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EUROPEAN CENTRE FOR DISEASE PREVENTION AND CONTROL

MEETING REPORT

Third meeting of the Chairs of Commission and Agency scientific committees/panels involved in risk assessment

Stockholm, 6–7 November

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1. BACKGROUND

The annual meetings of Chairs of Commission and Agency Scientific Committee/Panels involved in Risk Assessment are part of a collaborative process to help improve both the quality of EU risk assessments and the public recognition of its role. The third meeting took place in Stockholm on 6 – 7 November 2007. The list of participants and a copy of the agenda can be found at Annexes 1 and 2.

2. PRESENTATIONS

Robert Madelin (European Commission, Directorate-General for Health and Consumer Protection) first summarised the conclusions, results and progress with follow-up activities from previous meetings. Zsuzsanna Jakab (Director, European Centre for Disease Prevention and Control (ECDC)) introduced the Centre and described ECDC's mandate and the current process for making a risk assessment. She also outlined what ECDC has achieved so far in the area of risk assessment and highlighted the problems that are foreseen and explained ECDC's plans to address them. Professor Johan Giesecke (ECDC) presented an introduction towards a common risk assessment framework. During the plenary session Professor Vittorio Silano (European Food Safety Agency (EFSA)) presented the outcome of the discussion group and finalisation of the paper of the working group on emerging risk (see Annex 3). The participants agreed to extend the mandate of the discussion group to continue work on emerging risks issues. Professor James Bridges (Director General for Health and Consumer Protection) explained the risk assessment process and how risks/benefits are considered by the Scientific Committee on Emerging and Newly Identified Health Risks (SCENHIR) and the two other non-food Scientific Committees of the Commission (SCCP and SCHER). Dr. Dominique Monet (ECDC) illustrated the risk assessment process in ECDC with an example on anti-microbial resistance. The slides of these presentations are available on the ECDC website at http://ecdc.europa.eu/presentations.html.

3. WORKING GROUPS

Two working groups discussed how to move towards a common risk assessment framework. Both groups were asked to address the following topics:

- Mandate, goal, objectives of these meetings; how to ensure ownership by all (considering their role, future developments, harmonisation of procedures).
- Emerging risks/rapid risk assessment: how to further proceed, identify interest in initiating a common framework activity; how to ensure leadership, co-ordination and participation in the groups; whether the response to emerging risks can be backed up with urgent research mechanisms.

- Definitions, terminology, methodology, taking into consideration background documents, i.e. Scientific Steering Committee opinions and report on terminology.
- Follow up and monitoring of the impact of risk assessments that have been made (bearing in mind these will be different in different agencies, due to differing regulatory roles).
- How to achieve focused research that flows from risk assessments and how to better coordinate risk assessment, data needs within the Research and Technological Development framework process.

Sections 3.1 and 3.2, below, reflect the outcome of these discussions.

3.1. Working group 1

Facilitator: D Gee; Chair: B Jansson

Sharing best practices amongst risk assessors

EU risk assessment bodies operate in a global context (e.g. Codex Alimentarius Commission,World Trade Organization) and within the constraints of different EU legal requirements and of Commission/Agency work programmes and resources.

Despite these differences, the Chairs and Coordinators of EU risk assessment activities have decided to work together more closely in order to share experiences and best practices on risk assessment so as to further improve the quality, communication and utility of the assessments and thereby help improve risk management decisions.

The overall aim of this endeavour is the pursuit of a common framework for conducting risk assessments, that includes:

- an excellent, recognised common approach;
- clear and effective risk communication; and
- a framework for EU and international co-ordination.

Working more closely together will also help us to:

- identify and deal with overlaps and gaps in our coverage of risks;
- develop common and compatible approaches to risk assessment, where useful;
- make best use of scarce resources; and
- add more value to our existing work.

Priorities for sharing experiences and coordinating activities will include:

- methodologies for dealing with complex and emerging issues across different risk domains;
- approaches to risk assessments and to the handling of uncertainties;
- terminologies and methodologies for describing and characterising strengths of scientific evidence;
- engagement with stakeholders and with relevant international bodies;
- dealing with rapid requests for urgent preliminary advice;
- the exchange of data and information, within confidentiality constraints;
- successes and failures of joint activities;
- impacts of risk assessments on risk managers and stakeholders.

Responsibility for implementing and evaluating this work lies jointly with the Chairs of the risk assessment committees/panels, the Agencies and the Commission.

3.2. Working group 2

Facilitator: A Hardy; Chair: P Vannier

Harmonisation of procedures

- Need to compile the procedures from different agencies, to compare, to analyse possible differences.
- Transparency of the procedures, understanding of the current procedures for risk assessment, sharing knowledge of practices seems to be more important than harmonisation.
- In regard to methodologies for risk assessment, international guidelines already exist; need to follow them and not to deviate from those methodologies (including terminology).
- Need for transparency and formalised procedures governing the relationship between working groups (standing and ad hoc) and committees/panels. There was a consensus on the fact that committees/panels always have the full responsibility for the final opinions. Differences exist in the way divergent opinions from working group members are handled.
- Need for transparent procedures regarding the relationship with stakeholders: how to take their differing positions into consideration? There is an especial need for transparency when explaining the rationale for opinions that do not necessarily accord with those positions.
- It is important, when possible, that the opinions follow the pathways of RA to improve harmonisation including hazard identification, hazard characterisation, exposure assessment.
- It is important that risk assessors should be included in the process of opinions related to RA.
- Need to differentiate the natures of opinions for which the approaches are different, i.e. related to assessment of products or to generic questions.

