European Food Safety Authority

Scientific Committee and Advisory Forum Unit

Parma, 19 May 2011

MINUTES

1st Meeting of the EFSA Scientific Network for Risk Assessment of Nanotechnologies in Food and Feed

Agreed by the Network by written endorsement on May 12, 2011

Meeting details
Date: 22nd February 2011
Meeting venue: EFSA, Largo N. Palli 5/A, 43121 Parma, Italy
Time: 9:00 – 17:00

Participants
Member States and other national representatives (Member State):
Angelika Nester (AT), Luc Pussemier (BE), Angel Angelov (BG), Popi Kanari (CY), Jiří Ruprich (CZ), Alfonso Lampen (DE), Josep Samitier (ES), Pertti Koivisto (FI), Gilles Rivière (FR), Katerina Choupa (GR), Darko Mikec (HR), Andrea Zentai (HU), Patrick O'Mahony (IE), Francesco Cubadda (IT), Vaclovas Jurgelevicius (LT), Nijaz Salija (MK), Anton Rietveld (NL), Ragna Bogen Hetland (NO), Wojciech Wąsowicz (PL), Maria de Lourdes Bastos (PT), Maja Remškar (SI), Peter Simon (SK), Zehra Karagoz-Emiroglu (TR), Manisha Upadhyay (UK).

EFSA Scientific Committee, Panel or Working Group Experts:
Vittorio Silano, Klaus-Dieter Jany, Mona-Lise Binderup, Rolf Hertel, Hermann Stamm.

EFSA:
Djien Liem (Network Chair), David Carlander, Tomas Oberg, Theresa McFadden, Silvia Bellochio, Francesca Piombini.

1. Opening, welcome

On behalf of EFSA Executive Director Catherine Geslain-Lanéelle, Djien Liem, head of the Scientific Committee and Advisory Forum Unit and chair of the meeting welcomed the participants.

2. Tour de table and apologies for absence

During a tour de table the participants of the network presented themselves. The broad and complementing expertise of the participants of the meeting ranged from researchers to risk assessors. Apologies were received from the Danish representative. It was noted that some Member States have yet to nominate members of the network.

3. Adoption of the draft agenda

The agenda was adopted as tabled.

4. Declarations of interests

The participants were informed about EFSA's declaration of interest policy which is part of EFSA's strive for independence, openness and transparency. In line with this policy, participants are asked to provide an annual declaration of interest.

5. Mandate of the Nanotechnology Network (1)

Djien Liem gave a short introductory presentation on EFSA and EFSA's policy on cooperation and networking with Member States. The participants were informed that Member States nominate organisations to be members of the EFSA networks via the Advisory Forum, the network participants represent their organisations at network meetings and do not attend in their individual capacity.

The EFSA network of nanotechnologies in the food and feed area covers the whole food-feed chain corresponding to the remit of EFSA. Member States welcomed the network initiative as being a useful forum to share information on all aspects related to nanotechnologies in the whole food chain, including providing information on ongoing regulatory aspects.

6. Activities of EFSA in the area of nanotechnologies

David Carlander, Scientific Officer in the Scientific Committee and Advisory Forum Unit briefed the network on the background of the EFSA work in the area of nanotechnologies. EFSA's connections with the EU and international agencies and organisations working in the area of nanotechnologies include, e.g. JRC, EMA, the EU non-food scientific committees, WHO/FAO, OECD, US FDA and the Food Safety Commission of Japan.

The 2009 Scientific Opinion of the Scientific Committee "The Potential Risks Arising from Nanoscience and Nanotechnologies on Food and Feed Safety" was presented and the group was informed about two EFSA assessments of nanotechnology applications. The CEF Panel adopted an opinion titanium nitride for use as a food contact material in November 2008, and the ANS Panel provided a statement, in November 2008 on silver hydrosol for use as a food supplement where there was a lack of information to conclude the risk assessment. Several participants mentioned the presence of colloidal silver on their markets (especially via internet), and the lack of a reliable market inventory of products on the market. It was noted that several colloidal products have been available for a long time especially in the supplements area, without a formal risk assessment.

