EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate C - Public Health and Risk Assessment
C7 - Risk assessment

Brussels, 28 February 2006
C7/MM D(2006) 370004

REPORT OF THE FIRST MEETING OF THE CHAIRS OF SCIENTIFIC COMMITTEES OF COMMUNITY BODIES INVOLVED IN RISK ASSESSMENT (7 AND 8 DECEMBER 2005)

1. FIRST DAY MEETING

1.1 Introduction and objectives

Mr Madelin, DG SANCO Director General, welcomed the participants and briefly introduced the objectives of this first meeting which were to increase mutual awareness and cooperation between Scientific Committees/Panels of Community bodies. The document '**Maximising the contribution of Science to European Health and Safety (*'Science paper'*)** published on the SANCO webpage **(*Sanco-science-discussion-paper-comments@cec.eu.int*)** would be used as the basis for the discussion.

The meeting commenced with a "tour de table" by the Chairs who described their backgrounds and expectations from the meeting. List of participants enclosed (Annex 1).

1.2 Presentation and discussions in relation to the SANCO Science Paper

It emerged that most of the participants wished to discuss:

- information sharing, awareness, common approaches, assessment strategy, overlapping areas and borderline products, improved interaction, synergy, independence considerations;
- confidentiality, transparency;
- terminology, communication;
- coordination on specific subjects, avoidance of diverging opinions, responsibilities when same topics discussed by different committees and panels;
- quality of data and other factors which might have an influence, data source, data availability;
- integration of environmental health;
- training, experts and future risk assessors;
- proportionality and the tendency to estimate risk on a worst-case basis.

Mrs Husu-Kallio, Deputy Director General and DG SANCO's Head of Science, underlined the importance of scientific advice in SANCO policy, the vital role played by communication and the difficulties in communicating scientific facts to the consumer. Uncertainties needed to be expressed in a way which would allow the risk manger to take a decision without alarming citizens but maintaining their confidence in science. General terms such as "negligible risk" and "low risk" did not help the decision-making process, making it difficult for the risk manager to estimate the risk. The need to ensure the best possible assessors and the provision of training were also emphasised. Other items of importance were how to gather risk assessment data, encourage networking and ensure clear questions within the remit of the Committees.

This was followed by presentations from 5 of the Chairs which are briefly summarised below.
The slides are available at following web address
(http://europa.eu.int/comm/health/ph_risk/committees/ev_20051207_en.htm).

Quality of data (Dr. I. White, SANCO-SCCP)

The relevance of guidance for assessing substances and future prohibition of animal testing (problem for assessment of substances) was illustrated with examples from the cosmetic ingredients field. Data required for the dossier were quite often incomplete. On exposure, most of the time very little was known. Data availability remained one of the major problems. A mechanism to gather data could help.

Expression of uncertainties (Prof A. Hardy, EFSA-PPR)
It was difficult to estimate the magnitude and communicate to consumers. Mandates should preferably include a request to estimate uncertainties although there are problems in persuading experts to express them. However, uncertainty linked to variability should be explained e.g. degradation of pesticides and its link to temperature. (Derived uncertainties might also be different). Prof Hardy stressed the need for a good database.

Negligible risk (Dr D. Brasseur, EMEA – CHMP)
Transparency in communication was a problem. Risk/benefit was seen as a tool in assessing medicines but other risk assessment bodies considered it a risk management tool. Post marketing surveillance might be a tool in terms of public health for drugs and perhaps other areas. Environmental risk assessment should be included in the pharmaceutical area. Permanent collaboration was needed to assess potential problems.

Quantitative risk assessment (Prof V. Foà, EMPL – SCOEL)
For suggesting numerical figures in establishing occupational exposure limits (OEL), SCOEL follows the traditional approach for chemicals with a threshold and a quantitative risk assessment for substances non threshold calculated by different mathematical models. For genotoxic carcinogens, two examples are presented (benzene and 1-3 butadiene). Solid data are seldom available and there is a need for expertise in quantitative risk assessment, with money allocated for this purpose. The information which could arise from this exercise could be very important for the risk manager provided that a dialogue between assessors and managers will be implemented.

