



**PROGRESS REPORT MARCH - JUNE 2006: HIGHLIGHTS**

**Science Department**

1. EFSA convened a forum discussion meeting with scientific representatives from the 25 EU Member States, Switzerland and Norway to discuss with EFSA and its GMO Panel how to strengthen scientific co-operation in the risk assessment of GMOs. EFSA and the chair of the GMO Panel gave a detailed overview of its present risk assessment and consultation process and discussed together with the delegates how the Member States could be further involved in the future. This meeting is considered the first in a series of technical discussion meetings with MS national experts on GMO's. EFSA is currently developing a general approach for risk assessment of GMOs involving Member States' experts and providing adequate transparency on how experts' contributions are taken into account

**Number of scientific expert meetings**

2. In the period 30 March – 20 June 2006, 18 plenary and 75 working group meetings took place. An overview of the number of meetings and the 60 opinions (expected to be) adopted by the Scientific Panels, the Scientific Committee as well as the PRAPeR, Task Force on Zoonoses, and BSE/TSE working groups are presented in table 1.

**Scientific Committee**

3. The Scientific Committee endorsed the first part of its opinion on Transparency in Risk Assessment focusing on procedural aspects as well as an interim report on the safety assessment of botanicals and botanical preparations. Furthermore the SC is close to finalisation of two draft opinions on emerging risks and uncertainties in exposure assessment. In addition, the Advisory Forum was approached to help in establishing an EFSA network of food consumption database managers and an EFSA pool of exposure assessors with the aim to improve collaboration with Member States and initiate new harmonization activities in these areas.

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Table 1 Number of plenary and working group meetings, as well as the number of opinions and reports (expected to be) adopted in the period 30 March - 20 June 2006.

	Plenary meetings	Working Group meetings	Number of opinions/reports (expected to be) adopted
AFC	1	5	3 opinions + 2 statements
AHAW	3	8	3
BIOHAZ	2	13	4+1*
CONTAM	2	4	2
FEEDAP	3	9	11**
GMO	2	14	5
NDA	-	3	-
PPR	1	6	8
SC	2	4	2 (endorsed)
PRAPeR	2	-	18
Task Force on Zoonoses	-	9	1
<b>TOTAL</b>	<b>18</b>	<b>75</b>	<b>60</b>

\* 4 BIOHAZ opinions + 1 BIOHAZ chapter in an AHAW opinion

\*\* Seven documents have been endorsed by the FEEDAP Panel as part of the consultation to EFSA on the guidelines or as working documents to be submitted for public consultation

### AFC Panel

4. The last Plenary meeting under the current mandate was held early May in Rome where the opinion on aspartame was adopted. A successful press conference was organised in order to share the results of the assessment of the AFC Panel of a new carcinogenicity study on the sweetener conducted by the Ramazzini Foundation. In addition, the Flavouring Group Evaluations 24 and 26 were adopted as well as a statement on nickel chloride and on lactic acid for carcass decontamination.

### AHAW Panel

5. The panel has adopted scientific opinions concerning the role of migratory birds in the spread of Avian Influenza, the risk of dairy by products when used for feeding and the risk for calves health welfare with different housing systems. It is foreseen that the Panel will carry out an update of the Avian Influenza risk assessment later this year, taking into account all new data and the impact of migratory birds. The activities of the Panel also included work related to questions on Brucellosis, pig welfare, fish welfare, rabies, captive birds and Zoonosis.

### BIOHAZ Panel

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6. The Panel adopted an opinion on the quantitative risk assessment for human BSE risk posed by bovine vertebral column and dorsal root ganglia. This completes the set of five adopted QRA opinions. The opinion on the BSE-related risk from the use of skins and hides for technical purposes from cohort animals was also adopted.

7. Furthermore, a chapter on the food safety aspects of calf farming was adopted by the BIOHAZ Panel to be incorporated in the AHAW opinion on the risks of poor welfare in intensive calf farming systems. Other opinions adopted were on bovine tuberculosis aspects of a visual inspection system in veal calves and on the efficacy of a chemical to decontaminate meat surfaces.

