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Advisory Forum

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15 May 2007**

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Parma, 15 June 2007

Minutes

2ND MEETING OF THE STEERING GROUP ON COOPERATION BRUSSELS, 15TH MAY

PARTICIPANTS

Members and representatives of the Advisory Forum (AF)

Manuel Barreto Dias, Leif Busk, Vicente Calderon, Alecsandra Dida Cozachievic, Charles Crémer, Beate Folgerø, Andreas Hensel, Patrick O'Mahony, Agostino Macrí, Dace Šantare, Evert Schouten and Nick Tomlinson

Members of the Scientific Committee (SC)

Ada Knaap, Pierre Le Neindre and Vittorio Silano

European Commission (EC)

Jeannie Vergnettes

EFSA

Herman Koëter, Djien Liem and Daniela Maurici

1 WELCOME AND OPENING OF THE MEETING

Herman Koëter opened the meeting and welcomed the participants. He thanked Charles Crémer for hosting this meeting in his offices in Brussels. Apologies were received from Valérie Baduel and Nijolé Kazlauskienė.

2 ADOPTION OF THE AGENDA

The agenda was adopted without changes.

3 MINUTES 1ST MEETING

Minutes were approved subject to incorporation of a few editorial changes proposed by the participants.

In relation to the minutes the following remarks were made:

- Participants all agreed that there is a need for harmonisation of Risk Assessment (RA) methodologies and approaches; the question is how to do this.
- The suggestion of the first meeting was reiterated to circulate EFSA's guidance documents for risk assessment to the Member States for verification of their applicability at national level.
- It was also suggested to identify opinions where Member States had problems with (and vice versa), in order to better identify stages in the RA process for which harmonisation or clarification would be desirable.
- Furthermore, participants discussed to include a scientific assessment of different options for risk management and risk communication, a concept regularly included in risk assessments carried out by the BfR.

ACTIONS:

Secretariat to finalise the minutes and circulate them to the members of the SGC, SC and AF.

Secretariat to submit the draft Terms of Reference of the SGC as agreed by the AF and SGC to the SC for approval.

Secretariat to invite AF members to participate or designate MS experts to take part in the scientific cooperation activities proposed and agreed by the SGC, SC and AF.

4 FEEDBACK FROM THE SC AND AF

Preliminary drafts of the minutes of these two meetings were circulated to the participants for personal use. The participants approved the revised Terms of Reference for the Steering Group on Cooperation as proposed and agreed by the AF at its meeting in Berlin (ToR still to be confirmed by the SC at its plenary in July).

The question was raised whether the proposed project for the harmonisation of occurrence data would only focus on chemical substances and not on microbiological data. This was indeed intended as microbiological data would already be covered by the work carried out by the Task Force on Zoonoses.

Herman Koëter gave a feedback from the discussions in the AF about the establishment of focal points in the Member States and the possible financial support EFSA is proposing to facilitate the establishment of these focal points. The participants discussed the feasibility of

the proposed approach. It was noted that Member States already made some commitment to form a bridge to the EFSA in Regulation 178/2002. Participants also agreed that it was not intended that the focal point should coordinate, but should facilitate exchange of information and data between EFSA and the Member States.

5 DISCUSSION OF PROJECTS

5.1 Risks and benefits of fortification of foods with folic acid

Patrick O'Mahony introduced an updated draft of the terms of reference for the proposed activity. The following remarks were made:

- EFSA had already provided an opinion on folic acid on request of the Commission (EFSA Journal, 2004, 135, 1-20). On the basis of EFSA's opinion, the Commission is discussing a maximum fortification level for folic acid with the Member States. The added value of the proposed activity to what has already been done by EFSA could therefore be further clarified in the background.
- It was suggested to further clarify in the background the reasons why (e.g. the objective and goal of the activity) there is a need for this scientific cooperation activity and what could be the community interest.
- It was also requested to propose a timeline for the execution of the project and to indicate who will take the lead and which countries would participate in this joint activity. The participants agreed that aside from the SC and AF, also the SGC would be kept informed (last bullet of the ToR).
- Leif Busk indicated that Sweden would be willing to host the first meeting of a joint working group to address the carcinogenicity of folic acid.
- Dace Santare noted that the BRAFO project will start its activities on risk/benefit assessments in September 2007.

