

ADVISORY FORUM AND SCIENTIFIC COOPERATION UNIT

Parma, 30 April 2012
EFSA/AF/M/2012/414/RES/FIN

Minutes

**FORTY THIRD MEETING OF THE ADVISORY FORUM
PARMA (ITALY), 7-8 MARCH 2012**

MEMBERS OF THE ADVISORY FORUM

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

Austria	<i>Roland Grossgut</i>	Latvia	<i>Gatis Ozoliņš</i>
Belgium	<i>Benoît Horion</i>	Lithuania	<i>Snieguolė Ščeponavičienė</i>
Bulgaria	<i>Boiko Likov</i>	Luxembourg	<i>Patrick Hau</i>
Cyprus	<i>Popi Kanari</i>	Malta	<i>Ingrid Busuttil</i>
Czech Republic	<i>Jitka Götzová</i>	Netherlands	<i>Antoon Opperhuizen</i>
Denmark	<i>Jørgen Schlundt</i>	Norway	<i>Kirstin Færden</i>
Estonia	<i>Küllli Rae</i>	Poland	<i>Jacek Postupolski</i>
Finland	<i>Kirsti Savela</i>	Portugal	<i>Jorge Reis</i>
France	<i>Rozenn Saunier</i>	Romania	<i>Liviu Rusu</i>
Germany	<i>Andreas Hensel</i>	Slovakia	<i>Zuzana Bírošová</i>
Greece	<i>Eirini Tsigarida</i>	Slovenia	<i>Ada Hočevar Grom</i>
Hungary	<i>Maria Szeitzné Szabó</i>	Spain	<i>Ana Canals</i>
Ireland	<i>Raymond Ellard</i>	Sweden	<i>Leif Busk</i>
Italy	<i>Giancarlo Belluzzi</i>	United Kingdom	<i>Andrew Wadge</i>

OBSERVERS

Croatia	<i>Zorica Jurković</i>	Switzerland	<i>Michael Beer</i>
FYR of Macedonia	<i>Svetlana Tomeska Mickova</i>	Turkey	<i>Nergiz Özbağ</i>
Montenegro	<i>Nedeljko Latinović</i>	European Commission	<i>Jeannie Vergnettes</i>

REPRESENTATIVES OF THE EUROPEAN FOOD SAFETY AUTHORITY

Advisory Forum secretariat: *Sergio Gaiti, Saba Giovannacci, Elena Girolì, Jeffrey Moon, Torben Nilsson, and Saadia Noorani.*

<i>Bernhard Berger</i>	<i>Anne-Laure Gassin</i>
<i>Per Bergman</i> ¹	<i>Claudia Heppner</i> ¹
<i>Stef Bronzwaer</i>	<i>Juliane Kleiner</i> ¹
<i>Anna Castoldi</i> ¹	<i>Djien Liem</i> ¹
<i>Hubert Deluyker</i>	<i>Tobin Robinson</i> ¹
<i>Dirk Detken</i> ¹	<i>Johann Steinkellner</i> ¹
<i>Jean-Lou Dorne</i> ¹	<i>Katriina Willgert</i> ¹
<i>Albert Flynn (Chair of EFSA's NDA Panel)</i> ¹	

1 WELCOME AND OPENING OF THE MEETING

Catherine Geslain-Lanéelle opened the meeting and welcomed the AF members to EFSA's new premises. She greeted the new AF members from the Netherlands and Poland and the substitute for this meeting from Portugal and mentioned that apologies were received from Iceland. She also congratulated the former AF member from Finland, Jaana Husu-Kallio, on her nomination as Permanent Secretary of the Ministry of Agriculture and Forestry of Finland.

2 ADOPTION OF THE AGENDA

Catherine Geslain-Lanéelle informed that Denmark, Hungary, and Germany had raised additional matters for discussion at the meeting after the draft agenda had been finalised. These matters would be addressed under agenda item 4.6. In addition, Ireland wanted to make an announcement under agenda item 4.6. The agenda was adopted.

3 STRATEGIC DISCUSSION ON EFSA'S WORK WITH MEMBER STATES

3.1 Risk perception – risk communications: Independence of scientific advice

- **EFSA's policy on independence and scientific decision-making processes**

Dirk Detken presented EFSA's policy on independence and scientific decision-making processes and explained how declared interests were assessed.

¹ Attended part of the meeting.

