European Food Safety Authority

Brussels, 17 September 2004
EFSA/SC/92

MINUTES OF THE 8TH PLENARY MEETING OF THE EFSA SCIENTIFIC COMMITTEE HELD ON 28 JULY 2004 IN PARMA

[(adopted by written procedure on 16 September 2004)]

PARTICIPANTS[1]

Scientific Committee (SC):
Susan Barlow, Andrew Chesson, John D. Collins, Tito H. Fernandes, Anthony R. Hardy, Bo O. Jansson, Ada G.A.C. Knaap (Vice-Chair), Harry A. Kuiper, Pierre F.G. Le Neindre (Vice-Chair), Andreu Palou, Josef R. Schlatter, Vittorio Silano (Chair), and Josep Vives-Rego

European Food Safety Authority (EFSA):
Marie-Noëlle Costa (Administrative Secretary of the SC), Herman B.W.M.Koëter (Deputy Executive Director and Director of Science), Djien Liem (Scientific Co-ordinator of the SC), Samantha Mommens (Secretary of the Deputy Executive Director and Director of Science) and Valérie Rolland (Assistant Scientific Co-ordinator of the SC)

European Commission (EC):
Michael Walsh (DG Health and Consumer Protection /Unit D5 - Relations with the EFSA)

[1] Abbreviations: AFC: Panel on food additives, flavourings, processing aids and materials in contact with food; FEEDAP: Panel on additives and products or substances used in animal feed; GMO: Panel on genetically modified organisms; NDA: Panel on dietetic products, nutrition and allergies; BIOHAZ: Panel on biological hazards; CONTAM: Panel on contaminants in the food chain; PPR: Panel on plant health, plant protection products and their residues; AHAW: Panel on animal health and welfare

1. WELCOME, APOLOGIES FOR ABSENCE

The Chair welcomed the participants. Apologies for absence were received from Philippe Vannier and Albert Flynn.

2. ADOPTION OF THE AGENDA

The agenda was adopted as proposed.

3. DECLARATIONS OF INTEREST

There were no interests declared in addition to the annual declaration.

4 MATTERS ARISING SINCE THE 7TH PLENARY MEETING OF 13 MAY 2004

4.1 General feedback from EFSA

The Deputy Executive Director informed the Scientific Committee about the issues discussed at the recent meetings of the Advisory Forum and the Management Board.

Advisory Forum meeting of 8 June 2004
The meeting was hosted by the Hungarian Food Safety Authority. The following subjects were discussed:

- The success of the two stakeholders' meetings recently organised by the FEEDAP Panel on 6 May on the new Regulation 1831/2003 on additives for use in animal nutrition, and by the GMO Panel on 25 May on a draft guidance document for the risk assessment of genetically modified plants and derived food and feed, was reported. The outcome encourages the organisation of similar initiatives in the future. The impact of the new regulations relating to GMO, pesticides and feed additives was also discussed.
- The Advisory Forum of 8 November will be organised as a special event and will be open to all interested[2]. Sessions will take place on fundamental food safety issues (future perspectives in risk assessment, evaluation of risk/benefit). EFSA will invite members of the Scientific Committee to participate in this event. Members of the Panels are also welcome to participate. The Deputy Executive Director however made it clear that a meeting open for all interested in the work of EFSA should not be dominated by EFSA staff and allies. Consequently, based on logistic limitations and the number of registrations received from interested parties outside EFSA, a balanced representation will be sought.

[2] For more information on the event, see http://www.efsa.eu.int/advisory_forum/af_events/catindex_en.html.

