

**Network on
Harmonisation of Risk Assessment Methodologies**

**Minutes of the 2nd meeting
Held on 22-23 October 2013, Parma, (ITALY)
(Agreed on 20 December 2013)**

Participants

- **Network Representatives of Member States:**

Country	Name
Austria	Daniela Hofstaedter
Belgium	Xavier Van Huffel
Bulgaria	Boiko Likov
Croatia	Andrea Gross-Boškovic
Czech Republic	Jitka Sosnovcová
Denmark	Folmer D. Eriksen
Estonia	Piret Priisalu
Finland	Jukka Ranta
Germany	Klaus J. Henning
Greece	Panagiotis Skandamis
Hungary	Andrea Zentai
Ireland	Lisa O'Connor
Italy	Gaia Scavia
Latvia	Aija Melgaile
Malta	Ingrid Busuttil
Portugal	Fernando dos Ramos
United Kingdom	Diane Benford

- **EFSA Scientific Committee and Panel Members**

Tony Hardy (SC), Vittorio Silano (CONTAM).

- **European Commission and observers:**

- Natacha Grenier (EC DG Health and Consumers),
- Diana Herold (EC DG Health and Consumers),
- Maria Kammenou (EC DG Research and Innovation),
- Donata Meroni (EC DG Health and Consumers).

- Marie Louise Wiborg (Norway)

- Serap Hanci (Turkey)

- **EFSA:**

- **Scientific Committee and Emerging Risks Unit (SCER):**

Bernard Bottex, scientific officer, chair of the meeting

Jean-Lou Dorne, scientific officer

Daniela Maurici, scientific officer and co-chair of the meeting

- **Advisory Forum and Scientific Cooperation Unit (AFSCO):**

Djien Liem, lead scientist in international relations

Stef Bronzwaer, head of unit

- **Communications Directorate:**

Laura Smillie, senior officer Communications

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Jean Luc Volatier (France), Monica Neagu (Romania), Katarina Gorzink (Slovenia), Antonio Lopez-Martinez (Spain).

During a tour de table, the participants of the network introduced themselves, their background and affiliation.

3. Adoption of the draft agenda and scope of the meeting

The agenda was adopted without changes. The participants were reminded that the network meets once a year and the present meeting is the second meeting of the network. The terms of reference of the network can be found [here](#).

4. Declarations of interests

In accordance with EFSA's Policy on Independence and Scientific Decision-Making Processes regarding Declarations of Interests (Dols)¹ and the Decision of the Executive Director implementing this Policy², members of networks, peer review meetings, networking meetings and their alternates shall be invited to complete and submit an Annual Declaration of interest (ADoI).

EFSA screened the ADoI filled in by the experts invited for the present meeting. No conflicts of interests related to the issues discussed in this meeting have been identified during the screening process or at the Oral Declaration of interest (ODoI) at the beginning of this meeting.

The Chair thanked the representatives that have submitted an ADoI.

5. Agreement of the minutes of the 1st meeting of the network on Harmonisation in Risk Assessment Methodologies, held on 7-8 June 2012.

The minutes were agreed by written procedures on 16th July 2012.

6. Update on EFSA's workprogramme:

Bernard Bottex updated the participants on the opinions and guidance documents on topics of cross-cutting nature adopted by EFSA's Scientific Committee and Panels between June 2012 and October 2013. The presentation covered the various areas of activity of EFSA and more specifically:

- endocrine disruptors
- whole food feeding studies
- cumulative assessments of pesticides
- evaluation of risk reduction options for plant health
- risk ranking framework and the use of modelling for biological hazards
- expert knowledge elicitation.