Approaches to assessment of substances for which no-threshold can be set (e.g. genotoxicity) (Dr J. Schlatter, EFSA – CONTAM)
The presentation covered: non-threshold – "what is a safe dose?" and the issue of "no appreciable" or "negligible" risk. The current system used is ALARA but it has limitations. Testing with low doses is not helpful because too many animals would be involved. EFSA had reservations about using mathematical modelling for a quantitative risk assessment and proposed margins of exposure for key chemicals. Contaminants are seen as a major problematic area and research should be carried out to produce data. Mr Madelin commented that this is an area for long-term investment.

<u>Conclusions of first day</u>

The overall conclusion was there was agreement on a series of important issues that were of common concern to the chairs of the scientific committees and panels which would benefit from more detailed discussion. More assertive insistence on adequate data could oblige industry to provide better data. It was clear that learning about each other's activities encouraged sharing of information and possible interaction.

A table indicating the overlap with the Science paper and the additional topics identified by the participants is presented in Annex 2.

2. 2ND DAY – BREAKOUT SESSIONS

The plenary session was chaired by Mrs Husu-Kallio who outlined the agenda for the day. The participants then divided into three discussion groups, covering various issues, with the objective of sharing ideas on areas of mutual interest in order to facilitate greater awareness and cooperation. Each discussion group was asked to identify 3 to 5 areas which could support this objective. It was stressed that the discussion should take full account of the need for individual committees and panels to preserve their independence.

A copy of the background tabled for discussion within the groups is enclosed in the Annexes together with the distribution of participants within the three groups (Annex 3).

2.1 Discussion Group 1 (dg 1) – avoidance of diverging opinions

The EFSA and EMEA Regulations and Commission Decision 2004/210/EC setting up the SANCO Committees laid down a requirement for the avoidance of diverging opinions but this was not easy to apply in practice, particularly when linked to exchange of documentation and confidentiality restrictions.

The group discussed how to define a diverging opinion and concluded there was a need to distinguish between **"real" and "apparent" diverging opinions**. Reasons for diverging opinions might be varied: different data required, different data available for evaluation, different goals, and/or differences in use scenarios. A "real" diverging opinion, for example, refers to a situation where the same data leads to a different descriptions of hazard and consequently of risk. "Apparent" diverging opinions refer to situations/conclusions on hazards and risks which vary because of absence of awareness/provision of critical data, differing routes and amount of exposure, differing views on uncertainties or differing methods of addressing uncertainties.

An enhanced mechanism for information and data exchange between Scientific Committees and Secretaries was considered necessary, especially when new tasks were launched. A systematic search for previous opinions was needed and external experts were required for *ad hoc* working groups. Legal constraints in data sharing[1] needed to be solved. Rationalisation of web sites would enable wider and more intensified use of existing information.

More systematic dialogue with risk managers would ensure that opinions focused on the issues crucial for regulatory work. It was also considered necessary to explore ways to express a low risk coherently in the opinions. Better means were also necessary for the reconciliation of diverging opinions with the Member States. A European-wide policy on non-genotoxic issues was proposed (e.g. musk xylene). It was considered important to create good practice for the avoidance of diverging opinions covering the following points:

- A register of questions;
- clear mandates with a realistic timeline;
- identify relevant data and work done;
- improve the user-friendliness of web sites;
- identify cases for different approaches;
- ensure means for sharing information between committees;
- favour ad hoc working groups engaging highly specialised external expertise;
- ensure means for sharing experts between committees;
- search for solutions to the confidentiality problem;
- maintain systematic dialogue between risk assessors and risk managers with a view to identifying possible divergences at an early stage and resolving them;

[1] The data sharing between Committees would also reduce the need for demands for extra testing (both *in vitro* and *in vivo*).

- develop consistent expression of low risk in opinions;
- explain the data, approaches and assumptions used as well as possible divergence in the opinion (useful information for the risk manager);
- circulate the draft opinion for comments, where appropriate;
- put draft opinions for public consultation, where appropriate.