Sweden enquired about the reactions of stakeholders at the information meeting in Brussels on 5 March 2012, suggested that even the best system might not be sufficient to satisfy some critics, and commented that EFSA's approach worked already in the past.

Belgium shared the views of Sweden and suggested that Focal Points could play a role in explaining the new policy, and in particular the implementing rules, to Article 36 institutions.

Cyprus congratulated EFSA on a very clear policy and complimented the work to avoid grey zones and include staff leaving EFSA. Cyprus also noted that EFSA would spend a lot of time for audits.

Germany said that the different Article 36 institutions do not have the same status, questioned whether EFSA staff was competent in assessing the declarations of interests, noted that there were so few experts in the packaging area that sometimes industry experts could not be excluded, and finally asked if the EFSA experts were made aware at the time of application of the way their independence would be assessed and how.

France requested more information on the internal auditing procedure and suggested finding the right balance between the independence and competences of experts.

Anne-Laure Gassin reported that some critics of EFSA's independence had decided not to attend the information meeting with stakeholders, while the media coverage had highlighted that EFSA's rules had been clarified and strengthened. She agreed that this did not invalidate EFSA's previous independence.

Catherine Geslain-Lanéelle said that EFSA staff had been trained in assessing potential conflicts of interests and that EFSA had invested a lot of resources in ensuring its independence, since this was important for building trust, maintaining quality, and ensuring unbiased, scientific work of the Panels.

Dirk Detken clarified that EFSA's internal auditor reviews decision-making processes, while a commission comprising the three scientific directors and the Head of the Legal and Regulatory Affairs Unit had been established to review decisions on potential conflicts of interests.

- **Implementing rules of EFSA's policy on independence and scientific decision-making processes**

Hubert Deluyker presented some fictitious cases to illustrate the screening of Panel members' declarations of interests in practise. He emphasised, in particular,

the important distinction between food safety organisations (FSO)² and other organisations. FSOs would comprise national food safety agencies, public research institutions, and international bodies.

Austria asked if the new criteria had been applied for assessing the independence of the new Panel experts.

Germany said that it is important to take a balanced approach to independence and requested clarity on the definition of scientific committees, so that experts involved in work at national level would not be excluded from EFSA's Panels. Germany further suggested that EFSA should accept risk assessments from Member States and establish mechanisms for work sharing similar to those memoranda of understanding signed with a number of third countries and international organisations in order to avoid duplication of work.

Hubert Deluyker confirmed that the new criteria had been used when assessing the independence of the members of the new Scientific Committee and Panels starting in July 2012. For the ANS and CEF Panels and ongoing working groups, the new criteria would be applied as of July 2012. He saw no reason for concern about the previous scientific outputs, since the new implementing rules were merely clarifying some issues, while EFSA's experts had always been independent. He further clarified that third countries had no say on EFSA's opinions and that industry experts could not be members of Panels or working groups.

Dirk Detken added that hearing experts can provide expertise without contributing to the decision-making process. In addition, a waiver procedure was foreseen in case the involvement of a particular expert was judged to be essential despite potential conflicts of interests. The calls for expression of interest in becoming an EFSA expert clearly described the process for assessing conflicts of interests, so the interested experts were aware of the procedure. Finally, for its staff, EFSA respects the staff regulation of the European Commission.

- **National perspectives on independence**

The United Kingdom presented its views on independence, emphasising that what really matters is the openness, honesty, and clear decision-making process communicated effectively and confidently. For this reason, meetings of the Scientific Committee of the Food Standards Agency were held in open sessions.

Upon request from Anne-Laure Gassin, the United Kingdom clarified the role of lay members in the scientific working groups.

² Article 1 (3.f) of the Decision of the Executive Director of the European Food Safety Authority implementing EFSA's Policy on Independence and Scientific Decision Making Processes regarding Declarations of Interest, Parma, 21 February 2012. Available online at: <http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf>.

Catherine Geslain-Lanéelle informed that EFSA had launched a pilot project on opening Panel meetings to observers. This would not apply to discussions on confidential information, *e.g.* applications.

Upon request from Germany, the United Kingdom confirmed that the Food Standards Agency accepts and follows the advice provided by its scientific committee, since it represents the consensus view of its experts. However, while the scientific risk assessment is an important starting point, it is not the only point being considered in the political decision-making process.

Germany presented its best practice to ensure independent risk assessment and suggested that EFSA could consider national opinions more and rely on a rapporteur system, since EFSA's Panel members were overloaded.