¹ <http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf>

² <http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf>

Tony Hardy, Chair of the Scientific Committee (SC), presented the outcome of the prioritisation exercise for the next years made by the SC during its away day held last 17-18 July 2013. The criteria for prioritisation were i) across panel relevance, ii) critical importance/urgency for several panels, iii) topic not being addressed by a single panel, iv) sufficient information available to develop a guidance, and v) international dimension. As a result of this exercise, the Scientific Committee decided to prioritise for 2014 the development of some guidance on 1) how to use the weight of evidence approach for risk assessment, 2) on biological relevance vs. adaptive/homeostatic response and 3) to further harmonise the assessment of human exposure across EFSA Panels. Additional work will then be developed on guidance document for the interpretation of epidemiological studies, terminology in risk assessment and harmonisation of the assessment of human exposure. Combined exposure to multiple chemicals was also identified as a relevant cross-cutting issue, but activities in this field will need to await the outcome of two procurement activities that are currently ongoing in EFSA.

Vittorio Silano presented the ongoing EFSA work in the area of botanicals. Following the need expressed in 2006 by some Member States' competent authorities for tools to assess the safety of botanical preparations on the EU market, the SC developed i) a guidance document for the safety assessment of botanicals and botanical preparations intended for use in food supplements, ii) a report illustrating with several case studies how to apply the proposed approach for the safety assessment of botanicals and iii) a compendium of botanicals reported to contain naturally occurring substances of possible concern for human health. The compendium is updated on a regular basis. The SC is currently looking at the possible application to botanicals of the Qualified Presumption of Safety (QPS) approach which has been initially developed for the assessment of microorganisms deliberately added to food. It is also preparing the third version of the above-mentioned compendium.

Jean Lou Dorne presented EFSA's ongoing work in the area of newly emerging methodologies and tools for the hazard assessment of chemicals in humans. This activity is taking stock of previous work of EFSA and ongoing international activities (US-EPA, Toxcast, Tox21, WHO, JRC, ECHA) in this area. The activity has resulted in a scientific report that reviews the state of the science for toxicokinetic (TK) and toxicodynamic processes (TD), i.e. OMICs and biologically-based models. The report looks also into the applicability of evidence-based approaches for prioritisation and ranking of chemicals according to toxicological properties (TK/TD). The Members of the network were invited to send their comments on the report that will be finalised and published in the beginning of 2014.

6. Ongoing risk assessment and communication activities within EFSA's remit

Djien Liem informed the network about the development of EFSA's draft multi-annual programme on international scientific cooperation. The objectives will be i) to support the EU at international level, ii) to optimise the use of risk assessment capacity, iii) to develop and harmonise risk assessment methodologies and approaches, iv) to strengthen the scientific evidence for risk assessment and risk monitoring, and v) to promote coherence in risk

communication and build awareness of EFSA's activities at international level. A number of mechanisms, such as exchange of work programmes, visits, joint projects or exchange of staff are being considered to develop further EFSA's cooperation with its key partners, i.e. EU institutions and other EU agencies, international organisations with a responsibility in scientific advice and international standard setting, and third country risk assessment organisations.

The members of the network were invited to comment on the possible mechanisms for cooperation identified and to share their experience, planned activities and suggestions for future cooperation activities.

Laura Smillie presented the EFSA and Member States' joint lexicon initiative. The objective is to enhance the coherence and accessibility of EFSA's risk communication, simplify complex scientific terms while remaining true to their meaning, and develop layman definitions in cooperation the Communication Working Group of the EFSA Advisory Forum. The project is split in three phases: 1) create a list of about 200 scientific terms, 2) provide their scientific definition and 3) provide their layman definition. The EFSA Scientific Committee will be involved in the project to validate the definitions. The lexicon is intended to be launched early 2015.

Maria Kammenou updated the participants on research activities related to risk assessment supported by the European Commission. The following projects were highlighted:

- flavours, additives and food contact material exposure task (facet)³: the objective is to develop a risk management tool to estimate consumer exposure on food additives, flavourings and food packaging migrants. The public launch of the resulting software is planned for December 2013 but it was underlined that it has already been used by EFSA in the opinion on Bisphenol A;
- integrated approaches to food allergen and allergy risk management (IFAAM)⁴: this very big project (12.2 million euros – 12 work packages) will among other, gather data on minimum eliciting doses for the European list of priority allergenic foods, develop some representative consumption models for the risk assessment of allergens in Europe, develop representative contamination scenarios to be used in risk assessment and finally propose a tiered risk assessment approach. The completion of the project is expected in February 2017.

