European Food Safety Authority

SCIENTIFIC COMMITTEE AND ADVISORY FORUM UNIT

Parma, 12 June 2009
EFSA/AF/M/2009/244/PUB/FIN

Minutes

THIRTY FIRST MEETING OF THE ADVISORY FORUM BUCHAREST (ROMANIA), 22-23 APRIL 2009

MEMBERS OF THE ADVISORY FORUM

Chair: *Catherine Geslain-Lanéelle,* Executive Director, EFSA

Austria	*Roland Grossgut*	Luxembourg	*Felix Wildschutz*
Belgium	*Charles Crémer*	Malta	*Flavia Zammit*
Cyprus	*George Georgallas*	Netherlands	*Evert Schouten*
Czech Republic	*Miroslav Elčkner*	Poland	*Jan Krzysztof Ludwicki*
Estonia	*Hendrik Kuusk*	Portugal	*Manuel Barreto Dias*
Finland	*Kirsti Savela*	Romania	*Liviu Rusu*
France	*Lilian Puech*	Slovakia	*Zuzana Bírošová*
Germany	*Andreas Hensel*	Slovenia	*Urška Blaznik*
Hungary	*Arpad Ambrus*	Spain	*Ana Troncoso*
Ireland	*Alan Reilly*	Sweden	*Leif Busk*
Italy	*Agostino Macrì*	United Kingdom	*Alison Gleadle*
Latvia	*Gatis Ozoliņš*		

OBSERVERS AND INVITEES OF THE EXECUTIVE DIRECTOR

Norway	*Kirstin Færden*	European Commission	*Jeannie Vergnettes*
Switzerland	*Michael Beer*		

STAFF OF THE EUROPEAN FOOD SAFETY AUTHORITY

Bernhard Berger	*Georgi Grigorov*
Gian Luca Bonduri	*Djien Liem*
Ermanno Cavalli	*Riitta Maijala*
Hubert Deluyker	*Elena Marani*
Dirk Detken	*Jeffrey Moon*
Alexandre Feigenbaum	*Torben Nilsson*
Anne-Laure Gassin	*Ilias Papatryfon*

1 WELCOME AND OPENING OF THE MEETING

Catherine Geslain-Lanéelle opened the meeting and passed the floor to Marian Zlotea (President of the National Sanitary, Veterinary and Food Safety Authority). Marian Zlotea welcomed the AF and underlined the importance of the cooperation with EFSA. Catherine Geslain-Lanéelle thanked Romania for the hospitality and for Romania's active contribution to the AF. She welcomed the Hungarian AF alternate who attended an AF meeting for the first time and noted that apologies were received from Bulgaria, Denmark, Greece, Lithuania and Iceland.

2 ADOPTION OF THE AGENDA

The agenda was adopted without changes. Germany, Belgium, Czech Republic and France raised additional issues for agenda items 4.1 and 7.2.

3 GENERAL MATTERS ARISING SINCE THE 30TH ADVISORY FORUM MEETING

3.1 Management Board meeting in Prague on 30-31 March 2009

Catherine Geslain-Lanéelle informed the AF that the Management Board (MB) had agreed on the new composition of EFSA's Scientific Panels and Committee and adopted EFSA's preliminary draft Management Plan for 2010 with a slight budget increase of 1.9 % as compared to 2009. She also informed about the results of the expert survey. Furthermore, she reported back to the MB on the outcomes of the discussion at the last AF meeting, confirming EFSA's commitment to foster cooperation and harmonisation, following the presentation by four AF members at the MB meeting in January 2009. The MB requested regular updates on the cooperation with Member States.

Action 1: EFSA to share its preliminary draft Management Plan for 2010 for comments and discussion at the next AF meeting.

3.2 Renewal of EFSA's Scientific Panels and Committee

Riitta Maijala briefed the AF on the renewal of eight of EFSA's ten Scientific Panels and its Scientific Committee. The ANS and CEF Panels were created in 2008 to replace the former AFC Panel, so these two Panels were not yet up for renewal. The number of eligible applicants had increased by 7 % as compared to the call in 2006. 79 % of the Panel members had reapplied. 26 nationalities are represented in the new Panels and there is a good balance between experts in their first, second and third mandate. All nominated experts have been informed and the new composition of the Scientific Panels and Committee will be published in June 2009. Catherine Geslain-Lanéelle said that the new composition will be shared with the AF prior to publication.