2.2 Discussion group 2 (dg 2) - Environmental and health risks

The group compared and contrasted approaches to the environmental fate of substances examined in different sectors, the need for and practicality of developing common scenarios covering several types of substances, the potential for integrating ecosystem protection and the assessment of health risks for humans exposed through the environment.

The group considered that the main issues in the environmental areas were that the risk to human health from the environment was hardly addressed, the lack of a holistic approach – regulation orientated assessment - and a lack of a common platform to exchange data. Although there is significant knowledge related to chemicals and a growing knowledge on GMOs, there is a lack of knowledge on new technologies such as nanotechnology and cell therapy. Currently environmental risk assessments (RA) are handled differently in areas such as veterinary drugs, pesticides, agricultural use of GMO, human medicine and chemicals because of differences in legislation, guidelines and application.

In some cases, differences in environmental RA were justified, but there are inconsistencies, e.g. contaminants in fertilizers. The group proposed two scenarios:

– Agricultural soil and ground water and associated water bodies (terrestrial system);
– Emissions from municipal water treatment plants (aquatic system, e.g. point sources).

For each scenario the following three steps should be considered:
– independent assessments;
– combined assessment;
– overall risk.

These proposals could be implemented by an exchange in an inter-committee WG including European Chemical Bureau (ECB) and by identifying the research needs (DG Research).

2.3 Discussion Group 3 (dg 3) - Area for mutual cooperation

The following six issues were the focus of the discussion

– Training and manpower development in risk assessment, exchange of staff;
– Identification of experts in specific areas and on special issues;
– Data availability and quality;
– Cooperation amongst Committees and assessors;
– Cooperation amongst risk assessors and managers;
– Communication issues.

Needs related to these six areas were identified and ideas for resolving some of the existing challenges were proposed. While not all of them may easily be solved, not even with better collaboration of the scientific committees, there was a general agreement that increased mutual cooperation through harmonized approaches, mutual support and learning would be beneficial.

– Increase efficiency, consistency and transparency;
– Broaden level of expertise and skills in committee;
– Enhance access to data as basis for risk assessment;
– Avoid diverging opinions;
– Enhance communication, particularly with risk managers and the public, but also with the scientific community.

This should lead not only to an overall improvement of the quality but also to the visibility and impact of the work performed which would also attract more senior scientists to apply for membership of committees.

2.4 Joint discussion

The groups reconvened to present the conclusions of their discussions.

3. OVERALL CONCLUSIONS

The assessment bodies and participants expressed their agreement on the usefulness of the initiative and the need to pursue certain tasks such as increased cooperation and sharing of information. In this respect, EFSA would certainly re-enforce contact between the FEEDAP panel and the EMEA's CVMP. EFSA also favoured the exchange of working plans and the inter-committee WG on environmental issues. Its list of experts would be shared amongst risk assessment bodies present at the meeting. EEA made reference to the EEA report, which is published every five years. It is on the state of trends in and prospects for the environment in Europe. The data underpinning the European Environment State and Outlook report is collected by the Agency through the EIONET (European environment information and observation network). DG EMPL also stressed the relevance of the event although recognising that the activity of SCOEL varied from those of the other risk assessment bodies. The ECDC underlined the relevance of such an event, particularly for them as a newly established Agency.

With regard to substances which are both genotoxic and carcinogenic, EFSA proposed to discuss the subject further and wished to be involved in the SANCO strategy policy.

On communication, the difficulty of translating a scientific opinion into a lay language summary was underscored.

Mrs Husu-Kallio acknowledged the need for risk managers to improve the system of feedback to the risk assessors and for SANCO to consider better communication and the further involvement of other stakeholders. It was agreed that the next meeting would again be hosted by SANCO in autumn 2006 and that any subsequent meeting would be hosted by another Community risk assessment body.

4. FOLLOW-UP TO THIS MEETING

EFSA

- panels/committees having a common interest should start bilateral contacts with other Community Risk assessment bodies;
- legal possibility to share dossiers between those bodies;
- invite colleagues as observers;
- panels/committees receiving questions on same substances should receive same data (dossier);
- previous opinions should be referred to and work plans exchanged;
- list of contact points (direct contact ! – risk of no overview);
- conflict of interest – EFSA had prepared a document which could be shared.

