

SCIENTIFIC COMMITTEE AND ADVISORY FORUM UNIT

Parma, 2 May 2011

EFSA/AF/M/2011/381/PUB/FIN

Minutes**THIRTY NINTH MEETING OF THE ADVISORY FORUM****PARMA (ITALY), 15 MARCH 2011****MEMBERS OF THE ADVISORY FORUM****Chair:** *Catherine Geslain-Lanéelle*, Executive Director, EFSA

Austria	<i>Roland Grossgut</i>	Italy	<i>Giancarlo Belluzzi</i>
Belgium	<i>Benoît Horion</i>	Latvia	<i>Gatis Ozoliņš</i>
Bulgaria	<i>Boiko Likov</i>	Lithuania	<i>Snieguolė Ščeponavicienė</i>
Cyprus	<i>Popi Kanari</i>	Luxembourg	<i>Félix Wildschutz</i>
Czech Republic	<i>Jitka Götzová</i>	Malta	<i>Ingrid Busuttil</i>
Denmark	<i>Henrik C. Wegener</i>	Netherlands	<i>Evert Schouten</i>
Estonia	<i>Hendrik Kuusk</i>	Norway	<i>Kirstin Færden</i>
Finland	<i>Jaana Husu-Kallio</i>	Poland	<i>Jan Krzysztof Ludwicki</i>
France	<i>Valérie Baduel</i>	Portugal	<i>Maria João Seabra</i>
Germany	<i>Andreas Hensel</i>	Romania	<i>Liviu Rusu</i>
Greece	<i>George-Ioannis Nychas</i>	Slovakia	<i>Zuzana Bírošová</i>
Hungary	<i>Maria Szeitzné Szabó</i>	Spain	<i>Ana Troncoso</i>
Iceland	<i>Jón Gíslason</i>	Sweden	<i>Leif Busk</i>
Ireland	<i>Alan Reilly</i>	United Kingdom	<i>Andrew Wadge</i>

OBSERVERS

Croatia	<i>Zorica Jurković</i>	Switzerland	<i>Michael Beer</i>
Former Yugoslav Republic of Macedonia	<i>Dejan Runteviski</i>	Turkey	<i>Nergiz Özbağ</i>
Montenegro	<i>Jelena Vracar</i>	European Commission	<i>Jeannie Vergnettes</i>

REPRESENTATIVES OF THE EUROPEAN FOOD SAFETY AUTHORITY

Advisory Forum secretariat: *Gian Luca Bonduri, Georgi Grigorov, Elena Marani, Jeffrey Moon and Torben Nilsson.*

<i>Bernhard Berger</i>	<i>Djien Liem</i>
<i>Elzbieta Ceglarska¹</i>	<i>Riitta Maijala</i>
<i>Hubert Deluyker</i>	<i>Christine Majewski²</i>
<i>Anne-Laure Gassin</i>	<i>Saadia Noorani²</i>
<i>Kerstin Gross-Helmert²</i>	<i>Tobin Robinson</i>
<i>Michael John Jeger¹</i> <i>(Chair of EFSA's Plant Health Panel)</i>	<i>Didier Verloo³</i>
	<i>Victoria Villamar</i>

1 WELCOME AND OPENING OF THE MEETING

Catherine Geslain-Lanéelle opened the meeting and welcomed the new AF member from Bulgaria and the new observers from Montenegro that was granted status as EU candidate country in December 2010 and the Former Yugoslav Republic of Macedonia. She also informed that apologies were received from Slovenia.

2 ADOPTION OF THE AGENDA

Spain, Finland and Hungary raised issues for agenda item 4.9. Catherine Geslain-Lanéelle announced that she would like to add an agenda item 3.4 on the new organisational structure of EFSA. The agenda was adopted with this amendment.

3 STRATEGIC DISCUSSION ON EFSA'S WORK WITH THE MEMBER STATES

3.1 Follow up on topics for strategic discussions

Hubert Deluyker informed that an internal EFSA task force will continue liaising on the medium term planning of work to ensure completeness.

Catherine Geslain-Lanéelle said that the medium term planning will be the basis for cooperation and that the budget for grants and procurement would increase to 12 millions EUR in 2012.