### CONTAM Panel

8. The CONTAM Adopted an opinion on ochratoxin A (OTA) in food at its plenary meeting in April. In this opinion the Panel has given particular attention to the various mechanisms of toxicity as regards to OTA and was able to derive a tolerable weekly intake for OTA. It is foreseen that an opinion on hexachlorobenzene as undesirable substance in animal feed will be adopted in the June plenary meeting. Three new requests, one on marine biotoxins and two related to nitrite and mercury as undesirable substances in animal feed were received by the CONTAM Panel for the April meeting.

### FEEDAP Panel

9. The FEEDAP Panel has agreed and submitted the last of Guidelines / Guidance documents for the establishment of the dossiers for authorisation of feed additives, to the European Commission, which included : i) silage additives, ii) zootechnical additives : enzymes and microorganisms, iii) additives already authorised for use in food, iv) minor species and v) pets and other non-producing animals. This was the last part of a series of documents detailing the specific requirements for these categories / uses of additives and which complements the “Common Guidance / Specific Guidance(s) for the establishment of dossiers” sent to the EC on November 2005 and January 2006. A meeting has been held with DG SANCO in order to discuss the contents of the documents and the approach taken by EFSA in the preparation of these guidelines / guidance documents.

10. The Panel endorsed the working document on “Environmental Risk Assessment of Feed Additives : terrestrial and aquatic environments” which will be submitted to public consultation on EFSA’s website during a 3-months period.

### GMO Panel

11. The Panel adopted opinions on GM plants : GM maize 1507 x NK603 for food and feed uses, import and processing within the framework of Regulation (EC) 1829/2003 and GM Carnation Moonlite 123.2.38 for import of cut flowers for ornamental use within the framework of Directive 2001/18/EC. The Panel co-adopted an opinion with the FEEDAP Panel on Natuphos – 3 Phytase within the framework of

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Regulation (EC) 1831/2003, for which the GMO Panel performed the assessment of the GM aspects of the microorganism used for the production of the feed enzyme. The Panel adopted also an opinion on safeguard clauses invoked under Article 16 of Directive 90/220/EEC.

12. The Panel concluded on a guidance document for the risk assessment of GMMs and derived food and feed, after consideration of all comments received during the consultation of the draft guidance document which was published on the EFSA website for public consultation for a period of 2,5 months.

13. The Panel drafted a guidance document on the risk assessment of plants containing genetic modification events combined by crossing that will be published on the EFSA website for public consultation.

### NDA Panel

14. The NDA Panel did not meet in plenary in the above mentioned period, but its working groups made major progress on the establishment of nutrient based recommendations for macronutrients (such as energy, protein, carbohydrates, and fat) as well as on the assessment of novel food dossiers.

### PLH Panel

15. The creation of the new EFSA Panel on Plant Health was finalised. The panel was officially announced in the Commission Regulation No 575/2006 of 7 April 2006, which entered in force on 27/04. Also in result of the expert recruitment 21 experts with various expertises related to plant health were selected and approved by the MB. The entire internal infrastructure needed for running the new panel has been put in place and recruitment of staff planned for 2006 is well underway.

### PPR Panel

16. The Panel adopted in April opinions on the use of NOECs in long term risk assessment for mammals, on the mutagenic and carcinogenic properties of the insecticide dichlorvos, on the Guidance Document on AOEL, and on the overview of the risk assessment approaches and other toxicological considerations it concluded in the opinions adopted by the Panel in 3 years. The Panel adopted at the Plenary meeting in May, three opinions on the revision of Annexes II and III of Directive 91/414/EC and one opinion on the overview of the risk assessment approaches included in the opinions adopted by the Panel in 3 years in environment.

### Pesticide Risk Assessment (PRAPeR) Expert Group

17. For the assessment of pesticides, PRAPeR held two meetings with Member States to discuss the risk assessment of the remaining substances of the second stage of the review program. In the meeting from 6 – 8 April, 8 substances were discussed and the remaining 10 substances were discussed in a meeting from 6 – 9 June. The

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respective conclusions were finalized and submitted to the EU-Commission in May and June, respectively. The draft assessment report for 16 active substances of part A of the 3<sup>rd</sup> stage of the review program were distributed in weekly intervals to all Member States and the respective applicants for comments. In parallel, a 40-day public consultation on these reports was launched via EFSA's website.