Finally Maria Kammenou updated the participants on the latest developments of Horizon 2020, the financial instrument implementing the Innovation Union, a Europe 2020 flagship initiative aimed at securing Europe's global competitiveness. Running from 2014 to 2020 with a budget of just over €70 billion, the EU's new programme for research and innovation is part of the drive to create new growth and jobs in Europe⁵.

³ See http://ihcp.jrc.ec.europa.eu/our_activities/food-cons-prod/chemicals_in_food/FACET

⁴ See <http://www.manchester.ac.uk/aboutus/news/display/?id=9743>

⁵ See http://ec.europa.eu/research/horizon2020/index_en.cfm?pg=home

Donata Meroni presented the three Scientific Committees of the European Commission⁶, their mandates, the opinions published between 2009 and 2013, and their 2013-2016 term programme:

- the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) published a number of opinions / position papers of relevance for the past and ongoing activities of EFSA dealing with Threshold of Toxicological Concern (TTC), risk assessment of mixtures, new challenges in risk assessment, and with the evaluation of evidence/weight of evidence. The Committee will work further in 2013-2016 on new technologies (e.g. synthetic biology);
- the Scientific Committee on Health and Environmental Risks (SCHER) also worked on TTC and the risk assessment of mixtures; its activities for 2013-2016 are expected to continue in line with the current mandate but with an increased emphasis on health threats and risks to human health via the environment;
- the Scientific Committee on Consumer Safety (SCCS) also contributed to the opinions on TTC and risk assessment of mixtures. The Committee will continue to deal in 2013-2016 with a heavy workload on cosmetics, developing alternative methods and risk assessment approaches in light of the recently implemented animal test ban.

7. Ongoing activities in Member States and priorities for further work

A tour de table was organised at the beginning of the second meeting day to give the opportunity to the Member States Representatives to report back on activities relevant for this network. A very broad range of areas were mentioned such as:

- probabilistic modelling: the need for training on benchmark dose, Monte Carlo modelling, as well as on integrated probabilistic and quantitative microbial risk assessment was mentioned by several Member States Representatives. It was underlined that such training would greatly help with the dissemination and implementation of existing guidance or approaches;
- risk-benefit assessment: it was indicated that EFSA has already published a guidance document on this issue but the Representative from Norway indicated that the proposed EFSA approach shows some limitations when there are insufficient data;
- risk ranking: the members of the network were informed about the ongoing EFSA procurement for a critical review of methodology and application of risk ranking for prioritisation food and feed related issues, on the basis of the size of the anticipated health impact. Participants were informed about a Belgian initiative to organize a symposium on 'Risk ranking in the food chain' (Brussels - 29 November 2013);
- cumulative risk assessment: participants were informed about a joint DTU/Anses/BfR conference on chemical mixtures: challenges for research and risk assessment (10&11 December 2013 – Paris⁷), as well as on the EFSA Pesticides technical meeting with stakeholders on cumulative risk assessment next 11 February 2014⁸. The network took

⁶ See http://ec.europa.eu/health/scientific_committees/about/index_en.htm

⁷ See <http://www.anses.fr/en/content/chemical-mixtures-challenges-research-and-risk-assessment>

⁸ See <http://www.efsa.europa.eu/en/events/event/140211.htm>

also note of the opinions of the EC Scientific Committees⁹ and the ongoing EFSA procurements on the same issue;

