

SCIENTIFIC COMMITTEE AND ADVISORY FORUM UNIT

Parma, 10 July 2008
EFSA/AF/ESCOHarmRA/M/2008/158/PUB/FIN

Secretary notes

**SECOND MEETING OF THE ESCO WORKING GROUP ON
FOSTERING HARMONISED RISK ASSESSMENT APPROACHES IN EUROPE
PARMA, 26-27 JUNE 2008**

EXPERTS FROM THE MEMBER STATES

Roland Grossgut - AUSTRIA (chair)
Wendie Claeys - BELGIUM
Klaus-Jürgen Henning - GERMANY
Fabrizio Oleari - ITALY
Sniegulė Trumpickaitė-Dzeksčiorienė - LITHUANIA
L'ubomír Valík - SLOVAKIA
Tor Øystein Fotland - NORWAY

EXPERTS FROM THE EFSA SCIENTIFIC COMMITTEE

Vittorio Silano (second day only)
Ada Knaap (second day only)

EFSA STAFF

Djen Liem - Scientific Committee & Advisory Forum Unit (second day only)
Torben Nilsson - Scientific Committee & Advisory Forum Unit
Stef Bronzwaer - Scientific Cooperation Unit
Andras Szoradi - Scientific Cooperation Unit

1 WELCOME AND OPENING OF THE MEETING

Roland Grossgut, chair of the ESCO Working Group (WG), welcomed the participants and opened the meeting.

2 ADOPTION OF THE AGENDA

The agenda was adopted without changes.

3 UPDATE ON DISCUSSIONS OF THE WORK OF THE ESCO IN THE SC, SGC AND AF

Roland Grossgut updated the WG on the discussions of the work of the ESCO in the SC, SGC and AF. In particular, he emphasised that the delay of sending out the questionnaire was due to the need to coordinate closely with the work of the SC on the transparency document and also because the questionnaire was discussed with the SGC prior to circulation through the focal points. Torben Nilsson added that the AF has requested a report from the ESCO by the end of September 2008.

4 PRESENTATION OF THE FINAL QUESTIONNAIRE AND UPDATE ON THE SITUATION AS REGARDS REPLIES RECEIVED

Stef Bronzwaer presented the questionnaire that was send to the Member States. The first part addresses the countries' organisation of risk assessment within EFSA's remit. The second part addresses the specific areas nutrition, food additives, feed additives, chemical contaminants, biological hazards, plant health, and plant protection products in more details. Torben Nilsson explained that GMO and animal health were not addressed in the questionnaire, since specific questionnaires on these two topics had been sent to the Member States in connection with recent, dedicated meetings. Stef Bronzwaer said that, in principle, the deadline for replying to the questionnaire had expired, but that especially part two of the questionnaire requires consultation at national level, and the focal points had therefore requested an extension of the deadline, so that the replies would be submitted over the summer. Roland Grossgut mentioned that the analysis and reporting on the replies would be complex due to the descriptive parts and suggested extracting aggregate information and general conclusions rather than attempting to reflect all details or compiling replies into a table that would be difficult to read anyway. Klaus-Jürgen Henning suggested that a list of competent institutions in the Member States for risk assessment within EFSA's remit could be extracted from the replies to the questionnaires. Torben Nilsson warned against a parallel process to the formally established list of article 36 institutions, but agreed that the proposed list of institutions performing risk assessment at Member State level within EFSA's remit could be a useful document for internal use.

5 PROPOSAL ON THE NEXT STEPS

The WG agreed that the next steps would be as follows:

1. Agree on the structure of the report (see agenda item 7 below).
2. Analyse the replies to the questionnaire and draft the ESCO report.
3. Discuss the report with the WG before submitting it to EFSA's Executive Director and the SGC for discussion at its meeting on 23 October 2008.
4. Finalise the report for endorsement by the AF in November 2008 and the SC in December 2008.