### Zoonoses Task Force

18. The Member States as well as Norway and Switzerland submitted their national zoonoses reports from year 2005 by the beginning of June. The validation of this data is on-going. A preliminary report on the results from the Community-wide Salmonella baseline study in laying hens was issued in April, and it is now utilized by the Commission to set a Salmonella reduction target. A new working group on harmonisation of reporting on food-borne outbreaks started its work in collaboration with ECDC.

### Scientific Expert Services

#### *Colloquia*

19. EFSA's 5th Science Colloquium was held on 21-22 March 2006 with over 60 participants to discuss the state-of-the-art of scientific approaches being the basis for the development of food-based dietary guidelines (FBDG). It became clear that the 1998 WHO/FAO document is still a good basis. In order to translate nutrient goals into food goals it is necessary to combine recommendations, composition data, intake data and intake patterns. Also epidemiology is highly relevant for the development of FBDG. The outcome of the debate will be used as an input for the development of an EFSA guidance on suitable approaches for the translation of nutrient-based dietary advice into food-based dietary recommendations at national level.

20. EFSA's 6<sup>th</sup> Science colloquium will address methods and approaches for risk benefit-analysis of foods. It will be held on 13-14 July 2006 in Tabiano (Province of Parma) and will explore opportunities and limitations for defining a common scale of measurement (common currency) to quantitatively compare human health risks and human health benefits. About 100 participants are expected.

#### *Data collection*

21. In May 2006 EFSA organized in collaboration with DG SANCO and DG JRC a workshop on furan in food: analytical methods and brainstorming on the elements to be included in a database. As a follow-up a Steering group has been set up to develop a template for a furan monitoring database.

## **International and Institutional Relations Department**

### Advisory Forum

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The 17<sup>th</sup> Advisory Forum meeting took place in Vienna in May 2006. Main issues discussed were:

### *Initial discussion on EFSA's Management Plan 2007*

The Forum took note of the draft Working Plan and agreed to provide detailed input by the end of August.

### *Update on the progress of the Scientific Committee with regard to the work on the safety assessment of botanicals*

EFSA updated the Forum on the possible use of a Qualified Presumption of Safety Approach (QPS) for the assessment of botanicals and the different approaches for those without and those with possible medical effects. The AF members stressed their wish to stay closely informed on the progress of the work. The Forum also endorsed EFSA to keep close contact on this dossier with the industry as the number of botanicals is enormous.

### *Discussion on the paper prepared by the INA-AF Working Group.*

A year after it had been set up and after having discussed the issue on how to improve the exchange of scientific information between EFSA and the AF Members in four WG meetings, the Working Group reported back on their analysis and presented its recommendations to the Advisory Forum. The Forum adopted all recommendations and requested EFSA to draft a more formal document for the Forum to endorse as part of its terms of reference.

### *State of Play on the question from Germany regarding alternative tests for marine biotoxins*

The meeting document gave insight on how the CONTAM Panel will tackle the German question – as well as the Commission's on the whole series of marine biotoxins – was very much appreciated by the Forum including Germany.

### *Other issues*

The Extranet policy paper was introduced and got backing from the Forum for the next steps proposed.

The EFSA papers on setting up lists of food consumption database managers and exposure assessors were well received.

The EFSA's Risk communication Strategy was presented as well as discussions taken place in the Communications Working Group on experiences as regards communications on Avian Influenza.

### PHARE Programme:

#### *International and Institutional Relations*

On 27 March 2006 training on the EU and EFSA took place in Brussels. The training was given by EFSA staff and representatives from the Commission, the European Parliament and Hungary. The following topics were presented: The European Union Institutions, The European Parliament and the Commission and their institutional relations with EFSA and EFSA's relations with them. The scientific work process was presented and experiences of accession from a young national food safety authority

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### *Legal training*

On 17 and 18 May 2006 training on the legal issues relevant for EFSA took place in Bucharest. The training was given by EFSA staff to legally trained representatives from Romania and Bulgaria. It included, inter alia, issues on confidentiality, independence, liability, good governance and the diverse procedures linked to scientific opinions. The provision of simultaneous translation proved to be very helpful in order to allow interaction. The training was held in good constructive atmosphere and was considered as very fruitful from all sides involved

## **Communication Department**

### *Media Relations:*

Since the last Board meeting, EFSA has organised two press briefings, issued seven communications for the press, and made available on the web two *Frequently Asked Questions* documents.