Sweden presented its views on independence, stating that one should take a broader approach than merely considering financial independence, since there could also be social and political influence factors. The independence of risk assessment from risk management was important, while at the same time a certain degree of cooperation was required. This could best be addressed by open scientific processes and particular emphasis on the formulation of the question addressed to risk assessors and the scientific data provided.

France shared a national perspective on the independence of scientific opinions.

Upon request from Catherine Geslain-Lanéelle, France confirmed that they published the declarations of interests of its staff involved in risk assessments.

Upon request from Denmark, Sweden clarified the statement on possible political influence on risk assessments, saying that there are many value-based judgements in science, which could be influenced by political views on the industry.

Denmark advocated for a narrow focus on financial independence, *i.e.* avoiding that somebody is paid by the industry to promote certain views.

The United Kingdom agreed with Sweden that ideology could influence assessments. This would be equally true for the industry and NGOs.

Hubert Deluyker informed that EFSA also considers NGO membership, which would generally be acceptable, except when the NGO was involved in specific activities in the work area.

Spain agreed that some interaction between risk assessors and risk managers is needed and suggested that risk assessments performed by EFSA would be more independent of national political influence. Thus, while the Panels would consider national risk assessments, EFSA should perform its own risk assessments and not merely endorse risk assessments performed by Member States.

Germany agreed on the importance of cooperation at EU level, while questioning whether the quality of EFSA's opinions was higher than that of Member State risk assessments and stating that national risk managers could not wait for EFSA opinions due to the need for fast action at national level.

Norway found that the framing question for the discussion on independence was how to ensure transparency and referred to the need for transparency also of risk management processes, as discussed at the previous AF meeting.

Action 1: EFSA to share further information on the pilot project on open Panel meetings with the AF members.

- **Addressing communications challenges and opportunities and perspectives from the AFCWG**

Catherine Geslain-Lanéelle noted the importance of communicating properly and passed the floor to Anne-Laure Gassin, who presented communications challenges and opportunities, including ideas on how to jointly strengthen confidence in the independence of science. She also provided a feedback from the discussion on independence at the AFCWG meeting in Helsinki on 1-2 February 2012.

Germany agreed on the importance of working together and suggested a working group on the strategic approach to facing the communications challenges, since there may be different views on the priorities in different countries.

Hubert Deluyker invited the Member States to compare EFSA's implementing rules with national approaches in order to identify possible discrepancies.

Catherine Geslain-Lanéelle mentioned that EFSA had compared its implementing rules with those of the European Medicines Agency (EMA).

The United Kingdom said that transparency is important to demonstrate the independence defined by science- and evidence-based approaches, stressed the importance of rapid responses to criticism, suggested that some groups of critics may have financial interests, and encouraged the liaison with other EU agencies on independence, since the debate was not limited to the food safety area.

Catherine Geslain-Lanéelle emphasised the need for science to be considered in public decision-making and in the societal debate, so it was important for scientists to engage in the public debate and avoid becoming defensive or retracting when challenged.

Ireland found that the opponents to EFSA would never be convinced, so the aim was to convince the general public of EFSA's independence and reliability. The audit reports could be an authoritative voice in this regard.

Belgium was convinced of the need for a system to safeguard independence. However, going too far could lead to isolation and be counterproductive.

Germany advocated for trust in food safety agencies that work for consumer protection and complimented EFSA's work.

Sweden suggested that, paradoxically, the transparency of the risk assessment process made the scientific risk assessments more vulnerable to criticism than the consideration of other legitimate factors in the risk management process, which ought to be explained more scientifically. In addition, the social dimension of people's perceptions should not be underestimated.

Catherine Geslain-Lanéelle concluded that, in spite of the different arrangements and legal, social and cultural situations in the Member States, there were many commonalities. EFSA would welcome feedback on the implementation of the new rules and then consider their impact in a year's time.

Action 2: Member States to compare EFSA's implementing rules on independence and scientific decision-making processes with national approaches in order to identify possible discrepancies.

- **Article 36**

Bernhard Berger presented information on Article 36 organisations, including their sources of funding, and noted that many, but not all EFSA experts originate from Article 36 organisations. Based on this observation, Hubert Deluyker suggested establishing an AF working group to further reflect on the Article 36 list in this context.

Spain, Italy, and Belgium reflected on the reasons why many Article 36 organisations have never applied for grants from EFSA. Belgium suggested that Focal Points could assist the Article 36 organisations further in applying for calls.

