

SCIENTIFIC COMMITTEE AND ADVISORY FORUM UNIT

Parma, 15 January 2009 EFSA/SGC/M/2008/206/RES/FINAL

Minutes

5TH MEETING OF THE STEERING GROUP ON COOPERATION BERLIN (GERMANY), 23-24 OCTOBER 2008

Chair: *Hubert Deluyker*, Director of Scientific Cooperation and Assistance European Food Safety Authority.

MEMBERS OF THE ADVISORY FORUM

| Austria | Roland Grossgut |
|------------------------|---|
| Belgium | Charles Crémer |
| Bulgaria | Stefka Petrova |
| Czech Republic | Vaclav Stejskal |
| Denmark | Arne Büchert |
| France | Lilian Puech |
| Germany | Andreas Hensel; Klaus Jurgen Henning; Michaela Nuernberg |
| Ireland | Pat O'Mahony |
| Latvia | Gatis Ozolinš |
| Netherlands | Evert Schouten |
| Romania | Alecsandra Dida Cozachievici |
| Slovak Republic | Zuzana Bírošová |
| United Kingdom | Nick Tomlinson |
| European Commission | Jeannie Vergnettes |

MEMBERS OF THE SCIENTIFIC COMMITTEE

| SC Chair | Vittorio Silano |
|---------------|-------------------|
| SC Vice-Chair | Ada Knaap |
| SC Vice-Chair | Pierre Le Neindre |

EFSA STAFF

| Bernhard Berger |
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| Bernard Bottex |
| Stef Bronzwaer |
| Anne-Laure Gassin |
| Djien Liem |
| Elena Marani |
| Jeffrey Moon |
| Torben Nilsson |
| Saadia Noorani |
| Ralf Reintjes |
| Andras Szoradi |

1 WELCOME AND OPENING OF THE MEETING

Hubert Deluyker, and Andreas Hensel, BfR, welcomed the participants and opened the meeting.

2 ADOPTION OF THE AGENDA

The agenda was adopted without additional agenda items.

3 ESCO WORKING GROUP ON SAFETY ASSESSMENT OF BOTANICALS AND BOTANICAL PREPARATIONS

Bernard Bottex, presented the work of the ESCO Working Group (WG) to date, outlining the Terms of Reference, the priorities established by the group and the approach taken in carrying out the work. The 'next steps' were identified which included completion of work on 'deliverables' by April 2009 for submission to the Executive Director and by the end of 2009 to adopt and publish the guidance on safety assessment of botanicals and botanical preparations, and the compendium. The SGC saw the work of the ESCO and the development of the compendium as important for harmonising activities at Member State level with regard to supplements in particular and that the output of the WG will provide valuable tools for the risk assessors at national level.

4 ESCO WORKING GROUP ON HORIZON SCANNING TO IDENTIFY EMERGING FOOD SAFETY RISKS

Ralf Reintjes, explained the background to the work of the ESCO, citing the legal mandate of Article 34 of Regulation (EC) No. 178/2002 and outlined the evolution of the work to date. The 'next steps' were identified as finalising a suitable model for emerging risk assessment, obtaining information from member States via a questionnaire and producing a final report for the Executive Director by December 2008, with the possibility of a Scientific Colloquium being held in 2009. The SGC acknowledged the difficulty of the task of the WG and of the similar work being done by other EU institutions (such as the European Centre of Disease Control) and saw there was the opportunity for using a common approach. The collection of relevant data and using data collected from all sources (including non-food related) was seen as the important first step in being able to identify emerging risks. A collaborative approach in identifying, sharing and using data was seen as the only way to progress with the need for further information on Member States activities being acknowledged as a priority.

5 ESCO WORKING GRPOUP ON RISKS AND BENEFITS OF FORTIFICATION OF FOODS WITH FOLIC ACID

Pat O'Mahony (Ireland), standing in for the Chair of the ESCO WG on Folic Acid, presented the overview of the activities of the WG indicating that an interim report is under preparation, with the final report expected to be completed by June 2009. A workshop is being organised for 21-22 January 2009 in Uppsala, Sweden specifically on the topic of the cancer risk associated with high folic acid intake. The work of the group has been slowed somewhat due to the awaited publication of new research which would be important for WG to consider. The SGC acknowledged that it was appropriate that if the WG was aware of forthcoming publications to ensure they were taken into consideration. Additionally it was noted that any alarming information will need to be dealt with as a top priority and not necessarily wait for the conclusion of the ESCO.

6 ESCO WORKING GROUP ON FOSTERING HARMONISED RISK ASSESSMENT APPROACHES IN MEMBER STATES

Presentations were made by Roland Grossgut (Austria), Chair of the ESCO WG, Andras Szoradi and Stef Bronzwaer to explain the background, the mandate, the working methodology, the results of the questionnaire to the Member States and the conclusions and recommendations of the WG. It was acknowledged that some questions could have been interpreted differently as well as the responses, particularly with regard to whether formal risk assessment was being considered

or not. The SGC discussed that interpretation of the data should be done with great care also because there had been no possibility to validate the responses. It was acknowledged with thanks that responses were received from all MS. The continuation of National Expert meetings was seen as beneficial. The SGC agreed on the main body of the text presenting the results but considered that the recommendations of the group could be improved in terms of clarity. The revised text on recommendations is to be agreed by the members of the WG, following which the report shall be presented at the Advisory Forum meeting in November 2008.