EMEA

- Identifies priorities; evaluates progress; identifies areas for cooperation;
- Support for the meeting next year;
- Follow-up on transparency issues.

EMPL

- Announcement of a workshop on carcinogens by EMPL in March 2006.

SANCO:

- Proposal for next meeting in autumn 2006;
- Network – practical implementation;
- Examine the legal issues governing the sharing of data/dossier (confidentiality);
- Terminology and guidelines.

5. 2ND DAY - MEETING BETWEEN SECRETARIATS

The objective was to have an in-depth discussion to understand what was realistic and manageable in relation to expectations and available human resources. A "tour de table" took place to exchange information on activities and expectations. Items of common interest identified were:

- Transparency with respect to the conclusions reached;
- Identification of experts and database and cooperation for exchange of experts and procedures;
- Awareness, a database on who-is-doing-what, lessons learnt, sharing of information/ documentation and exchange of opinions;
- Confidentiality issues;
- Common approaches: common policy/procedures/feedback;
- Access to documents, stakeholders involvement, communication;
- Conflicts of interest;
- Environmental exposure monitoring;
- Importance of identifying priority areas;
- Need to consider global exposure;
- Emerging issue sharing, inter-committee group operational activities;
- Data collection, data availability, grey literature, follow-up to scientific opinions;
- Improving policy between DGs, involvement of other DGs (RTD).

Overall conclusion:

There was a general consensus that there should be direct contact between experts. A searchable database for work carried out would be useful. Emerging issues should be collectively identified and it would be useful to gather best practices in relation to access to documents. Participants agreed on the need for a centralised source of information on Committees/Panels and contact points. It was agreed that each agency/DG would coordinate its own contact points and send the information to M Marini – C7, by end of 2005, who would assemble and circulate the list. Most of the participants favoured direct contact, although several stressed the need to ensure coordination of inter-agency/Commission contacts. The date for the next meeting of chairs would be agreed as soon as possible. Finally, participants wished to have more frequent meetings of secretariats and the participation of RTD. EMEA undertook to share its criteria for selection and lists of experts by 15 January 2006.

6. DISCUSSION ON EMEA'S REFLECTION PAPER

A three step approach was proposed. Firstly, to identify each other's activities and decide whether there was a low or high risk of a diverging opinion. Secondly, to inform each other about identified high risk subjects and monitor draft opinions (low or high potential). These two initial steps would allow avoidance of a possible divergence and would imply a sharing of draft documents as well as monitoring of each other's activities.

To cover the eventuality that it is not possible to avoid conflict, it will be necessary to define the procedure governing the discussion between the bodies concerned and the structure of the report. The discussion should cover at least possible differences in the questions posed and the data examined. The body that initiates the procedure should retain responsibility for its completion.

SANCO.C7 described its procedure for initial screening of each question, which was designed to identify overlapping responsibilities of both scientific committees/panels and Community Risk assessment bodies. Where overlaps were identified, SANCO C7 made contact with the secretariats in the bodies concerned.

The final step concerned the procedure which should confirm that it is a 'real' divergent opinion taking account of the request/data, etc. If the data differed, the reason should be explained. Confidentiality issues for the exchange of dossier/data should be formally clarified with the involvement of the various legal services. Other types of international agreement e.g between EMEA and FDA (to be circulated by EMEA) should also be considered.

The possibility of using the EMEA reflection paper as a framework for the other risk assessment bodies was explored. In view of the common obligations on EFSA, EMEA and the SANCO Committees, SANCO favoured building on EMEA's proposal on diverging opinions for its Scientific Committees and hoped it could be used as a basis for a common document.

This proposal would be circulated to corresponding bodies for comments by end of January.