Germany asked if experts from the industry were included in EFSA's new Scientific Panels and Committee, emphasising their usefulness, *e.g.* due to a need for industry data. Catherine Geslain-Lanéelle replied that the Panel experts are mainly from national food safety institutions. More detailed information on the origin of the Panel experts is included in the expert survey report and can also be provided for the new Panels. However, EFSA's policy on the declaration of interests, adopted by the MB in 2007, generally excludes industry experts, except if their expertise is only available in the industry. However, industry experts can be involved as hearing experts. Germany found that it would be more appropriate to focus on the scientific content and approach than the employer when assessing declarations of interests. Italy welcomed a hearing system for consultation of industry experts. Hubert Deluyker mentioned emerging risks as an area where there is a need to work with the industry and consumer organisations.

3.3 Scientific Committee meeting in Parma on 7-8 April 2009

Djien Liem informed the AF that the Scientific Committee (SC) had adopted opinions on transparency in risk assessments and existing approaches incorporating replacement, reduction and refinement of animal testing.

3.4 Other general matters

An overview of the status of follow-up on action points agreed at the 30th AF meeting was provided for information. The few missing declarations of interests would be followed up bilaterally. The other actions were undertaken as agreed.

4 MATTERS RAISED BY THE MEMBER STATES

4.1 Matters raised by the Member States

Belgium requested an update on the assessment of health claims by EFSA's NDA Panel and more specifically on a meeting foreseen with the industry in June 2009. Riitta Maijala referred the different types of claims under articles 13.1, 13.5 and 14 and confirmed that a meeting with the industry would take place in Brussels in

June 2009. She also mentioned that companies can withdraw their claims at any stage prior to adoption of the opinion. Ireland asked if the industry could know how an assessment is going prior to the adoption of the opinion. Riitta Maijala replied that this would be possible through comparison with scientific opinions on similar claims and due to the questions asked to the applicants when additional information is required for the assessment. Catherine Geslain-Lanéelle added that withdrawn dossiers would be included in the register of questions, but the related opinions would not be published.

France informed that AFSSA has issued an unfavourable opinion on the use of *Stevia* as a sweetener. Notwithstanding this, its use has been authorised in France. Austria said that the European Commission has rejected *Stevia* as a novel food and asked if the French authorisation was as an additive. Belgium confirmed that *Stevia* is considered a novel food, while its extract is considered an additive. Also Belgium has issued a negative opinion and Germany now examines the dossier. Portugal said that *Stevia* is already used as a food supplement in many Member States without authorisation. Cyprus shared information about a recent case where *Stevia* import had been stopped at the border due to the lack of authorisation. Riitta Maijala informed that EFSA's ANS Panel is working on *Stevia* and will consider the AFSSA opinion.

Germany expressed concerns about the workload of EFSA's Panels, suggested involving Member States more in the work to avoid duplication of efforts, and requested a direct dialogue with the Panel members. The Netherlands agreed that the workload of Panel members is problematic and suggested discussing the relation between national and EFSA tasks. Catherine Geslain-Lanéelle said that EFSA's capacity has considerably increased and that there will be no backlog of opinions in 2010. She welcomed further discussion in the specific scientific areas and agreed to involve the Panel Chairs in future discussions.

5 COOPERATION BETWEEN EFSA AND THE MEMBER STATES

5.1 Cooperation in the area of food contact materials, enzymes, flavourings and processing aids

Catherine Geslain-Lanéelle introduced this agenda item by referring to the agreement at the last AF meeting to discuss further on the cooperation between EFSA and the Member States within EFSA's different scientific areas. Alexandre Feigenbaum presented the work of EFSA's CEF Panel and suggested that enzymes and non-plastic packaging materials could be areas for further collaboration with the Member States. In particular, Member States could actively screen applications.

Sweden mentioned the good cooperation with the EU Flavour Information System (FLAVIS). Germany welcomed the proposed collaboration with the Member States and proposed the establishment of an ESCO working group on

packaging materials. Belgium asked how JECFA evaluations concerning flavouring substances are considered and suggested that non-regulated fields concerning packaging materials could possibly be addressed by ESCOs. The Netherlands found that parts of the work could be outsourced and asked if the workload of the CEF Panel is realistic. Italy proposed research to obtain toxicity data. Germany commented that it is difficult to assess toxicity of smoke flavourings, since they decompose and cannot be reproduced. Germany proposed that EFSA could adhere to national opinions. The European Commission agreed on the need for close cooperation.

