EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Public Health and Risk Assessment
Risk assessment

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5TH MEETING OF CHAIRS AND SECRETARIATS OF EU COMMISSION AND AGENCY SCIENTIFIC COMMITTEES AND PANELS INVOLVED IN RISK ASSESSMENT

MEETING REPORT

1. SUMMARY

The 5th meeting of Chairs and secretariats of EU Commission and Agency Scientific Committees and Panels, organised by DG SANCO, took place in Brussels on 18-19 November 2009. It was well attended by the Chairs and Secretariat staff from EFSA, ECHA, EEA, EMEA, ECDC, SCCS, SCHER, SCENIHR and SCOEL (list of participants attached).

This year the meeting was devoted to discussion and decisions on the follow-up to the Action Points decided upon at the 2008 Chairs meeting; on two forward-looking issues of major importance for risk governance (next generations of nanotechnologies and synthetic biology); on the ongoing projects on emerging risks, terminology/weight of evidence/uncertainty and exposure assessment; and finally on further issues on the collaboration of the participating bodies. A special session on alternative test methods completed the meeting.

2. MATTERS OF THE AGENDA

Mr R. Madelin, Director General of the Health and Consumers Directorate General of the European Commission (DG SANCO), welcomed the participants with a short introduction on the scope and organisation of the meeting.

The meeting continued according to the agenda as following:

2.1. Follow-up on action points decided at the previous Chairs meeting (EFSA-Parma, 4-5 November 2008)

Mr B. Delogu (SANCO C7) presented a review of actions taken and results achieved following the 2008 meeting of Chairs, organised by EFSA in Parma. Based on the progress made since 2008, the following were decided:

- To use a note, disseminated in advance to the meeting by DG SANCO, as a basis for communication on the achievements of the Chairs collaboration. The positive results of such collaboration were highlighted, as well as the recent case of the joint opinion

on antimicrobial resistance. On the latter, although the collaboration was considered a success, ECDC proposed to use the experience with the joint AMR opinion as a case study in view of defining guidelines and operational arrangements aimed at facilitating inter-Agency collaboration in the future.

- To continue on a permanent basis with the application of the common guidelines on data sharing. This document, approved in Parma for application on a pilot basis, provides a framework for the exchange and use for risk assessment of data available to the Agencies.

- To adopt and apply on a pilot basis common guidelines for identification and management of potential divergences in risk assessment.

- To map the ongoing work on transparency as a basis for thematic exchanges between the Agencies. EFSA informed that in addition to the guidance adopted by its Scientific Committee on procedural and methodological aspects of transparency, it has launched work on default factors and margin of exposure.

- Finally, the compilation of operating procedures and rules applied by the Agencies will continue in 2010 following the arrangements already in place. It was recommended to provide a balanced presentation reflecting the specificities of each Agency.

2.2. Presentations and discussion on next generations of nanotechnologies and synthetic biology

Nanotechnology, Professor M. Roco

In the conclusion of his presentation, Professor Roco submitted five ideas to address the challenges of third and fourth generations of nanomaterials. They are (i) making available open sources systems to promote global self-regulation, (ii) creating and leveraging S&T nanotechnology platforms, (iii) addressing the sustainablility of resources as well as environment, health, and safety (EHS) issues and unexpected consequences—in this respect, Professor Roco also insisted on the importance of dealing with the risks of environmental nanoparticles, which are possible more relevant than those of nanomaterials in products, (iv) support global communication and international cooperation, and (v) commiting to a long-term, global, priority-driven governance supported by reliable system to monitor developments and detect problems. SANCO Director General Mr. Robert Madelin referred to the need to transform education in the face of such radical technological and risk governance challenges and to conceive a model to address them.

Synthetic Biology, Professor L. Serrano.

Professor Serrano concluded that “we don't know what is coming but, that we know it's coming.” This new technology waves not only bring along a wide range of useful applications but also possible misuse, environmental impacts, health impacts, and issues pertaining to justice, patent, and intelectual property rights. In addition, he remarked that Synthetic Biology marks the end of the so-called “Darwinian interlude” of slow evolutionary changes and re-opens a era of fast, now controlled biotic changes. Moreover, Professor Serrano stressed that Synthetic Biology raises complex policy issues because it will allow the design of novel life forms. In turn, these scientific and technological advances will likely trigger societal response. He also highlighted that

Synthetic Biology entails dual-use applications. As a result, Professor Serrano recommended (i) paying attention to public and media attitudes to perceived risks and benefits and (ii) developing proactive, predictive, regulatory frameworks.

These two areas partially overlap and pose similar risk governance problems. The need to focus on the applications with clear societal benefits and to ensure the appropriate framing of the public discussion on potential risks was highlighted.