Annex 1 - List of participants

NAME	INSTITUTION AGENCY	UNIT/FUNCTIONS
Mr Antonis ANGELIDIS	European Commission DG EMPL.D4	Policy Officer Occupational safety team Scientific Committee on Occupational Exposure Limits (SCOEL)
Dr Susan BARLOW	(EFSA)	Chair of the AFC Panel on food additives, flavourings, processing aids and materials in contact with food
Mr Sylvain BINTEIN	European Commission DG ENV.C3	Policy Co-ordinator - New Chemicals and Protection of Laboratory Animals
Dr Daniel BRASSEUR	(EMEA)	Chair of the CHMP Committee for Medicinal Products for Human Use
Prof. James BRIDGES	(DG SANCO.C7)	Chair of the SCENIHR Scientific Committee on Emerging and Newly Identified Health Risks
Ms Katja BROMEN	European Commission DG SANCO.C7	Scientific Secretariat of the SCENIHR Scientific Committee on Emerging and Newly Identified Health Risks
Ms Chantal BRUETSCHY	European Commission DG ENV.D4	Head of Unit "Health and Urban Areas"
Ms Elzbieta CEGLARSKA	EFSA	Scientific Co-ordinator Head of Team of Plant Health Activities Panel on Plant Protection and their Residues (PPR) and on Plant Health
Prof. Andrew CHESSON	(EFSA)	Chair of the FEEDAP Panel on additives and products or substances used in animal feed
Prof. John Dan COLLINS	(EFSA)	Chair of the BIOHAZ Panel on biological hazards
Mr Bernardo DELOGU	European Commission DG SANCO.B3	Head of Unit "Product and service safety"
Ms Muriel DUNIER-THOMANN	EFSA	Scientific Co-ordinator Head of Team of PPR Activities Panel on Plant Protection and their Residues (PPR) and on Plant Health
Prof. Vito FOÁ	(DG EMPL.D4)	Chair of SCOEL Scientific Committee on Occupational Exposure Limits
Ms Gigliola FONTANESI	European Commission DG SANCO.C7	Scientific Secretariat of SCHER Scientific Committee on Health and Environmental Risks
Ms Anne GAUTRAIS	European Commission DG ENTR.F2	Policy Officer - Veterinarian Pharmaceuticals
Prof. Johan GIESECKE	ECDC	Head of Unit "Scientific Advice"
Mr Baart GOOSSENS	EFSA	Senior Scientific Officer BSE/TSE Panel on biological hazards – BIOHAZ
Ms Kornelia GREIN	EMEA	Head of Sector

NAME	INSTITUTION AGENCY	UNIT/FUNCTIONS
		Safety of Veterinary Medicines
Prof. Anthony R. HARDY	(EFSA)	Chair of the PPR Panel on plant health, plant protection products and their residues
Mr Wolfgang HEHN	European Commission DG ENTR.G.2	Deputy Head of Unit "Chemicals"
Ms Claudia HEPPNER	EFSA	Scientific Co-ordinator CONTAM Panel on contaminants in the food chain
Ms Galina Georgieva HRISTOVA	EEA	Secretariat of Scientific Committee and of Management Board Corporate Affairs
Ms Marta HUGAS	EFSA	Scientific Co-ordinator BIOHAZ Panel on biological hazards
Dr Alicia HUICI-MONTAGUD	DG EMPL.D4	Secretariat of the SCOEL Health, safety and hygiene at work Occupational health team
Mr Juergen HELBIG	European Commission DG ENV.B4	Policy Officer - Plant Protection Products Biotechnology and Pesticides
Ms Jaana HUSU-KALLIO	European Commission DG SANCO	Deputy Director General
Dr Konstantin KELLER	(EMEA)	Chair of the HMPC Committee for Herbal Medicinal Products
Ms Sheila KENNEDY	EMEA	Secretary of CHMP (Committee for Medicinal Products for Human Use) and of HMPC (Committee for Herbal Medicinal Products)
Ms Juliane KLEINER	EFSA	Senior Scientific Officer Risk Assessment
Dr Herman KOËTER	EFSA	Acting Executive Director Director of Science
Dr Harry A KUIPER	(EFSA)	Chair of the GMO Panel on genetically modified organisms
Ms Birka LEHMANN	European Commission DG ENTR.F2	Administrator Human pharmaceutical products Pharmaceuticals
Mr Djien LIEM	EFSA	Acting Scientific Director Scientific Co-ordinator Scientific Committee
Mr Robert MADELIN	European Commission DG SANCO	Director General
Ms Marina MARINI	European Commission DG SANCO.C7	Scientific Officer Risk Assessment
Ms Barbara MENTRE	European Commission DG ENTR.F3	Policy Desk Officer - Cosmetics Cosmetics and Medical Devices
Prof. Bedrich MOLDAN	(EEA)	Chair of the Scientific Committee
Dr Gérard MOULIN	(EMEA)	Chair of the CVMP Committee for Medicinal Products for Veterinary Use