¹ Attended agenda item 3.3.

² Attended agenda item 4.

³ Attended agenda item 3.2.

Bernhard Berger informed that the [full document on medium term planning](#) was published on EFSA's website in January 2011. He also presented the draft summary brochure targeting a broader audience.

Norway, Ireland, Sweden, Finland, Belgium, and the Netherlands complimented the work on the brochure and made suggestions for improvement of the text.

Catherine Geslain-Lanéelle concluded that these suggestions will be taken into account when finalising the brochure.

Torben Nilsson presented the tentative planning of strategic AF discussions on the topics proposed at the 38th AF meeting. Like in the case of medium term planning, the AF members would be involved in preparing the discussions.

France found the planning useful and asked for clarification regarding the topics alternative risk assessment approaches and disease burden.

Austria asked how the discussion on novel foods would be prepared.

Sweden said that risk comparison was vital for prioritisation.

Catherine Geslain-Lanéelle said that the intention was to collect best practices and learn from each other.

Germany supported this approach, saying that the Member States should have a possibility to report. Germany further proposed to include risk perception and the impact of risk communications as a topic for strategic discussion.

Ireland agreed with Germany's proposal and suggested that this discussion should take place in 2011.

Anne-Laure Gassin informed that such a discussion was already ongoing in the AFCWG.

Catherine Geslain-Lanéelle said that EFSA would work with the AFCWG to prepare the AF discussion on risk perception. For the other topics, she reiterated the idea of establishing small preparatory working groups.

The United Kingdom agreed on this approach and expressed an interest in joining the preparatory working group on novel foods.

Djien Liem provided further information on new concepts in risk assessment and said that these would also be addressed by the SC network on the harmonisation of risk assessment methodologies.

On this basis, France suggested that the discussion on alternative risk assessment approaches should initially be addressed by a specialised working group before the AF discussion.

Catherine Geslain-Lanéelle agreed to refer this topic to the SC network on the harmonisation of risk assessment methodologies for an initial discussion.

Upon request from Germany, Riitta Maijala confirmed that EFSA would cooperate with ECHA.

Upon request from Sweden, Denmark clarified that the topic on disease burden raised at the 38th AF meeting was intended broadly rather than specifically linked with the One Health Initiative.

Sweden agreed with Catherine Geslain-Lanéelle that the discussion on disease burden would be related also with risk comparison and priority setting.

Catherine Geslain-Lanéelle concluded that small working groups would be established to prepare the strategic discussions and that sufficient time should be allocated to these preparatory activities.

3.2 Cooperation in the area of assessment methodologies

Didier Verloo presented the work of EFSA's assessment methodology unit, which consists mainly in assisting EFSA's Panels and scientific units, and mentioned examples of cooperation projects that the unit had been involved in.

France requested clarification on the outsourcing through framework contracts.

Ireland found that framework contracts were very useful and requested further information regarding a feasibility study with farming associations, in particular how it would feed into the emerging risks exchange network.

Finland emphasised that the work on emerging diseases would be a huge task.

Cyprus suggested that this work would need to involve traceability studies.

Germany advocated for revitalising the efforts to harmonise risk assessment methods and suggested discussing the models used.

Hubert Deluyker said that the experiences with outsourcing through framework contracts were successful.

Didier Verloo explained that framework contracts were used as a backup in case of an overload of work. He said that the feasibility study was still in its conceptual phase and confirmed that it would be conducted in cooperation with the emerging risk, the animal health and animal welfare and the plant health units.

3.3 Cooperation in the area of plant health

Michael Jeger, Chair of EFSA's Plant Health Panel, presented the work of the Panel and the main areas of cooperation with the Member States.

France informed that the National Plant Health Laboratory had been incorporated into ANSES on 1 January 2011. The resource allocations would now be based on risk prioritisation.

Denmark noted the shortage of expertise in the risk assessment of phytosanitary issues and asked how to avoid duplication of the work of the European Plant Protection Organisation (EPPO).

The Netherlands asked about the cooperation with EPPO, whether self-tasking was used only for the development of guidance documents, and if socio-economic aspects were covered.

Ireland noted the difference of the plant health work from other areas of food safety and emphasised that clarity about the roles of various actors in the EU plant health risk analysis system remained a challenge.