Germany emphasised the need for excellence, expressed scepticism about using funding as a criteria, volunteered to join the AF working group on Article 36, and encouraged EFSA to define what it wants to achieve under Article 36.

Greece reported from a useful seminar organised by the Focal Point for Article 36 and other organisations. However, this had not led to more applications.

Austria agreed with Greece and suggested analysing why many Article 36 organisations have not applied.

Hubert Deluyker concluded that a reflection and discussion on the Article 36 list is needed and took note of the support for an AF working group on Article 36.

Catherine Geslain-Lanéelle noted that some organisations giving valuable support through experts are not on the Article 36 list, which was approved by EFSA's

Management Board based on inputs from the Permanent Representations of the Member States. She explained that EFSA looked into the sources of funding, because the regulation refers to legal entities pursuing public interest.

Germany reminded that deciding on which organisations to propose for the Article 36 list would remain a task of the Member States.

Action 3: EFSA to establish an AF working group on Article 36.

Action 4: Focal Points to continue assisting the Article 36 organisations in applying for calls.

3.2 Status of the planning of strategic Advisory Forum discussions in 2012

Torben Nilsson updated the AF on the status of the planning of strategic AF discussions in 2012 based on previous AF discussions. The AF endorsed the planning with no further comments.

Action 5: EFSA to establish an AF discussion group on medium-term planning to prepare the strategic discussion on multi-annual planning at the next AF meeting.

Action 6: AF members to express their interest in joining the AF discussion group on medium-term planning by the end of March 2012.

3.3 Food safety research

Jeffrey Moon presented the current EFSA activities on prioritisation of research in the context of the development of the European Commission's next framework programme, Horizon 2020. Some detail was provided on the main headings in the proposals for Horizon 2020, indicating those of most relevance, but acknowledging that much of the detail was still to be developed. Jeffrey Moon also provided a summary of the previous consultations held with the AF, Scientific Committee, Panels and units as well as the AFCWG and reminded the AF members of the previous headings used to group the proposals. In 2011, proposals were received for specific projects, which were considered for forwarding to DG Research and Innovation, as well as broader proposals, which were kept for review in the context of Horizon 2020. Six of these proposals were presented as possible priorities. Finally, Jeffrey Moon indicated that for any research proposals to be successful in being selected for calls under the Horizon 2020 framework, there would need to be a clear indication of an outcome linked to the Europe 2020 Strategy with which Horizon 2020 is aligned.

Cyprus highlighted the relevance of the proposed Horizon 2020 theme on 'oceans of tomorrow'.

Germany commented on the importance of harmonised methodologies.

Sweden mentioned that research on computational toxicology, *e.g.* Tox21, could be applicable to the food area too with an aim to abolish animal experiments.

The United Kingdom informed that the Food Standards Agency's Science and Evidence Strategy 2010-2015 had been shared through the Information Exchange Platform.

Hubert Deluyker noted that DG Research and Innovation had been reluctant to fund applied research in the past.

Italy suggested research on feed and primary production to avoid toxins.

Jeffrey Moon invited the AF members to submit their proposals, demonstrating the anticipated impact of the proposed research in terms of benefits to Europe.

Action 7: AF members to share information on research activities and submit possible research proposals by the end of April 2012.

3.4 Chemical mixtures

Johann Steinkellner presented EFSA's ongoing work on the cumulative risk assessment of pesticides, which would be completed by the end of 2012.

Austria noted that the work would be relevant also for other substances.

Cyprus appreciated EFSA's work in this area due to its relevance, considering the use of complex pesticide mixtures, and asked about relations with the [ACROPOLIS project](#) on aggregate and cumulative risk of pesticides.

Denmark enquired about EFSA's cooperation with other international bodies and suggested that this important area should be addressed at the international level.

Malta referred to the new European directive on plant protection products calling for national programmes on the use and levels of pesticides, including cocktail effects.

Johann Steinkellner confirmed that EFSA follows the ACROPOLIS project and the work of international bodies closely.

Upon request from Denmark, Johan Steinkellner informed that EFSA is not coordinating the work of other international bodies.

Denmark replied that global level coordination would be needed.

Germany suggested that the European Commission should ensure cooperation.

Catherine Geslain-Lanéelle acknowledged the need for international cooperation and proposed a consultation meeting with Member State experts and relevant international bodies.