Alexandre Feigenbaum confirmed EFSA's intention to continue working with FLAVIS that prepares all data for the Panel working group on flavourings. The workload of the CEF Panel is very high in 2009, but should normalise next year. Riitta Maijala confirmed that EFSA considers both national and JECFA opinions. Alexandre Feigenbaum added that EFSA is aware of the work of the Member States. He also explained that the CEF Panel considers first genotoxicity and does not proceed further with the assessment when genotoxicity is found, whereas genotoxicity is only one aspect amongst others in the JECFA assessments. Riitta Maijala mentioned that regulations are different in different scientific areas, so different models for cooperation are required. Hubert Deluyker suggested that Member States could contribute in their areas of special expertise. Catherine Geslain-Lanéelle reiterated the need for close collaboration on enzymes and said that an enzyme network would be needed.

Action 2: AF members to nominate national contact points for an enzyme network.

Action 3: The proposed ESCO working group on non-plastic packaging materials to be considered at the next AF meeting.

5.2 Further work on harmonisation of risk assessment methodologies across Europe

Hubert Deluyker presented the proposed survey and process to determine the priorities for further horizontal harmonisation. The Member States would reply to the survey prior to the Steering Group on Cooperation (SGC) meeting; the SGC would then discuss the proposed priorities in preparation of the further discussion and agreement at the next AF meeting. Written comments on the draft survey received from Belgium, Portugal and the United Kingdom prior to the AF meeting were discussed and taken into account. Germany welcomed the proposal to discuss the priorities further in the SGC. Austria emphasised the distinction between harmonisation and standardisation. Catherine Geslain-Lanéelle said that there would be a need to focus on the essential aspects of harmonisation.

5.3 National expert meeting on aspartame in London on 2-3 April 2009

Jeffrey Moon updated the AF on the ongoing work on aspartame. The scientific literature review has indicated no need to revise previous opinions. The consideration of case reports is still ongoing. The draft report will be ready by the end of June 2009 and a second national expert meeting is scheduled for November 2009 to discuss the findings.

The Netherlands encouraged the work. Ireland requested information on the aspartame study previously proposed by the United Kingdom and suggested that EFSA should be involved. Sweden agreed with Ireland. Jeffrey Moon confirmed that the United Kingdom is preparing a pilot study and informed that the national experts have provided feedback on the proposed study design and agreed on the usefulness of the study. Sweden remarked that the reason for present work on aspartame was the post-marketing surveillance by consumers and drew the attention to the different approaches for food and pharmaceuticals. Hubert Deluyker mentioned that for pesticides the surveillance is intensive, while there is no surveillance in some other areas. This may be an issue for further discussion by the AF. Ireland said that drugs are different from food, since it is a balance between good and bad effects. Italy agreed with Ireland that for food there should be no risks, while drugs are different. Norway said that the communication aspects need attention. Jeffrey Moon confirmed that communications are indeed very important. However, the scientific work is still ongoing, so as soon as its outcome is known, the appropriate communication strategy can be defined. Catherine Geslain-Lanéelle concluded that the AF will discuss again before the end of 2009.

5.4 Report from the ESCO working group on risks and benefits from food fortification with folic acid

Alan Reilly (Ireland), Chairman of the ESCO working group on risks and benefits from food fortification with folic acid, presented the draft ESCO report and thanked for the EFSA secretariat for its support to the work. Catherine Geslain-Lanéelle thanked Alan Reilly for chairing the working group and all the experts involved for their contributions. She found that the report provides an excellent overview of the situation.

