at protecting public health.

*The Berliner Zeitung, the Berliner Morgenpost, Italian news agency ANSA and Les Marches* reported on the recommendations made by the BIOHAZ panel to industry and to the consumer on how to try to avoid listeria in ready to eat meals. The German language version of the *AFP* report focused on the particular risks to pregnant women and the elderly.

The Danish National Food Institute issued a press release on listeria linking it to EFSA's publication. Danish media's news angle focused on the fact that Denmark is among the countries with the most significant prevalence of listeria infections. The Press Office was able to point journalists to further data on listeria released by EFSA in its annual zoonoses report issued in December.

Nutrient profiles:

A number of European media reported on the press release on nutrient profiles and the press briefing. The coverage was neutral and factual, with an industry slant in some specialised press such as *NutraIngredients* and *Food Navigator*. The four press agencies present at the briefing (AGI, ANSA, EFE, APCOM) and some national dailies such as *El Mundo* (ES) as well as majority of specialised pan- EU press e.g. *Just-food.com*, *EU Food Law*, *Newsfood.com* and *Food Production Daily* generated informative articles about the nutrient profiles opinion. However, some publications, such as APCOM and *Agra Europe* picked up the news published by BEUC's (European Consumers' Organisation), criticising the issue and EFSA's advice, i.e. BEUC expressed disappointment and concern about EFSA's opinion expecting EFSA's advice to go further into the definition of nutrient profiles. Prof. Albert Flynn presented EFSA's opinion to a delegation of BEUC following the press briefing, explaining our remit and the panel's key conclusions. A communications challenge will remain for EFSA to explain that the classification of foods and the setting of nutrient profiles are policy decisions, involving both scientific and non-scientific considerations, and therefore are the responsibility of the policy makers.

Web News Stories:

- I. Panel on additives, flavourings, processing aids and food contact materials to split (17 January)
- II. The 34th meeting of the Management Board - 23 January 2008 (23 January)
- III. EFSA works with Member States on best approaches to GMO risk assessment (30 January)
- IV. EFSA opinion on okadaic acid marine biotoxins (31 January)
- V. EFSA's evaluation of the safety of food flavouring substances- an update (31 January)
- VI. Animal Cloning: EFSA consults stakeholders on its draft opinion
- VII. EFSA issues opinion on nutrient sources containing vanadium

Articles following web news stories appeared mainly in specialised press throughout Europe, such as *EU Food Law*, *Newsfood.com*, *Food Navigator*, *Food e-News*.

GMOs:

Although EFSA did not publish any press release on GMOs after France signalled its intention to invoke the safeguard clause suspending the cultivation of GMO maize MON 810, extensive coverage was generated, in particular by French media.

Media, predominantly in Germany, reported on the new rules there on the labelling of GM food and GMO products. The move by the Bundestag laid new regulations on distances between fields growing GM crops and those that do not. The coalition government also agreed on more precise regulations for labels declaring foodstuffs to be "without gene technology", indicating that an animal has not been fed with GM feed.

### 3. Web developments

A new web area with details about senior operational management was launched. The area contains biographies, photos and declarations of interest of EFSA Management Team members, further enhancing transparency in regards to EFSA day-to-day management.

New content of particular importance included in-depth Key Topics sections introducing EFSA's role in nanotechnology and animal cloning. Transparency was enhanced in the consultation process on cloning when a meeting with stakeholders in February was immediately followed by meeting documents/presentations and participant details on the web and a meeting report was published shortly afterwards. With the publication of EFSA's Opinion on Nutrient Profiles, the existing online information on health and nutrition claims (FAQs and Key Topics) was enhanced and updated. An announcement was published on the forthcoming split of the AFC Panel and a link to the call for experts placed on the AFC Panel homepage. Under Scientific Co-operation, a new section introducing ESCO projects was added and initial upgrades were made to the existing section on National Focal Points including publicising the first meeting in Parma. Online consultations and calls for

data were issued on issues including nanotechnology, cloning, recycling of plastics for food contact materials and *Salmonella* in pigs.