The participants also discussed, in general terms, the difficulties of setting a purely science-based definition of nanomaterials that would be applicable under legislation as the determining characteristics will have to be influenced by a risk management policy. Under REACH nanomaterials fall under the substance definition. It was a general agreement that the size for what is considered nanoscale should not focus on 100 nm.

7. Activities at the Joint Research Centre concerning Nanomaterials in EU Regulation

Hermann Stamm gave a presentation on the activities of the Joint Research Centre (JRC) in the area of nanotechnologies. The JRC has produced a repository composed of 25 different nanomaterials (but not 25 different substances, as some nanomaterials in the repository come in several shapes and size). This repository is supporting the OECD sponsorship program. Recently the JRC Institute for Reference Materials and Measurements (IRMM) has made available a certified silicon dioxide for specific size

measurements. The JRC is also hosting an IT platform called "Nanohub" which is building on the information requirements of IUCLID 5 (REACH information IT system).

The participants welcomed the presentation. The need for suitable measuring methods and validated tests methods, for both *in vitro* and *in vivo*, was reiterated by the participants. *In vitro* methods are useful for providing an understanding of mode of action and to give information relevant to design *in vivo* experiments. The current approach for risk assessing nanomaterials, in general, do not differ from conventional assessments where in the food and feed area risk assessments are seldom concluded without information also from *in vivo* studies.

One Member State asked the JRC how the prioritization of the materials in the repository was made. The materials are based on the OECD sponsorship program which, among various aspects, considered production volume and market application. The SiO2 and TiO2 in the OECD sponsorship program are especially relevant for the food and feed area. The nano calcium carbonate in the JRC repository is included as a case study under REACH.

The JRC is cooperating with several EU institutions and agencies and is involved in the REACH implementation as members of the REACH implementation steering group which is lead by DG ENV. The three REACH implementation projects on nanomaterials (RIPoN) will, most likely, be reported before summer. The JRC is also involved in a new REACH project aimed at looking at the provided nano-related information in dossiers submitted under REACH. This project is scheduled to be finalised next year.

8. Draft guidance on risk assessment concerning potential risks arising from applications of nanoscience and nanotechnologies to food and feed

David Carlander presented the draft guidance which is out for public consultation until the 25th of February 2011. Member States welcomed the guidance and provided comments and suggestions to clarify various sections.

The network participants suggested than an explanation be given on the fact that the guidance is aimed to cover the whole feed-food chain which is broader than applications to food and feed. The participants believed it would be useful to expand the glossary explaining the difference between nanoscience and nanotechnologies as well as to duplicate descriptions of terms from other reports and opinions (e.g. ISO and OECD).

A general comment was made that the effects of nanomaterials on biological tissue are independent of the exposure route once the material has crossed the first biological barrier.

It was noted that a balance is needed between general and detailed guidance. Some participants felt that it would be useful for applicants if more details could be provided in the guidance, although it was recognized that this may present difficulties as the area is rapidly developing. In this sense, it was also mentioned that the draft guidance may in some instances be too prescriptive.

The network thought that it would be useful to indicate the minimum required dataset for a risk assessment more clearly. Participants also suggested to highlight that for the proposed weight of evidence approach, information from a broad range of sources, including results from various types of modelling (*in silico*) approaches could be used to generate appropriate data although it was recognized that additional experience with modelling is needed before risk assessment could rely on modelling information.

Member States supported the importance of thorough identification and characterisation of nanomaterials, and noted that this information may currently be difficult to generate for some nanomaterials, especially in complex matrices.

The use and further development of *in vitro* methods is supported as suggested in the draft, and it is acknowledged that at present, *in vitro* methods can give indications to specific endpoints to be addressed by *in vivo* studies and add information to the weight-of-evidence approach. Member States recognized that the generation of ADME (absorption, distribution, metabolism, excretion) information may be difficult to generate in certain cases. It was suggested by one Member State that *in vivo* genotoxicity testing should always be considered. It was commented that the draft guidance does not provide information for assessing potential allergenic potential of nanomaterials. The use of uncertainty factors was also raised.