On sensitive issues, when several international and/or European national bodies are involved, the various positions, arguments and RA results should be exchanged in advance to identify any discrepancies and to understand and explain the reasons for them. It is acknowledged to be time consuming and cannot be done for each opinion, but it is important for the sensitive ones. This will help to avoid divergent opinions and to ensure ownership of methodologies and approaches used

Emerging risk/rapid risk assessment

- Need to differentiate between emerging risk assessment and rapid risk assessment, which are not managed in the same way: the group focused on *rapid* RA.
- When assessments are performed during a crisis, it is necessary to name them differently from those delivered in time of peace (e.g. ‘preliminary advice’ or ‘statement’ instead of ‘opinions’).

- Need to coordinate actions of agencies during a crisis, for example with the creation of an 'operational crisis group' comprising decision makers from the agencies concerned with the subject of the crisis; it is necessary to associate the Commission with that group (except in the case of food-related crises for which such procedures already exist). The purpose of such a group would be to coordinate, to exchange data and information, and to communicate, though it must be noted that this is ultimately the Commission's responsibility).

Can response to emerging risk be backed up by urgent research mechanisms?

- It is essential.
- It is already done, e.g. Avian Influenza.
- Need to initiate the proper actions, overcoming fragmentation of structures when an emerging risk is clearly identified and qualified as relevant and as a major one. Present mechanisms could be improved.

Terminology/understanding of the opinions

- For risk assessment, terminology for the main concepts is already defined by international organisations (e.g. FAO, OIE, WHO). This terminology should be used, where possible, to avoid confusion.
- Need for a dialogue with the risk manager (RM), taking a strong interactive approach with the RM to be sure that the outcome of the opinion is well understood, to allow a good transfer of the opinion, to prevent the perception that a quantitative RA might be misinterpreted, to highlight the degrees of uncertainties.

Follow-up and monitoring of the impact of the risk assessments

- After the first meeting of chairs, feedback from the Commission about most of the opinions was implemented, whether formally or informally.
- There is still a need for improvement as there are differences between committees, agencies, panels.
- Sometimes a clarification of the RM's expectation, with respect to both the broader and more detailed aspects of the question, would be helpful. Again, this requires a strong interactive approach with the RM.

4. CONCLUSIONS

4.1 A shared approach to best practices in risk assessment

Robert Madelin (DG SANCO)

The way forward: prospects 2008–2009

Plenary meetings of Chairs:

- 2008: EFSA, Parma, 4–5 November
- 2009: SANCO, Brussels, date to be confirmed

Themes and projects:

Emerging risks

- Mandate to working group extended. Terms of reference reflecting consensus at 3rd Chairs' meeting to be circulated by SANCO at the beginning of 2008.
- Meeting on data sources (existing networks): SANCO to convene, March 2008.
- SANCO to organise contacts with research coordinators in order to explore early access to relevant data from research (in co-operation with DG Research).
- Working group to conduct further work on indicators in the first half of 2008 (with possible support from the JRC).
- Working group to conduct further work on methodology for data-sharing before the end of 2008.

Nanotech

- Participants were encouraged to volunteer to join the existing dialogue: there will be an international seminar on 2–3 October 2008 in Brussels.
- SANCO to promote contacts between nanotech risk assessors (an informal network) and map activities and expertise.

International co-operation

- International Risk Assessment conference in Brussels: 13–14 November 2008 (tentative agenda includes emerging risks, carcinogens, antimicrobial resistance). Participants were asked to offer ideas on content and structure.

Terminology and evaluating evidence

- Pursue common reflection based on EEA and Hardy documents: Workshop in May 2008 (co-organised by EEA and SANCO).

Assessment-management interface on rapid advice

- ECDC, EFSA, SANCO Units C3 and C7 offer to facilitate some case studies on the way the interface operates, including, in particular, in urgent situations

Commission homework

- Antimicrobial resistance/biocides: SANCO to convene (if possible in co-operation with DG ENV and others) an early review of different work underway. Mapping of foreseeable overlapping issues (SANCO Unit C7 to lead).
- Overlapping issues: better standard operating procedures for the involvement of all potentially interested Agencies in networks on shared issues (e.g. avian influenza, antimicrobial resistance).
- Feedback: risk managers should give more structured and more systematic feedback on the use of assessments and opinions.
- 'Compilation project': SANCO Unit C7 to prepare terms of reference for further work to compare practices in key areas, growing out of debate at this meeting.

Agency follow-up

- ECDC/EFSA to report back to the group of Directors of Agencies and consider any additional points for action by the Secretariats.