- The Advisory Forum Event will be followed by a one-day Stakeholders meeting largely arranged as round-table discussions on issues brought to the table by stakeholders. This meeting will be a closed meeting and participation is upon invitation. The SC will be invited to this meeting.
- The Advisory Forum was informed that the EFSA extranet would be operational in July 2004. Possibilities for sending warning messages and virtual meetings through the extranet will be explored.
- The Advisory Forum was informed about the results of an assessment of the current image of the Authority. The Report of the Consultant[3], which undertook the exercise for EFSA, was based on interviews with interested parties and stakeholders and presents a generally positive view of EFSA's first months and the increased co-operation between Member States and the Authority. Under Article 61 of EFSA's Founding Regulation a formal review of the Authority will have to be commissioned by January 2005. The Report of the Consultant is not a substitute for this formal review, but gives a helpful critical indication of views EFSA could consider before the final review is likely to be ready.
- EFSA and the Commission convened a meeting to discuss how to improve co-operation and communication on issues of common concern, e.g. press releases addressing consumers' food safety issues.
- An EFSA document on "food and feed safety and the use of animals" (MB 22.06.2004-5), a draft of which was previously shared with the chair and vice-chairs of the SC, was discussed. It supports the adoption of a pro-active animal welfare approach by EFSA in line with the Management Board policy. EFSA would like to develop further guidance on how to implement these considerations in its future work in collaboration with the Scientific Panels and Committee.
- A survey published by US FDA in May 2004 showed the presence of furans in a number of foods that undergo heat treatment. Data available indicate that this may become an emerging issue. Therefore the CONTAM Panel established a working group to collect information on the methods of analysis, occurrence, formation, exposure and toxicity of furans.

Management Board meeting of 22 June 2004

The same items as mentioned above were discussed in the meeting of the Management Board (MB) of 22 June 2004. Besides, the following issues were discussed:

- The confidential part of the MB meeting included the re-election of the chair and vice-chairs of the MB for another term of 2 years as well as the appointment of 13 new experts in 5 Panels chosen in accordance with the scientific profiles needed, geographical and gender

[3] See: http://www.efsa.eu.int/advisory_forum/adv_meetings/465/annex_imageassess_af09_doc05a_e1.pdf

balance[4]. The MB expressed the wish to discuss the Authorities' policy in relation to applications of industry experts at a future meeting.

- Performance indicators will be developed to help assessing the Authority's work on a regular basis.
- MB rules of procedures will be revised, to take into account, among others, the adoption of documents by written procedure, quorum requirement, and the translation of minutes.

Scientific Colloquium of 27-28 June 2004

The Secretariat (Djien Liem) informed the Scientific Committee about the outcomes of the first EFSA Scientific Colloquium, which took place from 28-29 June in Brussels. This Colloquium addressed methodologies and principles for setting tolerable intake levels for dioxins, furans and dioxin-like PCB's.

A publication in January 2004 in the journal Science on the global assessment of organic contaminants in farmed salmon (Hites et al., 2004. Science 203: 226-229) triggered substantial comments from scientists and media around the world. The article was based on data concerning the occurrence of persistent organic pollutants found in a variety of farmed and wild fish. While the data collected were considered valuable, experts disagreed about the approach followed by the authors in assessing the comparative health risks associated with the consumption of farmed and wild salmon. Consequently, the article's recommendations with respect to the consumption of safe amounts of salmon were highly controversial and potentially confusing for consumers. The European Food Safety Authority took up this issue at its first Scientific Colloquium where recognised experts in the field discussed scientific aspects and issues relating to the setting of tolerable intake levels for mixtures of polychlorinated dioxins, furans and dioxin-like PCBs. In order to allow for international discussions, participation was not limited to European experts but was extended to experts from North America and Japan, including the authors of the Science article.

The objectives of the Colloquium were to analyse and discuss the differences in approaches and principles used by authorities in assessing the risks of dioxins, furans and dioxin-like PCBs to human health and helped understanding why and how scientific results can lead to different decisions in different Institutions. It is planned to publish a summary report on EFSA's website before the end of August[5] and to present the outcomes at the DIOXIN 2004 Conference that will take place in Berlin from 6-10 September[6]. It will not lead to any re-evaluation of the substances considered.

The EFSA Director of Science invited the members of the Scientific Panels and Committee to propose relevant subjects for future Scientific Colloquia.