It was concluded that the EU risk assessment bodies should monitor developments in these two areas as part of their emerging risk pro-active approach.

2.3. Projects on emerging risks, on terminology/weight of evidence/uncertainty in risk assessment, and on exposure assessment.

The ongoing activities for the three projects were reviewed in depth in the three parallel breakout groups. The approach and specific arrangements for the continuation of the work were discussed and endorsed. For each of the three projects, the following were decided:

2.3.1. Emerging Risks:

The pro-active approach proposed by the DGER was endorsed. It was decided that DG SANCO should discuss with EFSA a stepwise programme and prepare a mandate for the first stage of work. EFSA would involve the other Agencies in its working group and organise the appropriate transatlantic contacts in collaboration with DG SANCO. The opinion produced will be presented as a discussion paper at the 2nd Conference on Risk Assessment.

2.3.2. Terminology/Weight of Evidence and Uncertainty in Risk Assessment:

Again, the approach presented in the document of the working group was endorsed. However, it was concluded that the aspect of weight of evidence was more complex than the other two and could not proceed at the same speed. A staged approach will be necessary. DG SANCO will collect the final suggestions on the proposed questionnaires by the beginning of December 2009. The operational steps proposed (stocktaking exercise to be completed by February 2009 and two workshops before the 2nd Conference on Risk Assessment in 2010) were approved.

2.3.3. Exposure Assessment:

A document which has been discussed and agreed with the US and Canada colleagues formed the basis for the discussion. The objective is to assess the exposure assessment practices, identify test and best practices and to produce a report with guidelines for discussion at the 2nd International Conference of Risk Assessment. Participants endorsed the project and agreed to finalise the basis document and appoint contact points and participants for this project in the course of the next three weeks. Work is envisaged to start by the end of 2009. A first stage will consist of the identification and circulation of documentation on practices, guidelines etc. for exposure assessments The second and third stages will consist of identification of test cases (assessments) exemplifying the approaches used and the third stage will be the development of the guideline document. A mid 2010 (April – May 2010) progress review and document refinement for October

2010 are the two critical path dates towards the finalisation of the project in time for the 2nd International Risk Assessment conference in January 2011.

2.4. Dinner (18 November)

An intense dialogue on the relations between the Scientific Commitees and the European Parliament (EP) took place at the dinner among Robert Madelin, Prof. Roco, the Chairs and Jo Leinen (Chair of EP-ENVI), Ms Vergnaud (Vice-Chair of EP-IMCO), and Ms Roithova (Co-ordinator of the EP-IMCO for the Scientific Committees).

The conclusion was that there is a low level of understanding in the EP of the nature, organisation and added value of EU Agencies and Scientific Committees. Moreover, the opinions of the EU Scientific Committees and Panels are considered as just one of the inputs into the process through which members of the European Parliament establish their positions, along with scientific advice from other bodies, NGOs, etc.

It was determined that there is a need for a platform for more sustained exchange between the EU risk assessment bodies and the members of the EP, particularly the EP rapporteurs. DG SANCO should pursue with the EP the idea of such a platform.

2.5. Other Issues

The following issues were discussed:

2.5.1. Computational toxicology:

EFSA highlighted the difficulties related to the use of available computer programmes for predicting toxicity based on structure-activity considerations and for modelling metabolic fate of compounds and the need to exchange experience among assessors in this area. It was concluded that a dialogue should be established between scientists from the EU committees and panels, researchers and developers of such computer programmes for predicting toxicity. DG SANCO will explore with the JRC the possibility of establishing such a dialogue within the framework of the JRC activities on computational toxicology.

2.5.2. New challenges for risk assessment:

A discussion took place on the implications for risk assessment of developments such as toxico-genomics, proteinomics, etc. It was concluded that these challenges should be explored in a more systematic way. SCENIHR will set up a group to that aim, following a forthcoming mandate from DG SANCO, involving representatives from other agencies. This theme was also discussed at the transatlantic meeting in Washington and is a candidate for international collaboration.

2.5.3. Organisational aspects:

EEA announced its intention to organise the next meeting of Chairs in Copenhagen, on 11-12 November 2010. In turn, tentatively, ECHA is candidate for organising the Chairs meeting in 2011.

EEA has also announced a conference on the precautionary principle in Copenhagen, on 23-24 March 2010.

DG SANCO announced its intention to organise the 2nd International Risk Assessment Conference in Brussels on **26-28 January 2011. (***In the meeting, the dates of 1-3 December 2010 were announced as tentative dates for the Conference. However as a number of international events are scheduled for that period, the dates of 26-28 January 2011 have now been confirmed as the final dates for the 2nd International Risk Assessment Conference*). It was announced that a conference steering committee will be set up with representatives from the EU Agencies.