4.2. Next steps for ECDC

- Complete the draft internal standard operating procedures regarding risk assessments done at ECDC (including definitions of 'risk' and 'threat assessments') and circulate this to the ECDC Advisory Forum for comment.
- Support the European Environment Agency on their seminar on 'Approaches to evaluate evidence' (proposed dates 28–29 May 2008).
- Provide input to the EFSA and SANCO C7 planning for next year's meeting of Chairs of Commission and Agency Scientific Committee/Panels involved in Risk Assessment, specifically concerning case studies.
- Contribute to SANCO initiative on antibiotic resistance.

ANNEX 1 MEETING PARTICIPANT LIST

Participant	SC / Panel	Institution / Agency	Email address
Aronsson, Bo		EMEA	bo.aronsson@emea.europa.eu
Barlow, Susan	AFC	EFSA	suebarlow@mistral.co.uk
Bertelsen, Ulla		EFSA	ulla.bertelsen@efsa.europa.eu
Bridges, James	SCENIHR	DG SANCO	j.bridges@surrey.ac.uk
Bromen, Katja		DG SANCO	katja.bromen@ec.europa.eu
Ceglarska, Elzbieta		EFSA	elzbieta.ceglarska@efsa.europa.eu
Collins, John	BIOHAZ	EFSA	dan.collins@ucd.ie
Daskaleros, Panagiotis		DG SANCO	panagiotis.daskaleros@ec.europa.eu
Delogu, Bernardo		DG SANCO	bernardo.delogu@ec.europa.eu
Dunier-Thomann, Muriel		EFSA	muriel.dunier-thomann@efsa.europa.eu
Foà, Vito	SCOEL	DG EMPL	vito.foa@unimi.it
Fontanesi, Gigliola		DG SANCO	gigliola.fontanesi@ec.europa.eu
Gee, David		EEA	david.gee@eea.europa.eu
Giesecke, Johan		ECDC	johan.giesecke@ecdc.europa.eu
Hallas-Möller, Torben		EFSA	torben.hallas-moller@efsa.europa.eu
Hardy, Anthony	PPR	EFSA	a.hardy@csl.gov.uk
Hristova Georgieva, Galina		EEA	galina.georgieva@eea.europa.eu
Hugas, Marta		EFSA	marta.hugas@efsa.europa.eu
Jakab, Zsuzsanna	Meeting Chair	ECDC	zsuzsanna.jakab@ecdc.europa.eu
Jansson, Bo	SCHER	DG SANCO	bo.jansson@itm.su.se
Keller, Konstantin	HMPC	EMEA	konstantin.keller@bmg.bund.de
Kennedy, Sheila		EMEA	sheila.kennedy@emea.europa.eu
Killian, Karin		DG SANCO	karin.killian@ec.europa.eu
Kleiner, Juliane		EFSA	juliane.kleiner@efsa.europa.eu
Koeter, Herman		EFSA	herman.koeter@efsa.europa.eu
Kreysa, Joachim		ECHA	joachim.kreysa@echa.europa.eu
Kärenlampi, Sirpa	GMO	EFSA	skarenla@messi.uku.fi
Laconte, Pierre		EEA	pierre.laconte@eea.europa.eu
Liem, Djien		EFSA	djien.liem@efsa.europa.eu
Mackay, David	CVMP	EMEA	david.mackay@emea.europa.eu
Madelin, Robert	Meeting Chair	DG SANCO	robert.madelin@ec.europa.eu
Maijala, Riitta		EFSA	riitta.maijala@efsa.europa.eu
Marini, Marina		DG SANCO	marina.marini@ec.europa.eu
Martin, Philippe		DG SANCO	philippe.martin@ec.europa.eu
Monnet, Dominique		ECDC	dominique.monnet@ecdc.europa.eu

Participant	SC / Panel	Institution / Agency	Email address
Munn, Sharon		ECHA	sharon.munn@echa.europa.eu
Nicoll, Angus		ECDC	angus.nicoll@ecdc.europa.eu
North, Arielle		EMEA	arielle.north@emea.europa.eu
Renckens, Suzy		EFSA	suzy.renckens@efsa.europa.eu
Rodriguez Iglesias, Pilar		EFSA	pilar.rodrigueziglesias@efsa.europa.eu
Roncancio Pena, Claudia		EFSA	claudia.roncanciopena@efsa.europa.eu
Salmonson, Thomas	CHMP	EMEA	tomas.salmonson@mpa.se
Schans, Jan	PLH	EFSA	j.schans@minlnv.nl
Schlatter, Joseph	CONTAM	EFSA	josef.schlatter@bag.admin.ch josef.schlatter@bluewin.ch
Serratosa Vilageliu, Jorge		EFSA	jorge.serratosavilageliu@efsa.europa.eu
Silano, Vittorio	SC	EFSA	v.silano@sanita.it
Straetemans, Masja		ECDC	masja.straetemans@ecdc.europa.eu
Walsh, Michael		DG SANCO	michael.walsh@ec.europa.eu
Vanhoorde, Robert		DG SANCO	robert.vanhoorde@ec.europa.eu
Vannier, Philippe	AHAW	EFSA	p.vannier@ploufragan.afssa.fr
Wester, Pieter	FEEDAP	EFSA	Piet.Wester@rivm.nl
White, Ian	SCCP	DG SANCO	ian.white@kcl.ac.uk