Tobin Robinson informed the AF about EFSA's activities on mixtures in other areas of chemical risk assessments.

Jean-Lou Dorne provided information on work of the WHO, the OECD, and the European Chemicals Agency (ECHA) in the area of chemical mixtures, and how EFSA is collaborating with these organisations.

Germany indicated a need for a systematic, strategic and international approach.

The European Commission said that while an international framework for cooperation exists in the pesticides area, this was not the case in all areas, so there would be a need to follow the legal framework.

Catherine Geslain-Lanéelle concluded that EFSA would engage in international cooperation on chemical mixtures.

Action 8: EFSA to enhance the cooperation on chemical mixtures.

3.5 Cooperation in the NDA area

Albert Flynn, Chair of EFSA's NDA Panel, presented the work of the Panel and the cooperation in the NDA area. He mentioned that the new legislation on novel foods was being reconsidered, presented ongoing work on food allergies and dietary reference values, updated the AF on health claims, where the Article 13 claims on botanicals had been put on hold by the European Commission, and concluded by emphasising the importance of pursuing the good cooperation with Member States' authorities and encouraging applications by Article 36 organisations for calls launched in areas within the Panel's remit.

Catherine Geslain-Lanéelle referred to the improved quality of data submitted with the claims and Albert Flynn confirmed this tendency.

Upon enquiry from Austria, Albert Flynn confirmed the close collaboration with EMA in potentially overlapping areas, *e.g.* botanicals.

Austria and Germany commented on the workload of the Panel and asked about the cooperation with Member States in the area of allergens.

Albert Flynn welcomed the inputs from Member States on allergens and explained that they mainly addressed prevalence, while threshold levels would require further attention.

The United Kingdom thanked the Panel for its high amount of work and stated that the threshold issue was important from a risk management perspective, so scientific guidance on the principles for setting thresholds would be helpful.

Sweden mentioned ongoing research on thresholds. Sweden also asked how fees could be used to facilitate the work of the Panel.

Albert Flynn said that the amount of preparatory work done by EFSA staff has grown and that possibly fees would allow outsourcing of some work.

Per Bergman added that the intention was to request fees for additional services to better assist the applicants.

Catherine Geslain-Lanéelle said that the possibilities would be explored in the European Commission's impact assessment on fees.

The European Commission emphasised the importance of reflecting on making the work more efficient and said that fees would need to be justified in terms of extra services to the applicants. The European Commission has invited the Member States to share their views on fees.

Hubert Deluyker suggested benchmarking against EMA.

The European Commission confirmed that the experiences from EMA and ECHA were taken into account, but also said that the levels of fees in the medicines area, where the applicants obtained exclusive authorisations of specific drugs, would not be feasible in the food sector, where general authorisations were issued. Thus, it would be important to look into the planning of EFSA's work and estimate the related costs.

Catherine Geslain-Lanéelle stressed the importance of establishing a system that would increase consumer protection.

Sweden found that there was a risk that the core budget of EFSA would be reduced with the introduction of fees. This should not happen, since it would limit EFSA's possibility to undertake more self-tasks as recommended by the AF.

Hubert Deluyker questioned if EFSA's experts would continue working for free.

Regarding EFSA opinions on certain novel food and claims, Belgium stressed the need for a rapid revision when new information became available and suggested also that EFSA examines with a broader view the risks associated with a higher intake of certain substances as a consequence of multiple authorisations.

Albert Flynn replied that Member States sometimes request new data when they are uncomfortable with the risk management decisions, so it would be important to understand the issues behind their requests for new data. Notwithstanding this, EFSA always appreciates receiving new data and information on studies from the Member States and is prepared to respond very quickly to new hazards and exposure assessments.

Catherine Geslain-Lanéelle thanked the Panel for its impressive work.

4.1 Update on bisphenol A

Per Bergman updated the AF on bisphenol A. Following the discussion at the previous AF meeting, EFSA and ANSES had met to discuss their diverging views, taken note of the differences in the mandates of their opinions, and agreed to keep each other informed on further work. An Article 30 report had been published, ANSES would proceed with a full risk assessment, and EFSA would consider new literature and data from the Member States.

Upon enquiry from Sweden, Anna Castoldi confirmed that EFSA was aware of new results from the United States Food and Drug Administration.

Stef Bronzwaer informed that EFSA will organise a Scientific Colloquium on low dose response in toxicology and risk assessment in June 2012.