ACTIONS:

- Ireland to update the draft ToR based on the suggestions made by the SGC by end of May.
- Secretariat to circulate the revised ToR to the SGC for comments in writing.
- Secretariat to submit the final draft to the meetings of the Advisory Forum (28/29 June) and Scientific Committee (9/10 July) for discussion and possible approval.

5.2 Horizon scanning to identify emerging food safety risks

Vittorio Silano introduced a revised mandate with for a Scientific Cooperation Working Group of on Emerging Risks. The proposed project would focus on identifying indicators relevant for the identification of emerging risks, and on identifying and creating a network of the key sources to update relevant data and information on these indicators. A new definition

for *emerging risks*, as developed by the Scientific Committee Working Group on Emerging Risks, had been annexed to the draft mandate to clarify the difference between “emerging risks”, “emergency responses” and “risk assessments under crisis conditions”. Vittorio Silano noted that there is quite a different perception about the definition of emerging risks and emphasised that EFSA could do an effort to make more clear what it considers an emerging risk within the context of the Founding Regulation.

The participants were pleased with the scope of the proposed activity and suggested to link where appropriate to other organisations, research activities and international networks. In addition it was suggested to widen the perspective to Member States *as well as countries outside the EU* (e.g. US, Canada, Australia and New Zealand). It was noted that some countries (e.g. Germany, Netherlands) have already started to work on systems to systematically collect data on relevant indicators. The representatives from Belgium, Germany, Netherlands, United Kingdom expressed an interest to take part in this scientific cooperation project. The Secretariat will verify if there are also other countries that would like to participate. Countries that are not yet working in this area will be encouraged to participate for capacity building.

ACTIONS

- Vittorio Silano to update the draft mandate by end of May.
- Secretariat to circulate the revised ToR to the SGC for comments in writing.
- Secretariat to submit the final draft to the meetings of the Advisory Forum (28/29 June) and Scientific Committee (9/10 July) for discussion and possible approval.
- Secretariat to verify participation from other countries in this scientific cooperation activity.

5.3 Harmonisation of chemical occurrence data collection in food and feed

Djien Liem introduced the updated draft mandate for a scientific project entitled “Harmonisation of chemical occurrence data collection in food and feed” which would comprise the creation of a network of managers of chemical occurrence data to facilitate data collections for the occurrence of chemical substances in food, beverages and feed. Among possible tasks, this network could work on the development of general principles for data collection and of criteria for prioritisation. In addition, this network could be requested to advice on methodologies and procedures for generation and collection of chemical occurrence data.

The participants expressed a strong support to the proposal to create such a network. It was considered important that there should be a better streamlining of the various requests for submission of chemical occurrence data at European (e.g. for EFSA, the Commission services, for Eurostat) and International level (GEMS Food, JECFA/JMPR, etc.) in order to avoid duplication, different formats for the same data, etc. It is very difficult to get a clear picture on “who is asking which data”. Another question which was raised concerned the way data transfer, data storage as well as data access would be accomplished. There is no decision taken yet and the issue will be brought to the attention of the IT Working Group of the

Advisory Forum that will meet on 5th of June in Berlin. It was further suggested to consider data validation, existing information on food composition, the experiences of the German Research Centre and the UK FSA on methodologies/techniques for the collection of analytical data and legal aspects related to the ownership of the data to be collected.

As to the proposed mandate, suggestions were made to make the terms of reference shorter and less detailed than proposed. It was requested to keep the terms of reference more open to allow the network to be created more margins to manoeuvre when it would start this cooperative activity. The Secretariat will circulate an updated draft by the end of May to the Steering Group for consideration.

ACTIONS

- Secretariat to update the draft mandate by end of May (e.g. include a pre-amble, address close cooperation with organisations like JRC and Eurostat, clarify overall objectives).
- Secretariat to circulate the revised ToR to the SGC for comments in writing.
- Secretariat to submit the final draft to the meetings of the Advisory Forum (28/29 June) and Scientific Committee (9/10 July) for discussion and possible approval.