[4] See: http://www.efsa.eu.int/press_room/bg_documents/catindex_en.html
[5] See http://www.efsa.eu.int/science/colloquium_series/catindex_en.html
[6] See www.dioxin2004.org

4.2 Feedback from Scientific Panels

The Chairs of the Scientific Panels informed the Committee about opinions recently adopted as well as opinions in the process of adoption by written procedure[7]. In addition, the Chairs wished to bring the following specific issues to the attention of the Scientific Committee:

AFC

- Three experts had been appointed as new Panel members to better cover the areas of toxicology, exposure and naturally occurring substances. Two of them had already been able to participate in the last plenary meeting (12-13 July).
- During the last plenary meeting the opinion on the use of certain food additives in jelly mini-cups (suffocating risks) was adopted. Expertise in medical emergencies arising from physical hazards is not covered in the Panels and such questions are rare, but if similar questions arose in the future it might be more appropriate for EFSA to consult ad hoc experts.
- The Chair of the Panel confirmed the continuing high workload for the members.

FEEDAP

- Two new Panel members had been appointed.
- The Chair of the Panel raised the difficulty of assessing generic and brand specific products, which may lead to the assessment of similar products based on different data sets. A letter will be sent to the Commission to address these difficulties.
- The assessment of a series of coccidiostats has been completed, the last one by written procedure.
- The Panel was requested by the Commission to develop a guidance document on the assessment of silage additives in relation to the new regulation.
- A new self task has started on the environmental risk assessment of feed additives. The work will likely be based on the models developed for pesticides. A cross talk with the PPR Panel may be needed.
- The Chair also informed that the time commitment are quite high for the Panel members.

BIOHAZ

- The Panel met on two occasions since the last SC meeting. The BSE working group is dealing with 3 major projects and has recently received a request from a Member State.

[7] For more specific information, see the specific pages of the respective Scientific Panels providing the minutes of the plenary meetings and the opinions adopted at these meetings on EFSA's website.

- The Panel explored how to get more support from the Commission. For instance they had a meeting with representatives of the Commission's Directorate General for Research to discuss how to get access to ongoing research results on TSE before publication.
- A working group on microbiological risks in infant foods has been created and this activity will imply interaction with the NDA Panel.
- The October plenary meeting of the BIOHAZ Panel will take place in Parma.

PPR

- The PPR's self-tasking work on the surface and ground water models and the consistency of the different models available is close to finalisation. The models used to determine scenarios representing the European agriculture situations are mainly developed only for sprays. The question is whether these models can be adapted for application on other formulae (e.g. granules). In addition the theoretical distribution of pesticides in soil and water are inconsistent between some models. The Panel looked also into this.
- Work will start on a recent question on dimoxystrobin.
- Three new members have been appointed to the Panel to deal mainly with issues on plant health, environmental fate and residue.

GMO

- Following the Stakeholders' meeting in May 2004, the Panel is finalising the guidance document for the risk assessment of genetically modified plants and derived food and feed for adoption in September. The feedback received at this meeting was useful and led to clarification or extension of some chapters. A working group may be set up to look at the limitation/relevance of using certain standard animal tests applied for food safety for the evaluation of GMOs.
- A meeting will take place in September on post market environmental monitoring, involving industry and Commission representatives.
- One member resigned from the Panel and will be replaced as soon as possible.
- The Chair of the Panel expressed the necessity to be aware of activities at national level similar to those in the EFSA Panels in order to discuss any divergent scientific views before publication of the opinions. The EFSA Director of Science informed the Committee about the EFSA register of questions which has been made available on the EFSA website. For each question, it will become clear which documents are available for the evaluation by the Panel. Attention will also be drawn from the Advisory Forum to ensure awareness of parallel activities at EFSA and Members States' level.