7 LESSONS LEARNT FROM ESCO PROJECTS

Hubert Deluyker invited the chairs of the ESCO working groups (or their representatives) to comment on the Working Group experience in order to identify potential problems which could be addressed for future groups. Comments on the establishment and functioning of their group, with specific reference to the mandate, working procedures and time for reporting were requested.

Overall the experiences were very positive. For most of the ESCOs the mandates were very clear and the working processes well defined. Comment was made that initially there were concerns that the time allocated for some of the groups may have been too long, but the experience of the groups indicated otherwise and time allocated to reporting was seen as appropriate. In all cases there was good level of interest from Member States and in most cases a high level of involvement in the work by the members of the group. A number of obstacles which needed to be overcome were also identified and these included providing the necessary human and financial resources to carry out the work, maintaining momentum of work between ESCO meetings and balancing the size of a group against its performance.

The importance of a clear mandate was mentioned by several group reports and in one case (ESCO on Harmonised Risk Assessment) due to the ambitious nature of the mandate there was a need to revise the mandate to focus on what could be achieved in the available time. It was suggested that for complex or ambitious mandates there may be a role for Article 36 grants as a preparatory stage for ESCO work.

With regard to involvement of the Member States, it was highlighted that it would be beneficial at the time of requesting experts to indicate in some detail what expertise would be required for the working group and an indication of their expected input into the work. In order to ensure an optimal number of group members it was suggested that nominations be subject to a selection process, which would be made clear at the time nominations were being requested. The use of the Focal Point network as a possible means of identifying experts to recommend to AF members for participation in ESCO groups was also suggested.

The SGC noted the comments and agreed that they be incorporated into the Interim Strategy Review process.

8 REVIEW OF THE IMPLEMENTATION OF THE STRATEGY ON COOPERATION AND NETWORKING

Hubert Deluyker introduced the topic with an explanation that the review was an interim exercise originally envisioned in the Strategy to be conducted by the end of 2008. Bernhard Berger, provided the background and explained the structure and outline of the review, which followed that of the Strategy. Saadia Noorani, presented preliminary results of the questionnaire returned by Advisory Forum members. Anne-Laure Gassin, provided an overview of the communications aspects of the review. The SGC noted the relatively low response rate to the questionnaire.

(Hubert Deluyker had to leave at this point and passed the chair to Djien Liem).

9 DISCUSSION OF WORK PLAN FOR 2009

Torben Nilsson provided the background to the works under consideration for the forthcoming year.

As time permitted, before considering the work plan the SGC agreed to discus the operation and remit of the group. Concern was expressed that there was no apparent direct linkage between the proposals for future work and the Strategy, as set out in the Terms of Reference. Following discussion on the remit of the group and how it interacts with the Advisory Forum and Scientific Committee it was agreed that the work of the group should be consistent with the Terms of Reference. It was proposed and agreed that further discussion is held on the role of the SGC at the next Advisory Forum and Scientific Committee meetings.

Crisis Exercise - Ralf Reintjes provided an overview of the finalisation of the crisis plan that followed the exercise held earlier in 2008 and stated the need to test the plan in 2009. The SGC agreed that considering the activity and the short timeframe for planning an exercise that an ESCO was not appropriate, but Member States and the Commission could be invited to participate in the exercise planning.

Isoflavones - Klaus Jurgen Henning (Germany) introduced the proposal relating to isoflavones which followed on from work done at national level in Germany where an Opinion was issued that subsequently led to protest from Industry. Djien Liem highlighted the difficulties of considering the aspects of risk/benefit

analysis as posed in the question to EFSA and indicated that it may be appropriate to undertake preliminary work on data collection before convening an ESCO WG. The SGC agreed that as the matter was of interest to MS other than Germany it was appropriate to consider developing work and that work should progress initially on establishing data relating to the risks and benefits of isoflavones with the possibility of establishing an ESCO.

Integrated Probabilistic Risk Assessment (IPRA) Evert Schouten (The Netherlands) introduced the proposal and provided an overview of how the approach contributes to the risk assessment process. It was proposed that in 2009 there be a Workshop or Colloquium held, rather than an ESCO established. The SGC noted that some aspects of IPRA were being used in some areas of work (such as that on Bench Mark Dose) and agreed that it would not be appropriate to establish an ESCO at this stage of development, but that a Workshop/Colloquium should be held later in 2009 or 2010.

Nanotechnology It was noted that the Opinion on nanotechnology had been issued for public consultation and there would be further discussion at the forthcoming Advisory Forum meeting. The SGC agreed not to have any discussion on the topic at this stage.

10 SGC MEETINGS IN 2009

The dates for the meetings in 2009 were proposed and agreed.

The dates and venues are to be:

31 March, 2009 – Parma, Italy

16 October, 2009 - Dublin, Ireland

(At the kind invitation of the Slovak Republic, it has subsequently been agreed that the first meeting of 2010 scheduled for Spring, will be held in Bratislava).

11 ANY OTHER BUSINESS

No issues were raised.

12 CLOSURE OF THE MEETING

Djien Liem thanked the BfR for once again hosting the SGC and brought the meeting to a close.