Stef Bronzwaer also informed the AF that a Scientific Conference will take place on occasion of EFSA's 10th anniversary in November 2012.

Hubert Deluyker informed that the United States National Institute of Environmental Health Sciences (NIEHS) will organise a conference on endocrine active substances in Berlin in September 2012.

4.2 “Schmallenberg” virus

Claudia Heppner informed the AF that EFSA had received an urgent request from the European Commission for advice on “Schmallenberg” virus affecting seven Member States. An initial technical report on likely epidemiological scenarios was provided in February. The complete risk assessment would be available by the end of May 2012. The European Centre for Disease Prevention and Control (ECDC) had stated that it is unlikely that “Schmallenberg” virus can cause disease in humans. EFSA and the ECDC continued monitoring the situation.

Germany referred to further information on “Schmallenberg” virus in Germany on the websites of the [Friedrich-Löffler-Institute](#) and the [Robert Koch Institute](#).

Bulgaria suggested that “Schmallenberg” virus should be considered as an emerging risk, since Russia had banned trade and the problem might be more serious than the European Commission claimed.

Claudia Heppner replied that SCoFCAH had endorsed a guidance document on priority actions to be taken in the EU in the following month, so the European Commission did already pay attention to the problem.

Belgium mentioned ongoing surveillance research work and asked if EFSA would coordinate research activities and whether an Article 36 call was foreseen.

Claudia Heppner and Katriina Willgert informed that the technical report from February 2012 highlighted research and data needed to be able to assess the impact of the virus, which will be addressed in the full report in May 2012.

4.3 Update on the Scientific Committee opinion on threshold of toxicological concern

Djien Liem updated the AF on the Scientific Committee opinion on threshold of toxicological concern (TTC) and informed that due to diverging views on TTC between EFSA's Scientific Committee and the non-food Scientific Committees of the European Commission, the adoption of the final opinion on TTC had been postponed until May 2012 in order to allow sufficient time for addressing the divergences in an appropriate manner under Article 30.

Upon request from Catherine Geslain-Lanéelle, Djien Liem elaborated further on the current divergences regarding the substantiation of threshold values.

Germany enquired about international harmonisation and suggested that substances with well-known toxicity could be used to test and prove the validity of TTC.

Djien Liem replied that indeed retrospective studies to validate TTC values had been performed and should continue in order to justify the use of TTC. He added that TTC would be discussed at the meeting of the Scientific Committee network on harmonised risk assessment methodologies in June 2012 and that EFSA had already liaised with the OECD.

Hubert Deluyker mentioned contacts also with EMA and proposed extending the consultation to other agencies.

Germany agreed on the need to continue testing and comparing different methods, since more new approaches, *e.g.* margin of exposure, would be needed to assess the thousands of new substances after agreeing on the toxicological endpoints to be considered.

Sweden enquired whether it was possible to link margin of exposure and TTC.

Denmark recommended EFSA to engage in international cooperation in this new and important area that was already being addressed by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and the United States Food and Drug Administration.

The European Commission agreed on the importance of following international developments and avoiding duplication, but also emphasised the need to form views at the EU level on this sensitive topic to protect consumers.

Hubert Deluyker acknowledged that while EFSA was leading at EU level, the WHO and the United States had already worked more on TTC.

Denmark argued that international standards setting should be EU policy in order to share EFSA's good work at the international level and avoid using different definitions due to the lack of cooperation.

Catherine Geslain-Lanéelle concluded that while it was important to form views at the EU level before discussing with others, EFSA will now cooperate with the JECFA on the basis of the draft opinion.

The United Kingdom expressed support to this conclusion and emphasised that the use of TTC would lead to reduced use of animal testing. The European Commission's proposal on mandatory animal testing for GM risk assessments was contradictory to this new scientific advice, so there was a need to be alert to inappropriate use of animal testing.

Catherine Geslain-Lanéelle agreed and said that EFSA would comment on this and other aspects of the European Commission's draft proposal on GM food and feed guidance.

The European Commission reiterated the need to protect consumers and said that the European Commission actively contributes to the cooperation in the *Codex Alimentarius* with the support of EFSA.

Catherine Geslain-Lanéelle took note of the recommendation from the AF for EFSA to work with other EU agencies and bring the work to international forums.

Action 9: EFSA to update the AF on cooperation in the area of TTC at the next AF meeting.