The Netherlands took note of the conclusions and asked what would be the main recommendations. Ireland replied that recommendations would comprise for EFSA to keep the situation under review and for Member States to monitor food fortification with folic acid, while next steps would be on the risk management side. Sweden echoed the thanks to the EFSA secretariat and said that food fortification with folic acid is a risk-benefit issue. Catherine Geslain-Lanéelle thanked Sweden for hosting the international meeting on folic acid in January 2009. Germany mentioned that while there is uncertainty about the possible cancer risks, the benefits in terms of reducing neural tube defects are well-known,

so this is a risk-benefit issue, which is a challenge from a communication perspective. Ireland mentioned that risks are associated with high intake levels for an extended period of time. Sweden stated the importance of targeting food fortification with folic acid to young women. Anne-Laure Gassin emphasised the importance of an open and transparent communication approach. The Netherlands asked if risk-benefit assessments would be considered as risk assessment or risk management and said that a risk-benefit assessment may not be possible due of lack of information. Ireland suggested that risk assessors should consider also benefits in order to assist risk mangers in doing their job. Djien Liem informed the AF that the SC is presently working on risk-benefit assessments intended as health risks and health benefits, but not considering economical aspects. Folic acid is one of the case studies being considered by the SC working group. Sweden referred to a SAFEFOOD report addressing also economical and other relevant factors. Catherine Geslain-Lanéelle suggested that the final ESCO report could be more specific on possible research needs, thanked all contributors to the work and said that the final report will be shared with EFSA's NDA and ANS Panels for their consideration and recommendations on possible future work. The AF agreed on this approach.

5.5 Terms of reference of the IT working group on data warehousing and web reporting

Hubert Deluyker provided the framework and overview of networks for data collection and ongoing activities in different areas, *e.g.* zoonoses, pesticides, chemical occurrence and food consumption data, and presented the proposed terms of reference of the IT working group on data warehousing and web reporting. He mentioned that the work would be completed by the end of 2009.

Austria found the timeline ambitious and mentioned the work done by Eurostat. Germany raised concerns over data ownership in relation with its federal structure. Slovakia wanted information on the type of data to be shared. Hubert Deluyker emphasised that the proposed IT working group would focus on better IT tools, not additional data requests. Ireland asked if all parties would have access to all data. Hubert Deluyker said that the intention is to develop common data formats. Germany expressed support to the proposal, but requested more information on the legal aspects, since some data are made available to the European Commission only for legal purposes. Hubert Deluyker informed that EFSA is examining the legal aspects in conjunction with the European Commission. The United Kingdom supported the proposal. Austria mentioned that data are anonymous in Austria. The European Commission said that systems are in place already for certain areas, including the handling of federal data, and some data responsibilities have been transferred from the European Commission to EFSA, so there is a close cooperation. Hubert Deluyker confirmed that data are anonymous in many cases, depending on the legislation, which is not always clear as regards data ownership. Catherine Geslain-Lanéelle concluded that legal

aspects should be included in the work and that the IT working group should be composed of IT experts proposed by the AF and IT networks. The AF agreed.

Action 4: EFSA to share a document on the legal aspects of data collection and sharing for discussion at the AF meeting in September 2009.

5.6 2010 work programme for grants and procurement

Bernhard Berger presented the draft 2010 work programme for grants and procurement, which will be finalised and submitted to the MB for approval in the autumn 2009. An evaluation of the impact of grants and procurement projects will be prepared in the beginning of 2010. Catherine Geslain-Lanéelle added that the preliminary document will be discussed again at the AF meeting in June 2009 and that the budget will not decrease as compared to 2009.

Germany drew the attention to the possible overlap between the proposed chemical hazard database and similar plans of ECHA and requested that the AF should have access to more information on the studies and their results. The Netherlands asked which criteria were used to select the proposed projects. Bernhard Berger said that article 36 reports will be published. The projects are proposed by EFSA's scientific units based on their needs for outsourcing. Subsequently, the AF and SC are consulted on the proposal before it is submitted to the MB for endorsement. Catherine Geslain-Lanéelle informed that EFSA would soon visit ECHA to coordinate. Italy trusted that the list reflects well EFSA's needs and asked if it was to be considered as confidential. Ireland found that all topics relate well to EFSA's work and expressed appreciation of being consulted so early in the process. Catherine Geslain-Lanéelle said that a few lines describing each topic could be added to the list, which is confidential, since some institutions may be interested in applying to the calls. Germany proposed that the AF should be involved in the design of the studies and commenting through the AF Extranet. Germany did not consider confidentiality an issue, since the AF members have signed declarations of confidentiality. Also Norway would like to see the project descriptions, while the Netherlands expressed doubts, since reviewing the study designs would be a big task falling outside the scope of the AF. Catherine Geslain-Lanéelle concluded that more information would be provided on the 2010 projects for further discussion at the AF meeting in June 2009.