ANNEX 2: AGENDA

Chairs: Robert Madelin and Zsuzsanna Jakab

6 November 2007

Session 1	
13:00–14:00	Plenary welcome, opening, introduction
Session 2	
14:00–15:00	Plenary: Towards a common risk assessment framework. Short introduction by Johan Giesecke, ECDC
15:00–15:30	Tea break
Session 3	
15:30–17:00	Plenary: Emerging risks and two case studies Vittorio Silano: The paper of the working group on emerging risks James Bridges: Illustration of the RA Process in SCENHIR Dominique Monnet: Illustration of the RA process in ECDC (anti-microbial resistance)
19:00	Dinner

7 November 2007

Session 4	
09:00–11:00	Working Groups The working group items should relate to the issues raised on the first day on how we move towards a common RA framework. Topics to be addressed and distributed among the groups: – Mandate, goal, objectives of these meetings; how to ensure ownership by all – Emerging risks/Rapid risk assessment – Definitions, terminology, methodology – Follow-up and monitoring the impact of the Risk Assessments (will vary between the agencies, due to differing regulatory roles) – How to achieve focused research that flows from risk assessments
11:00–11:30	Coffee break
Session 5	
11:30–13:00	Plenary: Recommendations from the groups; summary, conclusions and next steps
13:00–14:00	Lunch for members of the secretariats
14:00–16:00	Meeting of the secretariats chaired by ECDC to further discuss the practical implications of the items discussed in the morning. A specific issue that needs to be discussed is the sharing of confidential information between panels/committees. Finally: arrangements for follow up to the conclusions of the 3rd meeting

EUROPEAN COMMISSION

HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate C - Public Health and Risk Assessment

C7 - Risk assessment

WORKING PAPER

ON

EMERGING RISKS

as a follow-up to the 2nd Meeting of the Chairs of Scientific Committees/Panels of Community bodies involved in risk assessment, Brussels, 24-25 October 2006

agreed by Discussion Group on 20 September 2007

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1. SCOPE AND AIM OF THE PRESENT PAPER

Following the 2nd Meeting of Chairs of EU risk assessment bodies[1] of 24-25 October 2006, the working paper at hand presents an analysis of current practice to detect and assess emerging risks and opportunities for cooperation between the Commission and different Community bodies and institutions competent for emerging risks. It aims to

(1) provide a summary of main outcomes on emerging issues from the above-mentioned 2nd Meeting of Chairs,

(2) identify current activities of different Community bodies (including different Commission services, e.g. SANCO C7, C3, and European Agencies),

(3) identify priority areas on which joint activities could be started.

2. BACKGROUND - SUMMARY OF DISCUSSION, 2ND MEETING OF CHAIRS, DISCUSSION GROUP 1

Following the outcome of the discussion at the 1st Meeting of Chairs of EU risk assessment bodies in 2005, a proposal for exchanging ideas on areas of mutual interest related to emerging risks was discussed in Discussion Group 1 and, subsequently, at the plenary session of the 2nd Meeting of Chairs in 2006. The aim is to develop and improve cooperation at the European level.

The following documents were provided as background information:

- EFSA Scientific Committee Opinion[2] 'related to the early identification of emerging risks', adopted by written procedure on 4 July 2006.
- SCENIHR – Draft working document on emerging issues.

Several key subjects were discussed. Main contributions emerging during the discussion in the working group and in the subsequent plenary meeting were those described in the following chapters 2.1-2.5.

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[1] Hereafter called the '2nd Meeting of Chairs'.

[2] http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620763427.htm also in: EFSA Journal (2006) 375, 1-14.

2.1. Definition of ”emerging risk” and its conceptual implications

The term "emerging risk" refers to an issue or effect resulting from a **newly identified hazard** to which an exposure may occur or from **new or increased** exposure and/or susceptibility to a **known hazard.**

Conceptually, the systematic and effective detection and assessment of an emerging risk require a process consisting of several components:

- Definition of relevant direct and indirect indicators, which can be measured or qualitatively evaluated together with their temporal and/or spatial trends (signals).
- Identification of data sources for indicators and signals which need to be available for effective reporting.
- Definition of criteria and procedures for assessing emerging risks. Although the assessment of emerging risks is within the general approach to risk assessment, distinct differences may exist particularly to cope with much higher levels of uncertainty when dealing with emerging risks.
- Availability of expert groups, such as Scientific Committees and Panels, able to analyze the existing data and draw conclusions on emerging risks, their possible impacts and possible developments as well as to identify additional data needed to reduce uncertainties.

The emphasis on emerging risks is rather recent and not all the different sectors have already established structured processes to detect and assess emerging risks. Very often emerging risks have been detected and assessed by scientific groups making use of their own expertises and of data gathered for a number of different reasons and made available to them in the open or grey literature or through other sources. The work of these highly qualified expert groups in specific sectors of emerging risk assessment is likely to become more successful and effective as soon as more structured systems are established by the European Commission, and European Agencies such as EFSA, ECDC, EEA and EMEA, to systematically gather data on relevant indicators and to elaborate on them according to agreed criteria and procedures. Input from relevant bodies in the Member States could also help in this respect.