5.4 Fostering harmonising risk assessment approaches

Herman Koëter reiterated the discussions and suggestions made at the previous meeting of the Steering Group related to harmonisation of risk assessment approaches. As suggested at the first SGC meeting, it is intended to make a compilation of EFSA's guidance documents as produced for the various areas covered by EFSA's Scientific Panels, Scientific Committee, Task Forces and other Expert Working Groups.

Andreas Hensel announced Germany's willingness to prepare an outline for a terms of reference for a scientific cooperation activity aimed at harmonising risk assessment approaches across Europe. It was proposed to take into account the existence of quality management systems already in place in some food safety agencies (e.g. Germany, France, Netherlands, UK), available reports on how to address uncertainty and variability in the risk assessment and the work produced by EFSA's transparency working group and the SC Working Group on the in-and external review of the quality of EFSA's scientific work.

ACTIONS

- Andreas Hensel to prepare a draft mandate for consideration by the Steering Group on Cooperation at its next meeting in October (26th October, in Berlin, date to be confirmed).
- All participants to send existing reports on the handling of uncertainty and variability in the risk assessment to the Secretariat.

5.5 Safety assessment of botanicals and botanical preparations

Vittorio Silano introduced a draft mandate for a Scientific Cooperation Working Group on botanicals and botanical preparations. The proposed mandate is building on the work of the Scientific Committee working group that is currently drafting a guidance document for the assessment of the safety of botanicals to be used in the food and feed area, is preparing two compendia of botanicals and is developing criteria for prioritisation of these botanicals for safety assessment. The SC working group intends to submit the outcome of its work to the plenary meeting of the Scientific Committee on the 9-10 July.

In the proposed mandate for the joint WG, it is explained that the main objectives of the proposed cooperation would be to prioritise the botanicals for safety assessment, to test the tiered approach for the safety assessment as proposed by the SC Working Group, to validate the compendia, to organise a public consultation on the proposed assessment approach and to finalise the opinion.

The participants expressed a strong support for the proposed activity and suggested to take into account: the list of botanicals as prepared by the Commission and the Member States in the area of novel foods, the work carried out in the framework of the 5th Framework Programme on bioactive compounds and the way consumers are using botanicals and botanical preparations.

The AF members will be requested whether they would like to participate in this activity. Belgium, Germany and Portugal already expressed their interest.

ACTIONS

The secretariat will update the draft mandate for the joint WG.

The mandate will be submitted to the next AF and SC plenary meetings for approval.

5.6 Risk Assessment of nanoparticles (NEW)

Herman Koëter informed the SGC that EFSA has created an internal task force that is preparing a working document that would provide a state-of-play with regard to the risk assessment of nanoparticles and nanomaterials and could be used as a starting point for the formulation of a scientific cooperation project with the Member States. It would bring together where we are, which aspects of the assessment need closer attention and which activities have been carried out so far in the field of risk assessment.

EFSA will prepare a draft terms of reference for the next meeting of the Steering Group.

5.7 Other proposals

Leif Busk and Andreas Hensel offered to prepare a paper on risk ranking. At the previous meeting of the SGC it was agreed to defer this subject to the AF WG on Communications, but this decision was considered as probably too premature. The participants agreed that a paper as offered by Busk and Hensel would help in defining a new position of the Steering Group.

6 NEXT STEPS

The participants agreed on the next steps:

- Draft mandates will be, where needed, updated and recirculated to the members of the Steering Group on Cooperation for comments in writing, or for consideration at the next meeting of the Steering Group.
- Once the SGC could agree on the mandates, these mandates are sent to both the SC and AF for discussion and possible approval.
- Once a project has been approved, the Secretariat shall invite members of the Scientific Committee and Panels, and members of the Advisory Forum, if they, or an expert to be nominated, would like to take part in this activity.
- The project leads will be requested to provide a regular update to the SGC, SC and AF about the progress of their activities.

7 NEXT MEETING

Berlin on the 26th October (to be confirmed).

8 ANY OTHER BUSINESS

There was no other business.