In addition to content, several procedures have been improved and documented, with new guidelines for Management Board webcasting and best practice PDF document publication. The manual guiding management of online PAD requests and general inquiries has been significantly enhanced.

With a view to continually improve usability, current work areas include content management system performance and site management.

#### 4. Publications

Since the last MB meeting the following publications have been published:

- EFSA Work Plan 2008
- EFSA Meeting Summary Report no. 2: EFSA conference on Nutritiuon and Health Claims.

A poster referring to the Zoonoses report 2006 has been produced and a brochure on European Food Consumption Database (EFSA Scientific Colloquium Summary Report no. 3 is currently being printed and will be ready for distribution at the beginning of April.

### ADMINISTRATION

#### 1) Human resources

*Number of new contracts for Temporary Agents and Officials (until 31<sup>st</sup> March 2008)*

|              |   | RECRUITMENT<br>(+)                    |                               |            |   | END OF CONTRACT<br>(-) |                                    |                 |  |  |
|--------------|---|---------------------------------------|-------------------------------|------------|---|------------------------|------------------------------------|-----------------|--|--|
|              | Staff foreseen<br>2008<br>(establishment<br>plan) | Total TA &<br>Officials<br>end Dec 07 | Number of<br>New<br>Contracts | New comers | Change in<br>contract, Cat.<br>or Grade (*) | Departures<br>(*)      | Change in<br>Cat. or<br>Grade (**) | "Net"<br>Result | Total TA &<br>Officials<br>end<br>March 08 |  |
| AD           | 185   | 144                                   | 13                            | 10         | 3   | 5                      | 2                                  | 6               | 150  |  |
| AST          | 150   | 129                                   | 6                             | 4          | 2   | 6                      | 0                                  | 0               | 129  |  |
| <b>Total</b> | <b>335</b>  | <b>273</b>                            | <b>19</b>                     | <b>14</b>  | <b>5</b>                                    | <b>11</b>              | <b>2</b>                           | <b>6</b>        | <b>279</b>                                 |  |

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

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

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

*Number of new contracts for all staff (until 31<sup>st</sup> March 2008)*

|                  |                                     |                                     |                               | RECRUITMENT<br>(+) |   |                  | END OF CONTRACT<br>(-)                            |                 |  |  |
|------------------|-------------------------------------|-------------------------------------|-------------------------------|--------------------|---|------------------|---|-----------------|--|--|
|                  | Total staff<br>number<br>end Dec 06 | Total staff<br>number<br>end Dec 07 | Number of<br>New<br>Contracts | New comers         | Change in<br>contract, Cat.<br>or Grade (green) | Departures (red) | Change in<br>contract, Cat.<br>or Grade<br>(blue) | "Net"<br>Result | Total staff<br>number<br>end March<br>08 |  |
| AT+<br>Officials | 173                                 | 273                                 | 19                            | 14                 | 5   | 11               | 2   | 6               | 279                                      |  |
| AUX <sup>1</sup> | 24                                  | 4                                   | 0                             | 0                  | 0   | 3                | 1   | -4              | 0  |  |
| CA               | 24                                  | 24                                  | 16                            | 15                 | 1   | 0                | 3   | 13              | 37                                       |  |
| END              | 7                                   | 9                                   | 0                             | 0                  | 0   | 0                | 0   | 0               | 9  |  |
| <b>Total</b>     | <b>228</b>                          | <b>310</b>                          | <b>35</b>                     | <b>29</b>          | <b>6</b>  | <b>14</b>        | <b>6</b>  | <b>15</b>       | <b>325</b>                               |  |

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

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

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

<sup>1</sup> Auxiliary Contract types ended at 31/12/2007

## 2) Budget execution

### Transfers

No transfers occurred during the first quarter of 2008, the first transfers will be processed in April based on the forecasts provided by EFSA Directorates.

### Execution ratio and Forecasts

At the end of February, the budget execution reached 25% of the total budget (representing 16.5 M€) but it is too early to consider this ratio as truly representative of the activities conducted. The budget forecasts to be processed in June will be more representative.