6 FEEDBACK ABOUT THE FIRST DAY'S OUTCOMES

Roland Grossgut opened the second session of the WG meeting (27 June 2008) summarising the main points agreed the day before. He welcomed Vittorio Silano, Ada Knaap and Djien Liem joining the meeting at this stage.

7 AGREEMENT ON THE STRUCTURE OF THE ESCO REPORT

Roland Grossgut presented a suggested structure of the ESCO report. The WG agreed on the structure outlined in Annex 1 below, but also agreed that the drafting team should feel free to adapt the structure as appropriate. It was agreed that the ESCO report should be concise, *i.e.* summarising and highlighting main findings and recommendations in approximately ten pages. The report will describe the organisation of risk assessment within EFSA's remit, identify differences in risk assessment approaches, and make recommendations on intensified cooperation aiming at fostering harmonised risk assessment approaches in Europe. The report will be published on EFSA website after endorsement by the AF and SC. All the supporting documents will be available to

EFSA and the Member States through the Extranet, but will not be published. It was agreed that the drafting team could contact the focal points who submitted the replies in case they need further information.

8 INTRODUCTION TO THE DIFFERENT TYPES OF RECOMMENDED FOLLOW UP ON THE WORK OF THE ESCO

Torben Nilsson introduced some ideas on different types of recommendations that could be considered by the WG, e.g. new working groups on specific topics, national expert meetings, ideas for article 36 projects, scientific colloquia. He emphasised that according to its mandate the WG should identify areas where further harmonisation would be desirable and suggest ways to address the identified needs, but this would not imply that the ESCO should follow up on the harmonisation itself, *i.e.* the required follow up would rather be by EFSA and the Member States.

Wendie Claeys said that there would be a need for a document providing a short description and overview of EFSA's risk assessment guidance documents. The WG agreed that such a document would be very useful for the Member States.

Roland Grossgut recalled the discussion at the first WG meeting that there would be a need to address definitions and nomenclature within risk assessment, since also the replies to the questionnaire reveals that terms are used differently by different institutions. Even though this aspect falls a bit outside the mandate of the ESCO, it could be considered as a recommendation for follow up.

9 SUMMARY OF MEETING'S DECISIONS AND ACTIVITIES UNTIL NEXT MEETING

Roland Grossgut summarised the agreements of the meeting as regards the tentative structure of the ESCO report (please refer to Annex 1) and the following future activities:

ACTION 1: Analyse the replies to the questionnaire and draft the ESCO report. This task will be undertaken by EFSA's Scientific Cooperation unit in close cooperation with the drafting team that developed the questionnaire. A meeting of the drafting team to discuss and finalise the draft report has been scheduled for mid-September 2008.

ACTION 2: Discuss the draft ESCO report with the WG at the third ESCO WG meeting on 30 September 2008 in Berlin.

ACTION 3: Submit the ESCO report to EFSA's Executive Director and to the SGC for discussion at its meeting on 23 October 2008.

ACTION 4: Finalise the report for endorsement by the AF at its meeting on 20-21 November 2008 and the SC at its meeting on 1-2 December 2008.

ACTION 5: If needed, organise an ESCO WG meeting in Parma on 8-9 December 2008.

Summary

Mandate of the ESCO

Summary of mandate, whole mandate in an annex

Introduction

Working methodology of WG

- Members of WG
- Meetings (WG, SGC, AF, SC)
- Questionnaire in an annex

Compilation and summary of answers

Organisation of risk assessment in the Member States (and EEA/EFTA countries)

Types of risk assessment → question of definition

Responsible organisation, involved institutions

Publications of risk assessments

Use of risk assessment guidance documents

Procedural aspects

Main challenges

Quality management in risk assessment

Identification of main differences

Need for harmonization (cooperation)

The way forward and recommendations

EXTRA DOCUMENTS FOR THE EXTRANET:

Annex I: Members of the WG

Annex II: Questionnaire

Annex III: Replies by the Member States

Annex IV: List of risk assessment institutions (out of questionnaire)

Annex V: Minutes of the WG

Annex VI: Presentations