A good example of a well structured system is the pharmacovigilance system of the EU, where the relevant indicators are the adverse reactions to human and veterinary medicinal products, the main data sources are the physicians and other health professionals in Member States and where the expert Groups who assess the emerging risks are located at the EMEA and at competent Authorities in Member States.

Although it is clear that a lot has been learned and can be learned from the analysis of specific past case studies, decision–making to deal with emerging risks was not discussed during the meeting as it was outside its remit.

2.2. Indicators, signals and their data sources

Indicators and their time or spatial arrangements (signals),that are useful to detect and assess emerging risks, depend very much on the nature of the risks considered. Therefore, it is for each different sector (e.g. foods, drugs, cosmetics, biocides, medical devices and animal health and environmental factors) to identify indicators and signals which are more helpful.

A number of data sources were identified during the meeting, some of which are of general interest, whereas others are more relevant for specific food and non-food areas. Existing Community "Alerts" networks (e.g. RASFF- Decision 200/57/CEE, EUCURIE-Decision 87/600/Euratom, RAPEX- Directive 92/59/CEE) may contain information of relevance to assessing emerging risks, but it should be understood that these networks where designed with other objectives in mind. Therefore, these networks would need to be supplemented with Community and National networks specific for emerging risks.

Other information scanning tools (e.g. MediSys, Promed and GPHIN) also need to be further analysed and assessed in the present context. Moreover, a network to ensure an early appraisal of new toxicity research data would also be very helpful.

An inventory of data sources should be developed to identify new hazards or newly increased exposures to known hazards such as:

- Data produced through scientific research activities. The main issue here is to develop adequate tools to reduce the time needed to make new important findings available to emerging risk assessors, including effective links with the scientific community and systematic screening of data in the open and grey literature,
- data derived from monitoring networks dedicated to specific indicators (see also the above-mentioned networks),
- occurrence of human, animal or plant disease outbreaks or changes in the distribution and occurrence of diseases or their causal agents (e.g. the European network established with the Decision 2119/98/CE),
- ad-hoc cooperation with stakeholders, to receive timely information on new technologies used in the different sectors, and
- post-market surveillance and other monitoring activities carried out in specific sectors in the Member States.

2.3. Procedures for the assessment of emerging risks

Current practices and ongoing activities have been reported during the meeting by EMEA, EFSA, ECDC, EEA and SANCO non-food committees. It became very clear that in some sectors the establishment of structured procedures is only in an initial phase. This makes it difficult to compare systems dealing with different types of emerging risks.

The main challenge is the lack of systematic contacts, exchange of information, horizontal thinking and coherent approaches to risk assessment among different sectors and organizations.

On the other hand, the present dynamic phase in the development of new mechanisms in some specific sectors offers some opportunities to consider the possibility of a general common framework in which all these activities would clearly fit and that would facilitate effective exchanges and joint activities.

2.4. Cooperation and way forward

The need was identified for developing a more cooperative approach to address emerging risks consistently across different sectors, while respecting the independence and autonomy of each organisation. The roles of the European Commission, European Agencies and Member States also need to be clearly defined. To this end, an extension of the present paper on the way forward on the cooperation among the Commission and the different institutions and agencies would be very helpful.

More detailed information of current activities of the main European and international bodies including different Commission sectors and proposals on actions which could be undertaken in order to establish a Community system to identify emerging risks would be helpful, together with the identification of priority areas on which joint activities could be started as soon as possible.

It was suggested that such an initiative should possibly be taken forward by the Commission, with the support of the Working Group.

Additional items proposed for the inclusion in the above-mentioned report were the following:

- Information screening to establish an inventory of useful existing networks to monitor outbreaks (such as rapid alert systems), new toxicity research data or information scanning tools;
- Propose to establish a Europe-wide system to screen new hazards;
- Keep the focus on new technologies to identify emerging risks (e.g. Nano, particle-size reduction in diesel emissions, new aerosol composition);
- Consider re-emerging issues and changes in disease and outbreak patterns;
- Keep the focus on the role of the Member States, as well as European and International Organizations, with a view to developing a global network for exchanging information and knowledge on emerging risks.

2.5. Discussion and Conclusions

It was concluded that starting from the present report, a much more detailed and comprehensive paper should be drafted on this matter jointly by SANCO C7 and the chairman of the Scientific Committee of EFSA, in collaboration with EFSA and the support of the working group members.

The present discussion paper should be seen as a first step to meeting the following potential medium-term goals, as discussed at the meeting:

- To identify all the bodies (organizations) which are operating at a European or international level, as possible partners of a European undertaking.
- To identify actions that could be undertaken to establish a co-operative Community system for emerging risks.
- To clarify the respective roles of different bodies participating in the above-mentioned European undertaking.

3. CURRENT ACTIVITIES OF DIFFERENT COMMUNITY BODIES

There is a variety of ongoing activities in relation to emerging issues at different services within the Commission and various agencies. These are listed in the Annex to this document.

4. PRIORITY AREAS ON WHICH JOINT ACTIVITIES COULD BE STARTED

A few areas were preliminarily identified during the meeting as possible priorities for inter-institutional cooperation:

- Biocides;
- Health Effects of Global Warming;
- Demography / Changes in Housing Conditions and Urban Structures (infectious diseases);

  and

- Re-emerging Infectious Diseases.