2.5.4. Documents sent as a follow up:

During the meeting, EMEA proposed to send some documents related to the discussions of the Plenary and Breakout-groups sessions. This information concerns definitions, classification of adverse reactions of medicinal products and benefit-risk assessment methods and where submitted by EMEA as a follow-up of this meeting:

2.5.4.1. Extract from the Pharmaceutical Forum Topic "Core principles on relative effectiveness". Working definitions:

Efficacy: is the extent to which an intervention does more good than harm under ideal circumstances.

Relative efficacy: can be defined as the extent to which an intervention does more good than harm under ideal circumstances, compared to one or more alternative interventions.

Effectiveness is the extent to which an intervention does more good than harm when provided under the usual circumstances of health care practice.

Relative effectiveness can be defined as the extent to which an intervention does more good than harm compared to one or more intervention alternatives for achieving the desired results when provided under the usual circumstances of health care practice.

2.5.4.2. Extract of the "Guideline on summary of product characteristics (SmPC)" for medicinal products on the terminology used to classify adverse reactions[1].

Section 4.8 related to "Undesirable effects" explains how to present the list of adverse reactions.

"The names used to describe each of the frequency groupings should follow standard terms established in each official language using the following convention: Very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to 1/1,000); very rare (<1/10,000)."

2.5.4.3. Reflection paper on benefit-risk assessment methods in the context of the evaluation of marketing authorisation applications of medicinal products for human use

This document has been drafted by the Committee for medicinal products for human use (CHMP) in March 2008.

[1] This guideline is included in The Rules Governing Medicinal products in the European Union-Volume 2C Notice to Applicants.

3. SPECIAL SESSION ON ALTERNATIVE TEST METHODS (19 NOVEMBER)

The session was intended to provide an opportunity for discussion between risk assessors and researchers on the state of development of alternative test methods. After an introduction on the EU policy and the activities of ECVAM, four specific projects were presented by the project leaders (EPAA, ReProTect, A-Cute-Tox**,** ASAT). Overall, the presentations and the discussion showed the gap between the state of the art on alternative methods, the need for data of the appropriate quality, and the expectations of policy makers. This is particularly relevant in relation to the assessment of systemic risks, for which *in vitro* methods do not provide suitable data and computational methods are still very far from adequate levels of development, reliability, and validation. At this stage, the target date (2012) for complete replacement of animal tests for cosmetic ingredients cannot be considered realistic. There are also uncertainties on the interpretation of the provisions of the Directive in that respect.

It was concluded that DG SANCO should raise with other services and the EP the impossibility in the foreseeable future for risk assessors to pronounce on systemic effects in the absence of data from appropriate (animal) tests.

Moreover, the Group of Chairs should monitor on a regular basis the development of alternative methods in order to assess the validity of data from alternative methods for risk assessment and to identify potential problem areas. The review of progress on alternative methods and the dialogue with researchers in this area should be a standing point in the Agenda of future Chairs meetings.

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ANNEX I

LIST OF PARTICIPANTS

5th Meeting of Chairs and Secretariats of EU Commission and Agency Scientific Committees and Panels involved in Risk Assessment 18/11/2009	
Chairs of Scientific Committees of EU Agencies/Institutions	
ECHA Chair of the Risk Assessment Commitee (RAC)	Prof. Jose TARAZONA
EFSA- SC	Prof Vitorio SILANO Prof. Michael John JEGER
EFSA - FEEDAP	Dr Andrew CHESSON
EFSA - PPR	Prof Anthony R. HARDY
EFSA - GMO	Dr Harry A. KUIPER
EFSA - BIOHAZ	Prof John D. COLLINS
EFSA - CONTAM	Dr Joseph R. SCHLATTER
EFSA - AHAW	Dr Philippe VANNIER
EFSA - ANS	John Christian LARSEN
EFSA - CEF	Klaus-Dieter JANY
EMEA	Hans-Georg EICHLER
EMEA - HMPC	Dr Konstantin KELLER
EMEA - DCO	Dr Daniel BRASSEUR
EMEA - AT	Dr Paula SALMIKANGAS
DG EMPL - SCOEL	Prof Vito FOA
DG SANCO - SCCS	Dr Ian WHITE
DG SANCO SCHER	Prof. Em. Helmut GREIM
DG SANCO SCENIHR	Prof. James BRIDGES