4.4 GLP studies

Per Bergman informed that the audit report on one out of five randomly selected GLP studies considered by EFSA had surprisingly been very critical. GLP studies are no guarantee for scientific quality and EFSA's Panels take into account also other studies. EFSA had decided to perform ten baseline audits of GLP studies per year in different areas. Per Bergman concluded by inviting suggestions from the AF members.

Sweden expressed astonishment that EFSA had found a GLP study that did not comply with GLP standards and said that the completeness check is done by the Member State.

Per Bergman said that a completeness check would also be performed by EFSA in the pesticides area where GLP studies were formally required.

Germany said that shortcomings of GLP studies would be due to a lack of quality assurance and that it is a national responsibility to ensure conformity.

Hubert Deluyker agreed in principle with Germany. However, the problem had occurred despite a signed GLP certificate, so EFSA would need to perform some background checking.

4.5 Heavy metals: nickel and total chromium in food and hexavalent chromium in water

Greece informed the AF about its request to EFSA for a scientific opinion on estimation of the risk to human health from the presence of nickel and chromium in vegetables and hexavalent chromium in bottled water. Greece had already requested information on this topic from the Member States through the Focal Points and shared the report through the Information Exchange Platform.

Claudia Heppner and Catherine Geslain-Lanéelle confirmed that EFSA's CONTAM Panel would consider the request and the information shared by Member States.

4.6 Other matters raised by EFSA and Member States

Denmark reminded the AF members about the event on antimicrobial resistance organised by the Danish EU Presidency in Copenhagen on 14-15 March 2012 with an aim to raise awareness on the adverse effects of antimicrobial resistance and a proposal to extend the ban on veterinarians selling drugs within the entire EU and beyond.

Catherine Geslain-Lanéelle said that EFSA would attend this important conference and informed that the European Commission had requested EFSA to coordinate its future action with EMA to assist the risk managers take action.

Hungary informed that as of 15 March 2012 the Hungarian Food Safety Office would be merged with the national risk management institution and become a special department named the National Food Chain Safety Office.

Hungary presented information on energy drink consumption in Hungary and reported 161 cases of adverse symptoms connected to energy drinks, primarily among children and adolescents.

Tobin Robinson informed that, in response to such concerns expressed by Member States previously, EFSA had launched a procurement in July 2011 to collect acute and chronic consumption data on energy drinks using questionnaires and the associated exposure to specific ingredients (caffeine, glucuronolactone, taurine) in different consumer groups, *i.e.* children, adolescents and adults and addressing specific moments of consumption (intense physical exercise and co-

consumption with alcohol). The data collection would be finalised by the end of 2012. Subsequently, further action could be defined.

Greece requested that the definition of energy drinks should not confound them with sport drinks.

Catherine Geslain-Lanéelle mentioned that the definition was just intended for the data collection, not for regulatory purposes.

Ireland announced the Euroscience Open Forum in Dublin in July 2012. In that connection, Ireland and EFSA would organise a joint event on 11 July 2012.

Germany presented findings regarding lead in game meat originating from the bullets used for hunting. The conclusion was that vulnerable consumer populations, *i.e.* pregnant women and children, are at risk if their game meat consumption is high, *e.g.* in hunters' families. Therefore, hunters' associations had been contacted to warn these groups.

Spain reported similar findings and recommendations in a scientific opinion shared through the Information Exchange Platform.

Norway and Sweden reported that they were conducting similar studies and would liaise with Germany and Spain to share information.

Upon enquiry from Cyprus, Germany informed that the environmental impact of the bullets was negligible, since the shells were collected and reused.

Germany announced a BfR summer school in August 2012 on risk assessment and communication, which will be open to partner institutions in all countries.

Stef Bronzwaer briefed the AF on the training courses in food safety risk assessment that would be provided from September 2012 onwards under the European Commission Better Training for Safer Food (BTSF) programme.

Action 10: Ireland to share further information on the Euroscience Open Forum in Dublin in July 2012.

Action 11: Member States to share information on lead in game meat through the Information Exchange Platform.

5 ANY OTHER BUSINESS

Hubert Deluyker thanked the AF members for their comments on the shortlisted experts for the new Scientific Committee and Panels.

Action 12: EFSA to share the report on the new composition of the Scientific Committee and Panels with the AF members when it is finalised.

CLOSURE OF THE MEETING

Catherine Geslain-Lanéelle thanked the AF members and observers for their active contributions. She also thanked the interpreters and EFSA staff.