Additional work is needed for a complete review of inter-institutional collaboration priorities

The SCENIHR has recently received a draft request on Biocides which could serve as an example for a joint collaboration between different Community bodies in providing a scientific opinion.

5. BACKGROUND DOCUMENTS

EC – 2nd Meeting of Chairs, Presentation of Discussion Group 1

EEA – Paper on Activities related to emerging issues

EFSA SC WG EMRISK – Working Document: A Proposal for an Action Plan for the Early Identification of Emerging Risks (Amended 11th December 2006)

EFSA Minutes of the 21st Plenary Meeting of the EFSA SC held on 6-7 November in Parma, the following is reported from the WG (Item 9)

EFSA Scientific Committee Opinion 'related to the early identification of emerging risks', adopted by written procedure on 4 July 2006. http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620763427.htm, also in: EFSA Journal (2006) 375, 1-14.

EMEA Memorandum

OSHA (European Agency for Safety and Health at Work) - Risk Observatory Report. Expert forecast on Emerging Biological Risks related to Occupational Safety and Health, 2005

SCENIHR – Draft working document on emerging issues

VWA - Forming a Global System for Identifying Food-related Emerging Risks (Final Report of EMRISK)
http://www.efsa.europa.eu/etc/medialib/efsa/science/sc_commitee/sc_opinions/sc_op_ej375_emrisk.Par.0001.File.dat/sc_report_emriskvwa_en.pdf

ANNEX 1 - CURRENT ACTIVITIES OF DIFFERENT COMMUNITY BODIES

1. EUROPEAN COMMISSION, DIRECTORATE GENERAL FOR HEALTH AND CONSUMER PROTECTION (DG SANCO)

1.1. Risk Assessment (C7)

The objectives of Unit C7 include providing SANCO management with early warning of emerging risks and initial risk assessments. The current work is focussed on ensuring that the Unit is kept aware of newly reported safety and health concerns that may have implications for SANCO policies and responsibilities. It is limited to newly reported health and consumer safety concerns in the areas corresponding to the mandates of SANCO scientific committees. While doing so, particular attention is paid to media reports of health risks because they both drive and reflect consumer and political concern, whether or not factually justified.

The following mechanisms for the identification of emerging issues were suggested:

1.1.1. Systematic mechanisms

a) In-house media monitoring - "C7 Risk Watch"

C7 has introduced a systematic procedure for periodic monitoring (several times per week) of media reports on health and safety issues – the "C7 Risk Watch". It is based on information services which are freely available to the Unit (either through Commission data bases or publicly accessible sources). The challenge is to develop a search strategy which provides a high likelihood of detecting important concerns (within the limited personnel constraints).

b) Existing network of scientific committee members

The 50 members of the 3 SANCO scientific committees collectively cover a very wide range of expertise across the EU and follow new developments in their areas of expertise as part of their professional duties. It is therefore unlikely that members will be unaware of substantial emerging issues or media concerns, especially at national level.

One important measure was the introduction of a standard item on the agendas of all Plenary meetings on "Newly identified concerns" or "Emerging Issues" (agreed with the Chairs and vice-chairs in the coordination meeting of 15 December 2004[3]). Thereby, members of the 3 non-food Scientific Committees are regularly being asked to identify new topics and to report systematically on emerging issues and new concerns. This mechanism might be suitable for all other Community SCs and panels.

c) Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR)

[3] http://europa.eu.int/comm/health/ph_risk/committees/coordination/docs/coor_mi_003.pdf

The SCENIHR has, as part of its broad mandate, introduced a procedure for the systematic identification and monitoring of areas which could give rise to new and emerging risks (e.g. chemical, biological, physical risks and risks associated with new technologies). Individual members of the Committee have been assigned the responsibility for monitoring new or emerging scientific developments in specific areas giving periodic reports to the committee. In practice, SCENIHR has compiled and is continuously updating a working document which provides a working definition of emerging risks and a list of topics considered by members as new and emerging non-food health risks. These are classified into exposure and hazard categories, which were suggested by SCENIHR. It should be noted that the collection is not necessarily referring to the mandate of SCENIHR but has the purpose to facilitate future collaboration between Community risk assessment bodies dealing with Emerging Risks. A short version of this paper has been provided as a background document for the 2nd Meeting of Chairs (see SCENIHR Draft Working paper in Annex). The role of SCENIHR and the other two non-food Scientific Committees managed by DG SANCO in identifying emerging issues is also summarized in a publication of the EC[4].