The United Kingdom welcomed EFSA's work on plant health and asked for more details on the current boundaries between the work of EPPO and EFSA.

Finland echoed the previous comments regarding EPPO and EFSA and suggested strengthening the cooperation between EPPO, EFSA and Member States further to be able to influence international standards and make best use of the resources.

Michael Jeger replied that so far self-tasking had been used to ensure transparency of the methods, while self-tasking on opinions could follow later. In the past, it had been a major challenge to obtain permission to use data from the Member States in opinions. This had been solved through an agreement in the Standing Committee on Plant Health.

Michael Jeger also explained that EPPO's pest risk analysis (PRA) addresses risk assessment, risk management, and environmental and socio-economic aspects. Until now, EFSA's Plant Health Panel had peer reviewed PRAs performed by EPPO or others, while it was only recently that the Panel had received a request from the European Commission to conduct a full PRA. Socio-economic aspects are outside EFSA's remit and evaluation of risk management options would only be considered if requested as advice to the European Commission. Since the Panel experts were well aware of ongoing activities elsewhere, there would not be any duplication of efforts. Finally, Michael Jeger confirmed that EFSA's opinions had already had an impact, *e.g.* on derogations, while one should remember the time lag between risk assessment and risk management.

Norway welcomed the work of the Panel and said that the development of models is seen as a special challenge in the work of the Norwegian Plant Health Panel. As the Norwegian Scientific Committee for Food Safety mainly deals with requests from risk managers on concrete cases, the use of International Plant Protection Convention standards is usually requested by the risk managers.

Riitta Maijala reiterated that EFSA's Plant Health Panel had developed from peer reviewing PRAs to now providing also full PRAs. The Panel was dependent on data from the Member States and its influence on risk management would be through the European Commission.

Finland compared to the area of animal health where the European Commission would refer to EFSA in meetings of the World Organisation for Animal Health. A similar approach in the area of plant health was suggested.

Catherine Geslain-Lanéelle concluded that the role of EFSA versus EPPO had now been clarified. She emphasised that there is no intention to duplicate efforts, while it is important to have an EU body in the area of plant health, since the aim is to protect the EU territory. She thanked Michael Jeger and the Panel experts.

3.4 New organisational structure of EFSA

Catherine Geslain-Lanéelle briefly outlined EFSA's core achievements to 2011 and then looked ahead. She explained EFSA's ongoing work on effectiveness and efficiency and presented the new organisational structure of EFSA, which would be implemented on 1 January 2012 (with a gradual move starting on 1 May 2011).

Sweden asked why biological and chemical monitoring would not be merged into one unit.

The United Kingdom expressed support to the reflections on achievements so far and the future role of the Panels and fees.

Austria welcomed the reorganisation and enquired how the pesticides and plant health units would cooperate.

Germany enquired about quality management in EFSA and emphasised the importance of close cooperation with the scientific world to ensure scientific quality. Germany further asked who would be in charge of urgent requests in the new organisational structure, since several units appeared to be involved.

Ireland appreciated the evolution and welcomed, in particular, the new application desk, which would correspond to the need of the food industry for one contact point to EFSA. Ireland also enquired about reflections on EFSA's independence in connection with fees.

Hungary wanted to know which unit would deal with novel foods.

Italy welcomed the application desk and the centralisation of administrative work.

Catherine Geslain-Lanéelle replied that quality management would need to be further developed in EFSA and informed that a new Head of Quality Management under the Executive Office would join EFSA on 1 April 2011.

Regarding the role of the Panels, she said that according to EFSA's Founding Regulation only the Panels can adopt opinions. However, EFSA staff could be more involved in preparing the opinions, not least in the area of applications. The services of the application desk could be boosted if EFSA would receive fees. The procedures related with the collection of fees should ensure independence.

Riitta Maijala added that the application desk would be good for planning and stakeholder contacts. She also said that urgent requests would continue to be considered first by EFSA's Mandate Review Committee and that the work would involve all relevant units.

Hubert Deluyker said that the different monitoring units would cooperate and that there would be a strengthened focus on knowledge management in the new 'human resources' unit to ensure and further develop scientific skills.