NAME	INSTITUTION AGENCY	UNIT/FUNCTIONS
Ms Sharon MUNN	European Commission JRC.I.03	Scientific officer Toxicology and chemical substances
Mr Jan MUYLDERMANS	European Commission DG SANCO.C7	Administrative Assistant Risk Assessment
Mr Alexis NOLTE	EMEA	Quality of Medicines
Ms Arielle NORTH	EMEA	Directorate - Executive Support
Ms Annette ORLOFF	European Commission DG ENTR.F3	Policy Desk Officer Cosmetics Cosmetics and Medical Devices
Ms Terje PEETSO	European Commission DG SANCO.C7	Scientific Secretariat of SCCP Scientific Committee on Consumer Products
Ms Maila PUOLAMAA	European Commission DG SANCO.C7	Scientific Secretariat of SCENIHR Scientific Committee on Emerging and Newly Identified Health Risks
Ms Susy RENCKENS	EFSA	Scientific Co-ordinator of the GMO Panel on genetically modified organisms
Ms Valérie ROLLAND	EFSA	Assistant Scientific Co-ordinator Scientific Committee
Ms Claudia RONCANCIO PENA	EFSA	Senior Scientific Officer Panel activities/Risk assessment of feed additives
Dr Josef Rudolf SCHLATTER	(EFSA)	Chair of the CONTAM Panel on contaminants in the food chain
Mr Jordi SERRATOSA VILAGELIU	EFSA	Scientific Co-ordinator of the AHAW Panel on animal health and welfare
Prof. Vittorio SILANO	(EFSA)	Chair of the Scientific Committee
Ms Marta STANISZEWSKA	European Commission DG SANCO.C7	Trainee Risk Assessment
Prof. Jose V. TARAZONA	(DG SANCO.C7)	Chair of the SCHER Scientific Committee on Health and Environmental Risks
Mr Antoon VAN ELST	European Commission DG SANCO.C7	Technical Assistant – Scientific Secretariat of SCCP Scientific Committee on Consumer Products
Mr Robert VANHOORDE	European Commission DG SANCO.D5	Head of Unit "Relations with European Food Safety Authority;Rapid Alert System"
Dr Philippe VANNIER	(EFSA)	Chair of the AHAW Panel on animal health and welfare
Mr Peter WAGSTAFFE	European Commission DG SANCO.C7	Head of Unit "Risk Assessment"
Mr Michael WALSH	European Commission DG SANCO.D5	Deputy Head of Unit "Relations with European Food Safety Authority; Rapid Alert System"
Dr Ian WHITE	(DG SANCO.C7)	Chair of the SCCP Scientific Committee on Consumer Products

NAME	INSTITUTION AGENCY	UNIT/FUNCTIONS
Administrative support :		
Ms Carol HUMPHREY-WRIGHT	European Commission DG SANCO.C7	Assistant to Head of Unit "Risk assessment"
Ms Cathy DEKINDT	European Commission DG SANCO.C7	Secretary of the SCENIHR, SCCP and SCHER Risk Assessment
Ms Bridie PRENDERGAST	European Commission DG SANCO.C7	Secretary to Head of Unit "Risk Assessment"
Ms Mirella BRANDIMARTE	European Commission DG SANCO.C7	Secretary Risk Assessment