1.1.2. Ad hoc mechanisms

Although the above mechanisms are likely to ensure a reasonably high likelihood of detecting new concerns, the Unit is receptive to ad hoc contributions from its own personnel, other Commission services or external sources. These would be via:

- Rapid access to scientific information
- In-house access to scientific literature data bases
- External expertise as sources of information
- Use of the network of the scientific committees, external experts and the reserve list
- Member State Institutes and National Academies of Science
- Networks of Community agencies – EEA, EFSA, EMEA, ECDC
- A Model for Preliminary risk assessments has also been prepared

1.2. SANCO – other services

1.2.1. Health Threats (C3)

Medical intelligence

Medical intelligence can be defined as all the activities related to early identification of potential health threats, their verification, assessment and investigation in order to recommend public

[4] Healthy People in a Healthy Environment – Environmental impacts on health: better understanding for better protection (Review of the European information base for policy), OPOCE, 2006, ISBN 92-79-02356-X

health control measures to control them. It covers epidemic intelligence on communicable diseases, but also chemical, radiological and nuclear information, it reviews the latest development in health, as for instance the progress in science, in medicine, vaccines and covers the preparedness and response activities.

Disease surveillance systems are providing information on potential threats by identifying abnormal events in the temporal distribution of known disease indicators routinely collected (number of cases, rates), including changing laboratory characteristics. New approaches have been developed to enhance the capacity of surveillance systems in detecting 'previously unknown' threats, such as monitoring of syndromes (syndromic surveillance), death rates, utilization of health services (e.g. emergency room admissions, drug prescriptions), behaviours, and exposure to risks related to the environment, food or animals.

As a certain amount of threats to public health are not detected by these systems but are reported in the press or by other sources, event monitoring systems are complementing surveillance systems for the detection of emerging threats at international level.

Primary information can be reported by individuals, the media or by information scanning tools (e.g. MediSys, Promed, WHO outbreak verification list, GPHIN), and may be further analysed, assessed and disseminated to identified actors and stakeholders.

The following two related projects/systems are managed by the Unit for Health Threats:

a) HEDIS (Health Emergency & Diseases Information System)
https://hedis.jrc.it/Default.aspx

This Health Portal has been developed by the European Commission to support DG SANCO and Public Health Authorities in Member States during disease outbreaks and health emergencies. It is a central point where all involved parties can get at any time an overview of the situation on an identified health threat. Information derived from various sources is gathered in a single place. The portal also gives access to a large set of useful tools (communication tools, geographic tools, mathematical models, databases,...).

b) MEDISYS (Medical Intelligence System - Web Intelligence for Medical Emergencies)
Internet monitoring and analysis tool to reinforce the Network for Surveillance of Communicable diseases and the early detection of bioterrorism activities
http://medisys.jrc.it/ (restricted access)
http://medusa.jrc.it/ (public access)

Medisys is one of the tools put in place by the Commission in order to detect potential threats for European citizens' health.

- MediSys is covering communicable diseases, animal health, chemical and radiological threats;

- The system provides support to national epidemic intelligence and will also tackle in the future the epidemic coverage of mass gatherings (like the upcoming cricket world cup and later on major sporting events);
- Epidemic intelligence is an essential part of the detection of epidemic events and its management and is fully integrated in the Preparedness and Response activities in the Commission (e.g. HEOF);
- Cooperation is ongoing between MediSys and GPHIN (Health Canada) for a better complementarity of the only 2 existing systems of this kind.

Medisys is an internet monitoring and analysis system developed by the European Commission Joint Research Centre (JRC) for DG SANCO to rapidly identify potential threats to the public health using information from the internet. These 'threats' include both communicable disease and chemical, biological and radio-nuclear threats which could have a widespread impact on the health of the European Community. The information processed by Medisys is widely derived from the Europe Media Monitor (EMM – http://emm.jrc.org) monitoring about 1200 news websites in 35 languages. Articles related to health threats are forwarded to Medisys.

In addition, Medisys itself monitors some 100 Public Health Websites and 20 newswires like Reuters. Articles collected are grouped into categories based upon pre-defined keyword search combinations. They are gathered into three big categories : "Diseases", "bioterrorism", and "other threats". Under these main categories, articles are classified in more precise categories such as "AIDS-HIV", "Respiratory infections", "Avian flu" or "Legionella", "Anthrax", "Nuclear weapon". Statistics are stored on the filtered categories and an algorithm is used to detect 'breaking news' in a given category. Based on the level of new articles and the detected keywords, an alert may be sent to key persons by e-mail and SMS.

Any detected report concerning known diseases and risks, is immediately classified. Medisys uses statistical techniques to detect sudden increases in the number of reports concerning known threats and diseases. This can then alert relevant authorities of new developments. Medisys also checks for emerging "unknown" disease reports around the world checking for symptoms and through an automatic incident detection system developed in collaboration with the University of Helsinki. This system analyses English only reports and extracts structured data on the number of cases, the location and the date. This then feeds an automatic incident database.

Since December 2006, a public version (http://medusa.jrc.it) is now also available. The version restricted to Member States and Commission services covers more sources that have restricted access. On the other hand, the public version performs the same functions including alert statistics, articles in various languages, and e-mail alerts. Therefore, any interested person can now have free access to this automatic information scanning tool.

2. EUROPEAN CENTRE FOR DISEASE PREVENTION AND CONTROL (ECDC)

Article 10 of the ECDC Founding Regulation gives details on the Centre's role in identification of emerging health threats:

1. The Centre shall in the fields within its mission establish, in cooperation with the Member States, procedures for systematically searching for, collecting, collating and analysing information and data with a view to the identification of emerging health threats which may have mental as well as physical health consequences and which could affect the Community.