Bulgaria questioned the separation of the work on biological hazards into a biological hazards unit and another unit on biological monitoring.

The European Commission said that there is a good cooperation on the assessment of fees, *i.e.* both EFSA and Member States would be consulted, and the work would be completed by the end of 2011 in support of EFSA's evolution.

Germany expressed appreciation that Member States would be consulted on changes to EFSA's Founding Regulation. Germany also argued that it is crucial for EFSA's success to understand Europeans' risk perceptions and how they are influenced by risk and crisis communication. Thus, Germany suggested investing in scientific work on how to improve and explain EFSA's communications work.

The Netherlands asked about staff reactions to the organisational changes and the new human resources strategy.

Sweden enquired about how to measure the effectiveness of different ways of working, *e.g.* comparing the pesticides system with work in other areas.

Hubert Deluyker explained that while some units support more than one Panel, in the area of biological hazards the relation between the biological monitoring unit and the biological hazards unit is one to one. In addition, harmonisation of monitoring will take place in cooperation between the monitoring units.

Catherine Geslain-Lanéelle said that in her perception, based on consultation of Heads of Units and an all staff meeting, the staff reactions to the organisational changes were constructive, albeit expressing some concern over the centralisation of meeting organisation and administrative tasks. It was important to say that the aim was to focus on science and the expert would still have a single contact person in EFSA. Also, staff would be involved in finalising the migration plan. The Human Capital Strategy would be developed with the support of consultants.

Riitta Maijala said that even the same Panel can use very different amounts of resources on different questions, so the Panels would benefit from support provided through outsourcing. The pesticides system was different from other areas due to differences in the legislation.

Hubert Deluyker said that the respect of quality and timelines was essential for outsourcing to be useful.

Anne-Laure Gassin acknowledged the importance of understanding the impact of risk communications. She referred to the consultations of the AFCWG and the Advisory Group on Risk Communications as valuable sources of advice and said that EFSA would take advantage of opportunities to further strengthen the cooperation.

4 OTHER MATTERS RAISED BY EFSA AND THE MEMBER STATES

4.1 Annual Focal Point Report 2010

Kerstin Gross-Helmert presented the Annual Focal Point Report 2010 and the proposed priorities for the work of the Focal Points in 2011.

In relation with the promotion of article 36 calls, Bernhard Berger informed that the MB had agreed to increase the co-financing under article 36 grants from 80 to 90 % and the overhead from 7 to 10 %.

Catherine Geslain-Lanéelle highlighted the importance of involving the Focal Points in promoting the upcoming call for experts for EFSA's SC and Panels, not least to achieve a better geographical diversity.

Germany complimented the achievements and good dynamics of the Focal Point network and recommended increasing the funds for the Focal Points.

Catherine Geslain-Lanéelle agreed that a tremendous progress had been made.

Italy said that Focal Points could play a role in assisting article 36 institutions and experts in preparing better applications.

Catherine Geslain-Lanéelle concluded that the AF conveyed its compliments to the Focal Points. She also thanked the AF for their input on the shortlist of experts for the ANS and CEF Panels and the reserve list for the SC and other Panels.

4.2 Evaluation of the Information Exchange Platform

Saadia Noorani presented the results of the evaluation of the Information Exchange Platform (IEP) and recommendations, including extending the access to the IEP and increasing awareness of this source of information.

France, Belgium, Sweden, Ireland, the United Kingdom, Germany, and Italy expressed that the IEP is an important tool for cooperation and thus supported promoting the use of the IEP and broadening the read-only access to all Extranet users and European risk assessment institutions.

Germany said that opening the access broadly would imply that information could be shared only after publication.

France commented that the IEP serves to facilitate access to public information available in the Member States and advocated for EFSA's staff and experts to actively use this valuable source of information.

Hubert Deluyker replied that the IEP was not intended for sharing of confidential information. Such information could be shared on a pre-notification basis.

Catherine Geslain-Lanéelle concluded that further IEP promotion activities would be developed, that the monthly IEP reports could be circulated freely, and that the access to the IEP would be broadened to include all Extranet users, article 36 institutions, and interested officials of the European Commission.