Invited Guest speakers	
Senior Advisor for Nanotechnology, US National Science Foundation	Prof. Mihail ROCO
Systems Biology Unit leader and Vice-Director, EMBL Centre for Genomic Regulation (CRG), Spain.	Prof. Luis SERRANO
Agencies' Secretariats	
ECDC	Prof. Johan GIESEKE Chief Scientist, Head of Scientific Advice Unit
ECDC - Scientific Advice Unit	Dr Helena de CARVALHO-GOMES
ECHA - Secretariat of the Risk Assessment Committee	Mr Steve HOLLINS
ECHA - Secretariat of the Risk Assessment Committee	Ms Katya VASILEVA
ECHA - Chair of the Committee for Socio-economic Analysis (SEAC)	Ms Ann THUVANDER
ECHA - Secretariat of the Committee for Socio-economic Analysis (SEAC)	Ms Adriana LIPKOVA
ECHA Secretariat of the Member State Committee (MSC)	Ms Liisa VAHTERISTO
EEA - Senior Adviser - Science, Policy, Emerging Issues IEA - Integrated Environmental Assessments	Mr David GEE
EEA	Dr Theodorus Gabriël VERMEIRE
EFSA - SC	Mr Djien LIEM (Head of unit)
EFSA Senior Scientific Officer	Dr. Leng HENG (NDA Panel)
EFSA	Dr Juliane KLEINER (HoU NDA)
EFSA	Dr. Christine FÜLL Senior Scientific Officer Deputy Head of PPR Panel Unit
EFSA - FEEDAP	Claudia RONCACIO PENA (Head of Unit FEEDAP)
EFSA - PLH	Mrs Elzbieta CEGLARSKA (Head of Unit PPR)
EFSA – CONTAM	Mrs Claudia HEPPNER
EFSA - AHAW	Mr Per HAVE
EFSA - ANS	Mr Hugues KENIGSWALD (Head of Unit ANS)
EFSA - CEF	Mr Alexandre FEIGENBAUM (Head of Unit CEF)
EFSA - GMO	Mr Per BERGMAN (Acting Head of Unit of GMO)
EMEA	Prof. Marisa PAPALUCA AMATI (Head Scientific Support and Projects European Medicines Agency)
EMEA - CVMP	Mrs Kornelia GREIN
EMEA	Mrs Arielle NORTH

DG SANCO	
DG SANCO – Director General	Mr Robert MADELIN
DG SANCO – Deputy Director General	Mrs Paola TESTORI COGGI
SANCO.DDG.03	Mr Robert VANHOORDE
SANCO.DDG.03	Mr Michael WALSH
DG SANCO C.7	Mr Bernardo DELOGU (Head of Unit)
DG SANCO C.7	Mr Takis DASKALEROS (SCCS/SCHER)
DG SANCO C.7	Ms Gigliola FONTANESI (SCHER)
DG SANCO C.7	Ms Karin KILIAN (SCCS)
DG SANCO C.7	Mr Antoon VAN ELST
DG SANCO C.7	Mr Philippe MARTIN (SCENIHR)
DG SANCO C.7	Mr Laurent BONTOUX
DG SANCO C.7	Ms Katja BROMEN (SCENIHR)
DG SANCO C.7	Mr Vladimir GARKOV
DG SANCO C.7	Ms Athanasia KANELLOPOULOU
DG SANCO C.7	Mr Jan MUYLDERMANS
Other Commission Services	
DG ENTR	Mr Cornelis BREKELMANS Conseiller ENTR.F
DG ENTR	Mrs Maila PUOLAMAA
DG EMPL	Mrs Alicia HUICI MONTAGUD
DG ENTR	Mr Martinus NAGTZAAM
DG ENV	Mr Bjorn HANSEN
JRC-ISPRA	Mr Christoph KLEIN
JRC-ISPRA	Mrs Sharon MUNN

ANNEX II

5th Meeting of Chairs and Secretariats of EU Commission and Agency Scientific Committees and Panels involved in Risk Assessment ***Alternative Methods session, 19/11/2009 pm***	
SCHER	Prof. Herman AUTRUP
SCHER	Peter CALOW
SCHER	Prof. Wolfgang DEKANT
SCCS	Prof. Vera ROGIERS
SCCS	Dr Maria Pilar VINARDELL
SCENIHR	Prof. Eduardo RODRIGUEZ-FARRE
SCENIHR	Dr Theodorus Gabriël VERMEIRE
Institute of Pharmacology and Toxicology, Department of Toxicology, University of Tübingen,	Dr Michael SCHWARZ
EPAA Steering Committee	Dr Odile de SILVA
ASAT project: Assuring Safety without Animal Testing	Dr Bart SANGSTER
Nordic Information Centre for Alternative Methods, NICA	Dr Cecilia CLEMEDSON