### *Press Conferences:*

On the 5th of May a press conference was held in Rome to present the results of an assessment by the EFSA AFC Panel of a new carcinogenicity study on the sweetener aspartame conducted by the European Ramazzini Foundation in Bologna. The conference, which was attended by 21 European journalists, was webcast on EFSA website and attracted 1 274 viewers. Over 800 viewers also watched the video of the web conference made available on the EFSA website. Nearly 130 articles have been published on the EFSA aspartame opinion and resulting coverage is well balanced and relays key messages from the assessment. Importantly, national food safety authorities in Finland, Ireland, the Netherlands, Spain and the UK as well as the FDA and Health Canada published statements on their website referencing and supporting the conclusions of the EFSA opinion.

On 15<sup>th</sup> May in Brussels a press briefing was held to present the outcome of the meeting organised by EFSA to discuss with national experts how to strengthen the scientific co-operation between EFSA and the EU Member States in the field of GMO risk assessment. 16 Brussels-based journalists participated with 22 articles published to date ranging in tonality from neutral to positive.

Communications for the Press (Press Releases and Press Statements) were issued on:

### *Press Releases*

- the role of migratory birds in the spread of avian influenza amongst bird populations in the European Union
- the invitation to the European Commission to dialogue and update on EFSA's scientific and procedural approach on food safety issues especially related to the risk assessment of GMO's
- the formal appointment of Catherine Geslain-Lanéelle as head of EFSA
- aspartame and the opinion published by the AFC panel, based on the carcinogenicity study conducted by the European Ramazzini Foundation in Bologna
- the meeting held with scientific representatives of 25 European Union Member States, Switzerland and Norway to discuss how to strengthen scientific co-operation in the risk assessment of GMOs.

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### *Press Statements*

- publication of a Scientific Report on Avian Flu and Food Safety
- reply to the European Commission's questions related to GMO safeguard clauses

Moreover, two *Frequently Asked Questions* Documents to answer general questions on Aspartame and EFSA Risk Assessment on GMOs were published in the context of related press activities.

### *Publications:*

Since the last Board meeting an updated version of the *Guidance Document of the Scientific Panel on Genetically Modified Organisms for the Risk Assessment of Genetically Modified Plants and Derived Food and Feed* was published.

CD-ROMs compiling all scientific advice published by four of EFSA's Scientific Panels during their first mandate (2003-2006) were produced. CD-ROMs for the remaining Panels will be available shortly taking into account publication of scientific opinions currently outstanding. These CD-ROMS were produced for Panel members, with further distribution under consideration . Moreover, *EFSAnews* nr. 11 in 4 languages was also realised.

### *Web:*

#### *Launch of EFSA web redesign tender:*

A service contract tender for the redesign of the EFSA corporate website has been launched, with the aim to enhance the website's function as a real communication tool between EFSA and its target audiences and is usable and resource-rich. The tender should be awarded in September, while its implementation is expected in Spring 2007.

#### *New sections on the website:*

In line with the EFSA Communications Strategy, specifically its goal to 'Bridge the gap between science and the consumer', several new sections have been added to the EFSA website aimed at improving audiences' understanding of EFSA's remit and work. These include a "Focus on the Issues" section which currently links to new pages on GMO and Aspartame, a new publications section and a section on EFSA's Audit Committee.

## **IT Unit**

In April 2006, the IT Unit presented its results for the first quarter 2006 to EFSA staff members. With the intent to increase transparency and accountability, the unit performances were summarized by 8 Key Performance Indicators (KPI) which are:

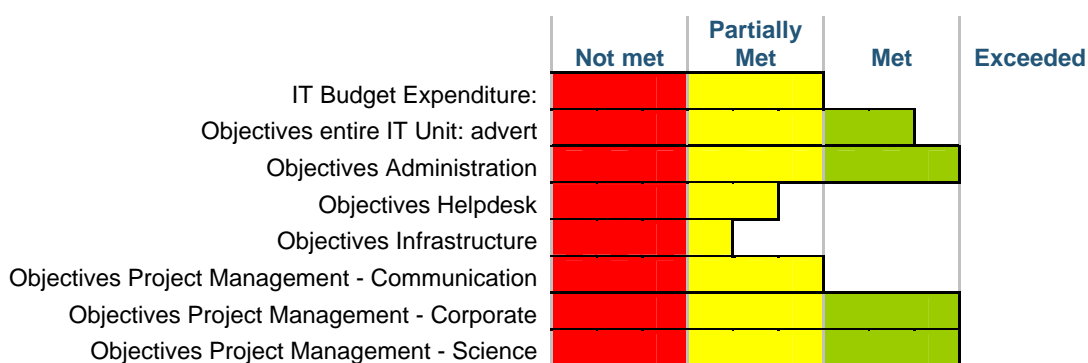
- IT Budget Expenditure (spend 25% of IT budget by March 2006)
- Objectives entire IT Unit (advertise posts, update unit procedures, etc...)
- Objectives IT Administration (hire consultants, launch tenders supporting key projects, etc...)



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- Objectives Helpdesk (improve call dispatching procedures; install a call tracking system, etc...)
- Objective Infrastructure (Upgrade key infrastructure components; install system monitoring tool, etc...)
- Objective Project Management (3KPI corresponding to the objectives assigned to Project Managers in the area of IT systems supporting EFSA Communication, Corporate and Scientific activities).

The results for the first quarter 2006 were:



A complete report is available on request.

Between March and June 2006, the IT Unit has focused on securing resources for IT projects by hiring 7 consultants and by launching new calls for tenders. The unit has also performed a security audit which yielded recommendations for improving the safety and reliability of EFSA's computing environment. The IT Unit delivered a new Web Content Management System to the Communication group, automated business workflows with our suppliers, and completed the first phase of the system supporting the implementation of Art 36. Finally the data collection phase of the Zoonoses Community Report was completed via the web system produced by the IT Unit.

The IT Unit will present its results for the second quarter 2006 in July 06, at which occasion, two additional KPI will be introduced: *User Satisfaction improvements*, as measured by quarterly user surveys and *Compliance with the Control Objectives for Information and related Technology (COBIT)* as assessed by EFSA Internal Auditor.

### *Advisory Forum IT Working Group*

The IT Working Group met in Parma on 22 March 2006 and in Vienna on 30 May 2006. Besides the usual participation on the development of the Advisory Forum Extranet and on the Videoconference Network, the IT Working Group is forming a Project Steering Committee that will oversee the implementation of EFSA's Data Collection Strategy.

## **Human Resources**

### Staffing

41. Total staffing levels as of 16/06/06 are: 94 AD posts (75 Temporary agents, 1 Official, 9 auxiliary agents and 9 ENDS), 103 AST posts (77 Temporary agents, 1 Official, 15 auxiliary agents and 10 contract agents) which equals 197 agents.

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### *Breakdown: active staff*

#### Number of temporary agents and officials recruited

Grade	Staff Foreseen for 2006	Staff Recruited	Percentage
AD	141	76	54%
AST	109	78	72%
Sum	250	154	61%

### *Staff distribution*

Type of contract	Number	percentage
Temporary Agents (AT)	152	77%
Official (FT)	2	0,1%
Seconded National Experts (END)	9	0,5%
Auxiliary Agents (AX)	24	12%
Contract Agents (AC)	10	0,5%
	197	

## **Annex I**

### **List of press releases and public statements March – June 2006**

- 23<sup>rd</sup> March 2006** PS. EFSA publishes scientific report on avian influenza and food safety.
- 12<sup>th</sup> April 2006** PR. EFSA publishes a scientific statement on the role of migratory birds in the spread of avian influenza amongst bird populations in the European Union.
- 12<sup>th</sup> April 2006** PR - EFSA invites European Commission to dialogue on GMO issues
- 12<sup>th</sup> April 2006** PR EFSA replies to European Commission questions related to GMO safeguard clauses.
- 21<sup>st</sup> April 2006** PR. Catherine Geslain-Lanéelle appointed head of EFSA
- 5<sup>th</sup> May 2006** EFSA assesses new aspartame study and reconfirms its safety.
- 15<sup>th</sup> May 2006** PR. Strengthening the scientific co-operation between EFSA and the EU Member States in the risk assessment of GMOs.