4.3 Internal project on enhancing efficiency in EFSA's processing of applications

Riitta Maijala briefed the AF about EFSA's work on building a more efficient process for the evaluation of regulated products. This topic was related with the discussion on EFSA's new organisational structure under agenda item 3.4.

Austria appreciated EFSA's wish to develop further in this field and enquired how EFSA was involved in designing new regulatory processes.

The United Kingdom enquired if EFSA could do more to work with other international bodies to avoid duplication, *e.g.* EPPO as discussed under agenda item 3.3 or the Joint FAO/WHO Expert Committee on Food Additives.

Riitta Maijala was grateful that the European Commission had consulted EFSA on the recent legislation on food additives. The international cooperation is not included in the work of the task force on enhancing efficiency in EFSA's processing of applications. EFSA has a strategy on international cooperation, which guides the way of working.

Catherine Geslain-Lanéelle said that a key priority for EFSA's international activities was the harmonisation of risk assessment approaches and mutual recognition. This task would fall under the new Directorate of Science Strategy and Coordination.

France suggested discussing the optimal model and benchmarking with other international bodies.

Riitta Maijala said that the intention was to develop the most appropriate model based on various models tested and benchmarking with EMA and ECHA.

Catherine Geslain-Lanéelle said that the optimal model should be considered as a 'tool box' and a standardised approach would be advantageous also for the applicants and Member States.

Upon request from Sweden, Catherine Geslain-Lanéelle clarified that companies cannot currently pay for advice from EFSA, but such a model is used by EMA.

4.4 Independence and transparency in risk assessment: the new governance setup of ANSES

France presented the new governance setup of ANSES, including a committee for ethical standards and prevention of conflicts of interests, and explained the difficulties in finding completely independent experts who are still competent.

Catherine Geslain-Lanéelle thanked France for sharing this information that was relevant also for EU agencies. She informed that EFSA has initiated reviewing its policy on declarations of interests. A reflection paper would be shared with the MB on 17 March 2011 and subsequently also with the AF. The intention was not to focus narrowly on independence, but to see this in the broader context of scientific quality.

The United Kingdom agreed with this comment, since the primary consideration should be the competence of experts, while ensuring also their absence of financial conflicts of interests. The United Kingdom added that the mere fact of having worked on something does not constitute a conflict of interests and those who criticise the lack of independence do not declare their own interests.

Finland enquired if the members of ANSES' new committee for ethical standards and prevention of conflicts of interests were paid and what the annual costs were.

Austria noted that the focus should be on competences rather than independence, since research funding for university experts often comes from the industry.

Germany said that science is defined by the scientific methods applied, so industry studies were normally accepted. The risk in EFSA's design, where scientific decisions are delegated to Panels, was the focus on the independence of individual experts, while it should rather be on the independence of the institution providing the scientific advice. This would be important to be able to draw also on the expertise of the industry.

Italy said that the best experts often cooperate with the industry, so there would be a need to ensure transparency, while keeping in mind that EFSA's Panels are characterised by scientific discussions, where the influence of each individual expert is limited and depends on scientific arguments.

Upon request from Hubert Deluyker, France said that independence and transparency were handled in the same way for authorisations and other risk assessments. France also replied that the members of the committee for ethical standards and prevention of conflicts of interests receive no payment and that the public expects experts to be both competent and independent, which excludes experts from the private sector.

Catherine Geslain-Lanéelle mentioned that discussions on independence and transparency were foreseen also at the joint meeting of EFSA's MB and AF on 16 March 2011 and at the MB meeting on 17 March 2011.

4.5 Update on Q-fever

The Netherlands updated the AF on Q-fever, saying that the epidemic had subsided. The Netherlands also mentioned that Q-fever can be transported over long distances via aerosols.

Germany informed that no Q-fever infections had been detected in Germany.

Upon request from Anne-Laure Gassin, the Netherlands said that communications were active after the outbreak, but not before.

Upon request from Ireland, the Netherlands said that most animals are kept in stables in the Netherlands.

4.6 Update on aspartame

Riitta Maijala updated the AF on ongoing activities related with aspartame, saying that EFSA's ANS Panel will undertake further work on aspartame to issue an opinion on the interpretation of recent results reported by Soffritti *et al.* and suggested implications of methanol by December 2011.