CONTAM

- The CONTAM Panel considered a considerable number of undesirable substances in animal feed at its last plenary meeting.
- The Panel was also asked to assess the health consequences of consumption of fishery products belonging to the family of Gempylidae. However, it was not possible to establish the minimum amount of such fish to be consumed to elicit diarrhoea and other gastrointestinal effects.
- The working group on safety of wild and farmed fish has set priorities for the compounds (3 classes) and fish species to be considered (7 species harvested). Members of the NDA Panel are involved.
- The Panel is working on the finalisation of its opinion on organotin compounds and has started a self task on the collection of data on furan.
- The Panel is looking for an expert in veterinary toxicology to replace the member that resigned from the Panel in the beginning of this year.

NDA

- The NDA Panel adopted opinions at their last plenary meeting on the upper safe level for boron and the health effects of trans-fatty acids.
- A number of requests are being received to evaluate applications submitted for temporary labelling exemption (pursuant to Art. 6, par. 11 of Directive 2003/13 EC) concerning ingredients/substances derived from allergenic foods (legal deadline for submissions 25 August 2004). The legal timeframe for delivering of Opinions on these dossiers is less than 2 months.
- In addition two novel foods are currently being assessed (Enova oil and betaine).

All Panels

- Members of the SC asked for general advice on the location of the meetings. The Deputy Executive Director advised that the SC/Panels should preferably organise their meetings where the related SC/Panels Secretariats are based. In other words, as soon as the EFSA staff of a particular Panel has moved to Parma, the meetings of that Panel will be held in Parma. Other meeting locations can obviously be chosen if appropriate but justification should be provided.
- The temporary office building in Parma will be available by the end of October, and the progressive move to Parma will start early November this year and last one year. Moving plans took into account staff preferences and constraints. Options to facilitate transportation to Parma are being considered.

4.3 Feedback from Working Groups of the Scientific Committee

GENTOX

The Working Group on a Harmonised Approach for the Consideration of Genotoxic and Carcinogenic Substances (GENTOX) met on 19-20 July. The Working Group intends to submit a first draft opinion to the Committee at the plenary meeting in October. The working group will propose a new approach (Margin of Exposure) which aims to provide better safety indication to the risk managers. A working group meeting will take place on 6-7 September to finalise the first draft. The organisation of a workshop in 2005 in collaboration with WHO (IPCS) and ILSI Europe addressing the issue is being considered. In any case an event will be organised early 2005 to discuss the new approach within EFSA panels in first instance.

EXPOSURE

The Exposure Assessment WG had its last meeting on 24 June 2004. The WG is preparing a document that will give guidance to the Scientific Panels and Committee pointing out relevant existing documents or information available. The WG is also further developing a simplified food consumption database that should help the scientific panels to make quick worst-case exposure estimates for their evaluations. For further refined exposure assessment, EFSA could contract out work to database managers in Europe. To improve collection of information on occurrence data, the WG intends to recommend the creation of a data warehouse (e.g. links to databases) in EFSA. It would be based on existing databases such as the WHO GEMS/food programme. WHO representatives will be invited to one of the next working group meetings. A document on uncertainties in relation to exposure assessment is also being prepared taking into account all Panels' areas. The Panels will be involved when the document is more advanced. The next meeting will take place in September.

EMRISK

The Working Group on Emerging Risks (EMRISK) had a meeting on 22 June and 27 July, prior to this plenary meeting. The WG devoted its last meetings on the evaluation of the tenders that EFSA received for the creation of a network of key sources to support the Authority in identifying emerging risks and on questions that should be raised with the potential contractor. It is hoped that a first meeting with the awarded contractor can be held in September. The Chair of the EMRISK WG asked the Chairs of the Scientific Panels to identify within their area the five most relevant (specific and generic) emerging risks. This information will constitute a basis of continued discussions in the EMRISK Working Group to define the kind of "emerging risk information" that would be relevant for the Authority. A number of parallel similar activities have been identified and will also be considered. The working group questioned also how the outcome of such an exercise could be eventually validated (efficiency of the network and mechanism set up).