Annex2

	Topics raised by Chairs in "tour de table"	Nr of mentions	SANCO PAPER (nearest actions)
1.	Identifying overlapping question/responsibilities	4	
2.	Common approaches Assessment strategies e.g. anti-virals, anti-microbial resistance Information sharing	6	12
3.	Common terminology	3	12
4.	Next generation of risk assessors	2	1,2
5.	Diverging opinions	1	
6.	Quality of data	2	5, 6, 7, 9 (vi)
7.	Asking the right question	2	9 (i)
8.	Uncertainty statements	2	9 (v), 9 (vi)
9.	Communication (various purposes)	3	11
10.	Total exposure	2	
11.	Environmental issues	4	
12.	Risk management – Risk assessment (e.g. mutual understanding/ "no harm")	3	9 (i), 9 (ii), 10
13.	Proportionality in advice for low risk problems	1	

Annex 3

Meeting of the Chairs of Scientific Committees/Panels of Communities bodies involved in risk assessment

(7 and 8 December)

2nd day Discussion groups

Each session

Objective : - to share ideas on areas of mutual interest with a view to facilitating greater awareness and cooperation;

- Each discussion group is asked to identify 3 to 5 areas which could support the above objective.

N.B.: It is stressed that the discussion should take full account of the need for individual committees and panels to preserve their independence.

Discussion Group I Avoidance of diverging opinion

The participants should draw on practical experience in their own areas.

Parts to consider include:

- Legislative background – EFSA/EMEA/SANCO SCs and its implementation (see compiled legal texts)
- The role of the scientific committees and panels
- How to identify potential overlap and risk of diverging opinions
- How to avoid divergence (e.g. joint meetings)
- Resolving divergent opinions e.g. meetings, chairmanship, etc.
-

Discussion Group 2 Environmental health risks

The participants should take note of following background documents:

- Updated Opinion of the Scientific Steering Committee on Harmonisation of Risk Assessment Procedures (adopted on 10-11 April 2003)
  http://europa.eu.int/comm/food/fs/sc/ssc/out355_en.pdf

- Guidance for the expression of opinions and other outputs of Scientific Advisory Committees adopted by the Scientific Steering Committee (SSC) as part of its exercise on Harmonisation of Risk Assessment Procedures (adopted on 21-22 February 2002)
  http://europa.eu.int/comm/food/fs/sc/ssc/out250_en.pdf

- Communication from the Commission to the Council , the European Parliament, the Economic and Social Committee of the Regions on the health strategy of the European Community
  http://europa.eu.int/eur-lex/en/com/pdf/2000/en_500PC0285.pdf

An overview on these documents will be presented by Dr Tarazona

EMEA documents:

- Environmental risk assessments for medicinal products containing of, genetically modified organisms (GMOs) (Module 1.6.2) – EMEA/CHMP
  http://www.emea.eu.int/pdfs/human/bwp/13514804en.pdf

- Note for guidance: environmental risk assessment for veterinary medicinal products other than GMO-containinbg and immunological products – EMEA/CVMP
  http://www.emea.eu.int/pdfs/vet/regaffair/005596en.pdf

- Guideline on environmental impact assessment (EIAS) for veterinary medicinal products – phase I – EMEA /CVMP
  http://www.emea.eu.int/pdfs/vet/vich/059298en.pdf

- Guideline on environmental impact assessment for veterinary medicinal products phase II – EMEA/CVMP
  http://www.emea.eu.int/pdfs/vet/vich/079003en.pdf

- Note for guidance: environmenatal risk assessment for immunological veterinary medicinal products – EMEA/CVMP
  http://www.emea.eu.int/pdfs/vet/regaffair/007495en.pdf

- Guidelines on GMOs updated notice to applicants (NTA) guidance – EMEA/CVMP
  http://www.emea.eu.int/pdfs/vet/regaffair/115104en.pdf

- Standard operating procedure on GMOs – Article 28 compliance – EMEA/CVMP
  http://www.emea.eu.int/pdfs/vet/sop/SOPV4012.pdf

An overview on these documents will be presented by Dr Moulin and A. Nolte

  - Note: Additional guidelines are under development for biocides (see European Chemicals Bureau web page)

The group should compare and contrast approaches to environmental fate of substance examined in different sectors, the need for and practicality of developing common scenarios covering several types of substances (e.g. a scenario for agricultural soils receiving fertilizers, sludge, manure, etc.) and the potential for integrating ecosystem protection and the assessment of health risks for humans exposed through the environment.