Anne-Laure Gassin said that EFSA is also following aspartame closely from the communications perspective.

Upon request from Hungary, the United Kingdom informed that the double-blind testing of possible acute symptoms of aspartame intake is ongoing. The United Kingdom would also issue a statement on methanol shortly.

France informed that ANSES published an opinion on 15 March 2011 concluding that from a toxicological point of view the new results did not raise any need to re-evaluate previous opinions. However, nutritional aspects of the use of artificial sweeteners should be considered further.

Norway said that a risk-benefit assessment of sweeteners versus sugar had been made in Norway, concluding on the benefits of limiting sugar consumption. The opinion would be shared through the IEP.

4.7 Update on dioxins

Germany briefed the AF on a recent incidence of dioxins in animal feed in Germany, which had caused major public concern, even though it was clear from the beginning that there was no risk for consumers. Hence, the handling of the crisis had highlighted the importance and challenges of risk communications.

France mentioned that even if the maximum residue levels were exceeded at the source, due to dilution, this would not necessarily imply any health risks.

Denmark said that closing farms had led to the perception that the contamination was very dangerous and Hungary asked why the farms had been closed if there were no risks.

Germany explained that the farms were closed as a precautionary measure until the source of the contamination had been confirmed. Germany also said that the main challenge from a risk communications perspective had been how to explain the difference between acute toxicity and long term preventive measures.

The Netherlands informed the AF about a fire at a chemical plant that had led to a plume of smoke over the Netherlands. The sampling and analysis of the potential chemical contamination of grass and vegetables had shown that limit values were not exceeded, so there were no risks for consumers. However, the background contamination of dioxins in grass during the winter was higher than the norm, while in the spring, when the grass starts growing, concentrations quickly drop. These findings could be of concern regarding animals, *e.g.* goats, grassing outside during the winter.

Hubert Deluyker suggested that due to the repeated dioxin incidences, dioxins should be considered also outside crisis situations.

Germany agreed and said that although the environmental contamination had successfully been reduced, the background contamination of dioxins remained relatively high, so grassing should be avoided in industrial areas and sheep liver products may exceed the limit values.

4.8 Weight loss diets: risks and benefits

France presented a recent [report on the health risks related to dietary weight-loss practices](#). This scientific assessment of diets had been appreciated by consumers.

Catherine Geslain-Lanéelle said that the AF might wish to come back to this interesting subject.

4.9 Other matters raised by EFSA and the Member States

Spain informed the AF about its national food consumption survey conducted in the four seasons of the year.

Catherine Geslain-Lanéelle said that this would be good for exposure assessments of the Spanish population.

Finland noted that, according to the Eurobarometer 2010, two thirds of the EU citizens are worried about food additives and some products contain up to 20 different additives, so it was suggested that EFSA should consider the risk assessment of combined effects.

Riitta Maijala said that combined effects are considered in the pesticides area and also relevant in other areas, so these could be discussed at a future AF meeting.

Hubert Deluyker agreed that the work should go ahead without awaiting the more sophisticated risk assessment methods being developed.

Sweden suggested that EFSA could launch an article 36 call to test a ‘cocktail’ of pesticides on rats or mice.

France informed that such tests were already ongoing in France.

Catherine Geslain-Lanéelle said that this area could be an idea for a research proposal to DG Research. She also mentioned that EFSA’s communication on [chemicals in food](#) addresses the topic of ‘cocktail’ effects.

Hungary announced a joint event on emerging risks in Budapest on 27 May 2011, *i.e.* back to back with the 40th AF meeting.

5 ANY OTHER BUSINESS

In the light of the radioactive spill in Japan and the potential spread of radioactivity to neighbouring countries in Asia, Tobin Robinson briefed the AF on food imports to the EU from these countries.

The European Commission informed that surveillance is ongoing through the Rapid Alert System for Food and Feed and that the EU has special regulations for this kind of radioactive incidences.

END OF THE ORDINARY ADVISORY FORUM MEETING

Catherine Geslain-Lanéelle closed the ordinary AF meeting⁴.

⁴ The report on the joint meeting between EFSA’s MB and AF on 16 March 2011 is a separate document.