6 MATTERS RAISED BY EFSA

6.1 EFSA's approach to public consultations on scientific outputs

Dirk Detken presented a document on EFSA's approach on public consultations on scientific outputs. The objectives of the document are to provide criteria for the identification of the need for a public consultation on a scientific output, to identify the types of scientific output on which public consultations can be performed, to identify by which means the effectiveness of a public consultation

can be ensured, and to establish a means to report on the outcome of the consultation processes. The scope of public consultations is to reach the public, *i.e.* stakeholders, academics, NGOs and all interested and affected parties, whereas EFSA's institutional partners and other statutory bodies are consulted through other channels, *e.g.* the AF. The document was presented also to EFSA's stakeholder platform and will be finalised in June 2009.

The Netherlands said that the document could be useful also in the national context and referred discussions in the Netherlands on a possible one week pre-notification of opinions. Catherine Geslain-Lanéelle said that it would be interesting for EFSA to know more about national criteria for public consultations and said that EFSA could only pre-notify under embargo 1-2 days in advance due to the risk of leak. Ireland found the document useful and asked if information from the public consultation is published and which influence the public consultations have on the opinions. The United Kingdom welcomed EFSA's approach. Dirk Detken informed that EFSA is preparing a separate document on pre-notification of opinions that will be ready in the second half of 2009. Djien Liem said that the public consultations have an impact in terms of ensuring that all information is considered and that comments made during public consultations often lead to further explanation of the risk assessment in the final opinions. Riitta Maijala added that the comments are often on the clarity of the scientific outputs and hence lead to improved quality of the final scientific output. She further confirmed that a report on the comments made during public consultations and how they were taken into account is always published for transparency reasons.

6.2 US mission report

Catherine Geslain-Lanéelle briefed the AF on EFSA's visit to US federal institutions in March 2009 and the agreement to cooperate and exchange information. She said that EFSA will keep the AF informed and invited the AF to share information on possible bilateral exchanges on food and feed safety issues between Member States and third countries, in particular the US. Hubert Deluyker mentioned the high research capabilities in the US and also said that public consultation is very extensive in the US due to less involvement of external experts in developing scientific outputs.

6.3 Update on the internal and external review of EFSA's scientific outputs

Riitta Maijala presented EFSA's internal and external review process aiming at quality assurance of EFSA's scientific outputs. She announced a call for external evaluators within seven scientific areas identified by the SC. Catherine Geslain-Lanéelle requested the assistance of AF members and focal points in disseminating information on the call for external evaluators. The Netherlands found that the presentation would be useful also for national procedures and requested further information on the external review. Riitta Maijala explained that

the external review will comprise a random sample of 30-40 scientific outputs annually and consider the aspects highlighted in the SC opinion on transparency.

6.4 Further work on nanotechnology and cloning

Djien Liem informed the AF that EFSA will continue to follow nanotechnology developments through its expert working group, since there is still only limited information available on applications in the food and feed area.

Djien Liem also informed the AF that the European Commission has requested EFSA to detail the underlying information of the recent SC opinion on animal cloning. The request was considered thoroughly by the SC that expressed some concerns. The European Commission explained that it is not requesting a new opinion, neither for the SC to make scientific judgements, but rather a technical report to make possible new information available. Djien Liem said that the AF will be kept informed.

Sweden referred that the SC opinion on nanotechnology concludes that there is high uncertainty due to insufficient data. Sweden also said that consumer perception of nanotechnology is negative and therefore requested information on the extent to which nanotechnology is presently used by the industry, suggesting that reality is possibly ahead of legislation. Djien Liem said that the development in the area of nanotechnology is huge, that there is a lack of knowledge on the exposure to nanoparticles through food and feed, and that the fate of nanoparticles in the food and feed chain is not known. Catherine Geslain-Lanéelle added that the SC opinion addresses some potential uses of nanotechnology, *e.g.* food supplements and packaging materials. Ireland commented that EFSA focuses on engineered nanoparticles, not the naturally occurring nanoparticles, and confirmed that engineered nanoparticles are used in fridges, food processing plants and food packaging materials. Germany said that there are a few other applications of nanotechnology, *e.g.* in clothing, that public perception differs from reality, that the European Commission does not have an overview on products on the market, and that nanotechnology is mostly a challenge from a risk communication perspective. The Netherlands said that the use of nanoparticles in food is rather remote, except for food supplements. The European Commission mentioned that both DG Health and Consumers and DG Research are considering nanotechnology, that normal monitoring is ongoing and that engineered nanoparticles are discussed in the novel foods context for possible legislation. However, it is still a field of research, so more information is needed. Belgium announced that a scientific colloquium on nanotechnology will be organised jointly by the Belgium EU Presidency and EFSA during the second half of 2010.