BMD

It was confirmed that the Working Group on the Benchmark Dose Approach will start its activities in the fall of this year due to overlapping expertise with the WG GENTOX.

QPS
The composition of the working group will be finalised to allow the organisation of a first meeting.

5. INVESTING IN FOOD SCIENCE

The Deputy Executive Director presented approaches and priorities in relation to the future developments of the Science Department including the establishment of the EFSA Scientific Expert Services. One major aim is to provide better scientific support to the members of the Panels and SC to lighten their burden. In addition, the Scientific Expert Services will be responsible for the establishment and maintenance of expert networks, the organisation of the Science Colloquia, the coordination of extracurricular SC/Panel activities such as the work on BSE/TSE, annual zoonoses report and pesticide assessment. The structure of EFSA/Panels will obviously have to evolve to meet the increasing needs. The possible increase in number of Scientific Panels or Working Groups will not be sufficient without the Scientific Expert Services to cope with the increasing workload.

In house expert units have already been established and will continue to grow in the areas of pesticide risk assessment (PRAPeR), maximum residue level assessment (MRL) for pesticides, geographical BSE risk assessment, TSE Test Evaluation (evaluation of diagnostic tests), management of the European zoonoses data collection and preparation of the European zoonoses annual report.

Other similar units could be built on to expand in house expertise on data collection, epidemiology, toxicology, environmental effects, exposure assessment, analytical chemistry, animal welfare etc. The in house experts will assist and closely co-operate with the SC/Panels. Among others they could provide background documents, do literature surveys, draft initial assessments, collect and analyse data, develop guidance documents, develop further the EFSA network etc.

Due to a lack of time for questions and comments, the agenda item will be resumed and discussed again at the next SC plenary meeting.

6. FEEDBACK FROM AN EFSA MEETING ON TRANSPARENCY IN RISK ASSESSMENT

Feedback will be given at the next meeting.

7. THE INTERFACE BETWEEN RISK ASSESSMENT AND RISK MANAGEMENT – STATE-OF-PLAY OF DISCUSSIONS IN THE SCIENTIFIC PANELS

The final report of the European Workshop[8] on the Interface between Risk Assessment and Risk Management, held in The Netherlands in September 2003, was distributed to the members of the SC and scientific Panels. The document reports the conclusions of the workshop and consider ways of improving the interface between risk assessment (RA) and risk management (RM). The Scientific Panels were requested to identify aspects that are particularly relevant to their work and focus their review of the report on approaches and tools for quantitative risk assessment, appropriate ways to achieve a proper implementation of approaches relevant to their Panel, the identification of options other than those indicated in the workshop report in order to ensure an efficient interaction between risk assessment and risk management, other RA-RM links and interactions than the current participation and involvement of the RM representatives in the discussions of the Panels, possible risk management options aiming at improving the interface with RA to be considered by the Commission. The SC will discuss the comments from the scientific Panels once they are finalized and compiled.

8. NEXT MEETING

The next meeting will last 1.5 day on 13-14 October 2004.

9. ANY OTHER BUSINESS

Members of the Scientific Committee were asked to complete their annual declaration of interest following the Guidance on Declarations of Interest the latest draft of which was provided during the meeting. A final draft of the Guidance on Declarations on Interest will be circulated to the SC/Panels for comments before endorsement by the Management Board.

NB. Following the meeting, the SC met during a working lunch with the management and senior scientists of the University of Parma to exchange information on current activities and interests.

[8] *Improving the interface between Risk Assessment and Risk Management* (Hart, A., Ed.), Final Report of a European Workshop on the Interface between Risk Assessment and Risk Management, held at NH Leeuwenhorst Hotel, Noordwijkerhout, The Netherlands, 3-5 September 2003. Central Science Laboratory Sand Hutton, York, YO41 1LZ, UK, www.csl.gov.uk, ISBN 1 859 45 015 6, 2004 (also available at www.ra-rm.com).