The comments raised by the Member States will be communicated to the EFSA Working Group to be taken into consideration for the finalisation of the guidance document.

9. Ongoing activities in Members States relevant for risk assessment of nanotechnologies in food and feed

The outcome of the questionnaire "Member State Activities in the Area of Nanotechnologies in Food and Feed" was shared and discussed. Members States were supportive of this activity, but felt that the presentation of information could be improved. The document should focus on the food and feed area and be kept updated on a regular basis. It is, therefore, important that the information is provided in a short, concise and comprehensive.

10. Presentation of selected projects from MS

UK – Nanotechnologies and Food Discussion Group

Manisha Upadhyay, from the UK Food Safety Agency (FSA), presented the background and the ongoing activities of the Nanotechnologies and the Food Discussion Group recently set up by the FSA in relation to a recommendation from the 2010 House of Lords report. This discussion group is composed of representatives from the FSA, government, academia, industry and consumer groups. The group exchanges information on research and applications in the food sector, regulatory developments and discuss a register of nanofoods and food contact materials. The group has an 18 months mandate. The outcomes of the discussions of this group are regularly published on the FSA website.

DE – Nanokommission and NanoDialogue

Alfonso Lampen from the Federal Institute for Risk Assessment (BfR) presented ongoing activities in Germany. BfR is involved in several task related to nanotechnology, many in cooperation with other public authorities and federal institutes as well as in an international context (EFSA, ECHA, OECD). BfR has supported several research activities related to risk communication which have been published (e.g. Delphi expert study on the use of nanomaterials in food and consumer products, an analysis of media coverage etc.). The NanoDialogue, among other tasks, discussed the criteria of nanomaterials that would likely result in reduction of hazards and discussed a three level ranking system, from low to high concern, based on identified criteria. Five general principles have been developed for the responsible use of nanomaterials and there are recommendations to develop a product register for nanoproducts to support traceability. The NanoDialogue also recommends the development of guidelines for the use/benefit and risk analysis of nanomaterials. The outcomes of these discussions are regularly published on the BfR website.

11. Mandate of the Nanotechnology Network (2)

The activities of the network were discussed in more detail. Cooperation and information sharing is an important tasks of the network. Sharing information where capacity is available in Member States would be useful to provide ways to monitor and control products on the market. The network could be a useful means to support dialogue with industry on what could be expected from future applications. Member States raised the point that information on products aimed for children could be a priority.

The early incorporation of risk assessment considerations when providing funding for research was raised to avoid a bottle neck for putting products developed by innovation on the market. Safety assessment research should be funded early to allow safety aspects to be a part of the product innovation ("safety by design"). The Network will be useful to give proposals for research requirements and provide advice on research activities as an input to the DG RTD framework program process.

There are ongoing initiatives discussing product registers in several Members States, as well as at the EU level, it was noted that the Network would be a suitable forum to exchange information on this topic. The network would also be a useful way to share information on best practices and experiences related to analyses and monitoring of products on the market and support development of detection methods and identification of laboratories in Member States that would be able to participate in ring trials. This activity could be done in close cooperation with JRC. Such an effort is considered to be important as there is still limited expertise in public authorities and laboratories in this area.

12. Any other business

- *Presentation of the Information Exchange Platform and the Expert Database (EDB)*

Carola Sondermann from the Scientific Cooperation Unit presented the EFSA Expert Database and the EFSA Information Exchange Platform (IEP). Member States are encouraged to promote the Expert Database and to ask nanotechnology experts in their countries to sign up.

- *Function and use of EFSA Network Workspace on EFSA ScienceNet*

David Carlander gave a short practical explanation on the basic functionalities of the EFSA Network Workspace on the EFSA ScienceNet which is a password protected area where documents are shared with members of the network.

13. Summary of the chair and closing address

Djien Liem summarised the discussions that the network should aim to gather and share intelligence on products under development and what is on the market for supporting development of a repository, to promote sharing toxicological information, detection methods and to give input for risk assessment relevant research.

The meeting was closed and the participants were thanked for their valuable contributions to the discussions and the network.