Discussion Group 3 Area for mutual cooperation

The group should consider where there is scope for mutual benefit through cooperation on scientific matters for example

- Identification and exchange of expertise
- Exchange of technical information and mechanisms to ensure data availability
- Common issues such as replacement of animal testing, approaches to non-thresholded substances, anti-microbial resistance, endocrine disrupters, products of nano technologies, etc
- Training, exchange of staff

MEETING BETWEEN THE CHAIRS OF COMMISSION AND AGENCY SCIENTIFIC COMMITTEES INVOLVED IN RISK ASSESSMENT
7-8 DECEMBER 2005

GROUP LISTS FOR BREAKOUT SESSIONS – *REVISED LIST*

dg1 avoidance of diverging opinions (CCAB 2A)		**dg2 environmental health risks (CCAB 2C)**		**dg3 area for mutual cooperation (CCAB 1C)**	
INSTITUTION/ AGENCY	CHAIR /SECRETARIAT	INSTITUTION/ AGENCY	CHAIR /SECRETARIAT	INSTITUTION/ AGENCY	CHAIR /SECRETARIAT
EFSA – ACF (Chair of the dg)	Dr Susan Barlow	SANCO – SCHER (Chair of the dg)	Dr Jose Tarazona	EFSA – SC (Chair of the dg)	Prof Vittorio Silano
EMEA (rapporteur)	Arielle North	EFSA CONTAM (rapporteur)	Claudia Heppner	DG SANCO (rapporteur)	M. Walsh
EMEA - CHMP	Dr Daniel Brasseur	EEA – SC	Prof. Bedrich Moldan	ECDC Sc advice Unit	Professor Johan Giesecke
EFSA - CONTAM	Dr Josef R. Schlatter	EFSA - PPR	Prof Anthony R. Hardy	EFSA - AHAW	Dr Philippe Vannier
SANCO - SCCP	Dr Ian White	EFSA - FEEDAP	Dr Andrew Chesson	EMEA - HMPC	Dr Konstantin Keller
EFSA – BIOHAZ	Prof John D. Collins	EFSA - GMO	Dr Harry Kuiper	SANCO - SCENIHR	Prof James Bridges
EFSA - SC	Djien Liem	EMEA - CVMP	Dr Gerard Moulin	EMPL - SCOEL	Prof Vito Foà
EFSA - PPR	Muriel Dunier-Thomann	DG SANCO - SCHER	Gigliola Fontanesi	EEA - SC	Galina Georgieva Hristova
EFSA GMO	Suzy Renckens	DG EMPL - SCOEL	Alicia Huici Montagud	EMEA - CHMP/HMPC	Sheila Kennedy
EFSA Biohaz	Baart Goossens	EMEA	Alexis Nolte	EMEA	Kornelia Grein
DG SANCO SCENIHR	Maila Puolamaa	EFSA SC	Valerie Rolland	EFSA	Juliane Kleiner

DG SANCO SCCP	Terje Peetso	EFSA- FEEDAP	Claudia Roncacio-Pena	EFSA	Herman Koëter
DG SANCO	Marina Marini	EFSA PPR	Elzbieta Ceglarska	EFSA AHAW	Jordi Serratosa Vilageliu
DG SANCO	Bernardo Delogu	DG SANCO	Marta Staniszewska	EFSA Biohaz	Marta Hugas
DG SANCO	Robert Vanhoorde	DG JRC	Sharon Munn	DG SANCO SCCP	Antoon Van Elst
DG ENTR	A. Gautrais	DG ENV	Juergen Helbig	DG SANCO SCENIHR	Katja Bromen
				DG SANCO	Peter Wagstaffe
				DG ENTR	Birka Lehmann
				DG ENTR	Barbara Mentre