- new risk assessment approaches: the joint opinion of the EC Scientific Committees¹⁰ was mentioned, as well as the ongoing work of SCCS and the EFSA review of the state of the science on new/emerging tools as presented by Jean Lou Dorne during the first day of the meeting. EFSA is waiting for the outcome of these activities to decide whether some guidance should be developed;
- dietary exposure assessment: several Member States representatives indicated that their countries conduct total diet surveys and would like to have further guidance on how build the survey. The joint guidance of EFSA, FAO and WHO towards a harmonised total diet study approach¹¹ can be considered;
- allergens: the UK Representative underlined the need for some guidance on how to assess the risk of food allergens and start exchanging views on how this risk should be taken up in risk management. The DG RTD-funded and just started IFAAM project (see section 6) will help gathering existing knowledge on this issue before deciding on the possible development of a guidance on the risk assessment of food allergens;
- risk communication – harmonisation of risk assessment terminology: the importance of the EFSA Lexicon project that will soon be initiated was once again mentioned.

8. Follow-up activities for the network

Following the discussions held during this second meeting of the network, the participants identified three main areas as possible follow-up activities by EFSA and this network:

a) Awareness and knowledge of existing guidance / harmonised assessment methods in Europe

There is a need to increase the awareness of relevant organisations about the existence of guidance documents / methods but also to enhance their knowledge on how to use them. The Network proposed the following solutions for consideration of EFSA:

- A better use of the network in the preparation phase of new guidance:
 - inform the network as soon as a new mandate for methodological guidance is adopted;
 - when the mandate for methodological guidance is a self-task mandate, offer the possibility to the network members to comment on the draft mandate / terms of reference before it will be finalised;
 - offer the possibility to the Member States to submit background information and to present relevant related activities to the working group dealing with the mandate. This could be done either using the EFSA ScienceNet, or by inviting the Member State as a hearing expert during a meeting of the working group.

⁹ See http://ec.europa.eu/health/scientific_committees/environmental_risks/docs/scher_o_155.pdf

¹⁰ See http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_131.pdf

¹¹ See <http://www.efsa.europa.eu/en/search/doc/2450.pdf>

- Besides organising public consultation on the draft guidance prior to its finalisation, to organise workshops / training sessions in a more systematic way, each time a methodological guidance is adopted, to train Member States' Competent authorities on the new approach. Some Member States representatives indicated their willingness to help with the organisation of such workshops.
- To give access to Member States Competent Authorities to training schemes in place. Following a presentation from Stef Bronzwaer about the European Commission's Better Training for Safer Food (BTSF) programme¹² in which EFSA contributed to the development of the risk assessment module, the participants asked EFSA to also consider giving access to the Member States to its advanced training in risk assessment courses.
- A better use of the Information Exchange Platform by creating a "methodological guidance" folder where all EFSA horizontal guidance could be consulted rapidly.

b) Better monitor the implementation of existing EFSA guidance documents

A recommendation was made to gather regular feedback from the Member States Competent Authorities on how they use EFSA methodological guidance and on possible encountered difficulties when applying them.

c) Give this network its right dimension

In view of the various presentations given during the meeting, it was noted that harmonisation of risk assessment methods would require the participation of more parties than just EFSA and the European Member States. To this end, a recommendation was made to consider the possible upgrading of the current structure of the network by incorporating as full or partial members of the network representatives from the European Commission (DG Health and Consumers Scientific Committees, DG Research and Innovation, DG Joint Research Centre), from EFSA's sister agencies (e.g. ECHA, EMA) and from international organisations (e.g. WHO/IPCS, JECFA).

9. Any other business

The annual report on the 2012-2013 activities of the network was published on the EFSA website in September 2013¹³.

The minutes of the 2nd meeting will be circulated for approval by written procedure to the members of the network. Once agreed, the minutes will be published on the EFSA website.

The Chair closed the meeting thanking the participants for their valuable contributions to the discussions and the experts for their presentations.

¹² See <http://www.btsf.eu/>

¹³ See <http://www.efsa.europa.eu/en/supporting/pub/489e.htm>