6.5 Other matters raised by EFSA

Anne-Laure Gassin reminded the AF that information pre-notified under embargo by EFSA is for restricted use only and will be circulated with a cover page

defining this in the future, following a recommendation from the Internal Auditors of the European Commission.

Catherine Geslain-Lanéelle informed that EFSA had received a request from the European Commission for an urgent scientific opinion on the risks for public health due to the presence of nicotine in wild mushrooms.

7 ANY OTHER BUSINESS

7.1 AF meeting dates and venues in 2010

Torben Nilsson informed that four AF meetings are planned for 2010, in addition to the special AF meetings on animal health and plant health. The duration of the AF meetings will be 1½ days in order to allow sufficient time for the discussions. He thanked the host countries for their kind invitations and mentioned also the planning of SGC meetings in 2010. The agreed meeting dates and venues are:

AF meetings
11-12 February 2010, Sevilla (Spain).
19-20 May 2010 (venue to be announced at the next AF meeting).
22-23 September 2010, Malta.
25-26 November 2010, Brussels (Belgium).

SGC meetings
20 April 2010, Bratislava (Slovakia).
Autumn 2010 (to be decided later).

7.2 Other issues

Torben Nilsson drew the attention of the AF to a request for updating of previous nominations of national GMO experts in view of a consultation workshop with Member States on the environmental risk assessment guidelines of EFSA's GMO Panel in Berlin on 17 June 2009 and a European Conference addressing "Assessing risks of GMOs for health and environment" in Brussels on 14-15 September 2009.

Action 5: AF members to submit possible updates to previous nominations of national GMO experts to the AF secretariat by 25 May 2009.

Torben Nilsson further mentioned that a national expert meeting on dietary reference values would take place in Barcelona on 7-8 September 2009.

The Czech Republic updated the AF on the outcomes of an international conference of food safety organised by the Czech EU Presidency in Prague on 21-22 April 2009. Catherine Geslain-Lanéelle congratulated the Czech Republic on the interesting conference and suggested sharing the presentations through the Information Exchange Platform (IEP).

Sweden asked about EFSA's view on its balance between requests and self-tasking with reference to an overview on EFSA's self-taking activities that was shared with the AF members. Catherine Geslain-Lanéelle said that EFSA monitors resources allocated to self-tasking, which is often used to address the important development of risk assessment methodologies and guidance documents. EFSA has not encountered difficulties to undertake self-tasking, but some Panels have not yet done so due to their workload. Riitta Maijala highlighted the importance of the SC for EFSA's self-tasking. Sweden emphasised that the question should not be perceived as criticism, but rather as an offer to help prioritising self-tasking.

The Netherlands informed the AF that a decision tool on when to implement risk-benefit assessments had been shared through the IEP and that a Dutch report on children's temporary exceedence of ADIs for chemicals would also be shared soon. Catherine Geslain-Lanéelle thanked for the useful information.

Germany proposed that the AF and MB should meet in 2010. Catherine Geslain-Lanéelle replied that she would consult with the Chair of the MB on this idea.

Sweden referred to previous discussions on the difficulty for smaller countries to contribute to all EFSA's work areas and suggested a need to know EFSA's future needs well in advance in other for the Member States to assist within their areas of special expertise. Sweden proposed the establishment of a working group for further discussion on this topic. Catherine Geslain-Lanéelle asked Hubert Deluyker to discuss further with Sweden and other interested parties and report back to the AF.

8 CLOSURE OF THE MEETING

Catherine Geslain-Lanéelle closed the meeting by thanking Romania for hosting the meeting, the AF members and observers for their active and constructive participation, the interpreters for their excellent work, and EFSA staff for the preparation of the meeting.