2. The Centre shall forward to the European Parliament, the Council and the Commission an annual evaluation of the current and emerging threats to health in the Community.

3. The Centre shall also inform the Commission and Member States as soon as possible about findings which require their immediate attention.

These tasks are an integral part of the ECDC Epidemic Intelligence activities.

2.1. Risk Assessments vs Threat Assessments:

Mark that the text of the ECDC regulations uses the word 'threat'.

Threat assessments tend to be more short term, have an immediate output and usually dealt with inside an organization engaged in the process. Examples might be an outbreak of a particular disease in a particular place, a specific food contamination etc. while a risk assessment would be in response to the same disease anythere and the type of food contamination wherever it was. Classical risk assessment more often involve the engagement of external experts and there is often a degree of consultation in the process. Threat assessments are always done quickly and with less external consultation on the outcome, and they may or may not be published.

Risk assessments are usually handled by setting up an *ad hoc* Scientific Panel of external experts, who have put their names on a list after an (always open) call in the OJ and on the ECDC web site. The final assessment is seen by the ECDC Advisory Forum for comments, befoe being finally approved by the Director. The text of the assessment cannot be changed by the Advisory Forum or the Director, but either may append comments to the assessment before it is published. Risk assessments may be done rapidly if they are urgent. They are always subject to review externally and are usually published.

Some of the differences are listed in the following Table:

Characteristic	Threat assessments	Risk assessments
Issue	Specific to time and instance	More general
Speed	Always rapid	May be rapid
Lead	Preparedness and Response Unit drawing on existing internal expertise	Any Unit
Formal Consultation	Internal plus selected external	The ECDC Advisory Forum (AF)
Sign off	Head of Preparedness and Response Unit	Chief Scientist
Publication	Sometimes	Usually

2.2. Risk assessment – process

The full process of performing a risk assessment is currently being formalised at the ECDC. The steps being considered are:

- process to select experts from list
- process to handle conflicts of interest
- process to review existing risk assessments or guidelines (Member States, WHO, CDC), including those that may not be written in one of the common languages
- process to collect evidence
- process to review evidence
- scale to be used to grade evidence
- scale to be used to grade recommendations
- standard format(s) to be used for assessments
- process to arrive at final draft
- (if required) external consultation process
- preparation of final draft to be taken to the AF
- revision of draft after AF input

- rules for publication and authorship
- process to follow up implementation in Member States.

2.3. Epidemic Intelligence

Epidemic intelligence can be defined as the process to detect, verify, analyze, assess and investigate public health events that may represent a threat to public health. It encompasses activities related to early warning functions but also signal assessments and outbreak investigation. Providing early warning signals is a main objective of public health surveillance systems.

2.4. ECDC communicable disease threats report (CDTR)

The ECDC communicable disease threat report (CDTR) is intended as a tool for European epidemiologists in charge of epidemic intelligence activities in their national surveillance centre. It includes information gathered from multiple sources regarding potential communicable disease threats that may affect the European Union.

Epidemic intelligence information included in the CDTR relates - at times - to threats that are not yet confirmed and may prove to be unsubstantiated. Therefore, the CDTR is not intended for public release but restricted to authorised users. In addition, events which are exclusively reported through the EWRS are not included in the CDTR for confidentiality reasons.

3. EUROPEAN ENVIRONMENT AGENCY (EEA)

The following provides a short summary of EEA activities on future trends, scenarios and emerging risks, including cooperation with other bodies.

3.1. EEA activities

"Late lessons from early warnings" volume 2 – working subtitle is "*Towards improving research and decision-making in the light of the Precautionary Principle*", planned to be published around mid 2008. Similar to the structure of volume 1 (http://reports.eea.eu.int/environmental_issue_report_2001_22/en), the core of the analysis will be summaries of case studies on the histories of some well known environmental and health hazards, structured around the date of the first scientifically based early warning and subsequent actions/inactions and the associated pros and cons. It therefore provides a retrospective analysis of the way that previous early warnings and emerging issues have been dealt with. The current chapter list comprises around 25 titles, 10-11 of which are focused on health issues, while the rest are environmentally based. The chairman of the SCENIHR has offered to do an analysis of the 12 "late lessons" from vol. 1 as applied to the emerging nanotechnologies.

The Chair of the EEA Scientific Committee and a couple of SC members are in the Editorial Committee of Late Lessons, vol.2.

PRELUDE project (PRospective Environmental analysis of Land Use Development in Europe) uses different models to simulate five contrasting future environmental scenarios for a Europe affected by changing patterns of land use, climate change, agriculture and demographics 30 years from now. The purpose of PRELUDE project is to inform the public and inspire discussion about the potential impacts of changes currently taking place on Europe's landscape (http://www.eea.europa.eu/multimedia/interactive/prelude-scenarios/prelude).

Research foresight for Environment and Sustainability project, initiated by the EEA Scientific Committee in early 2007. The objectives of project are to:

- Analyse, within the STEEP framework, mega trends, uncertainties and "prediction of surprises" of relevance for exploratory research;
- Produce a research outlook with a long-term perspective (20 years) based on a judgement of experts within and outside the EEA scientific committee, also based on EEA assessments and outlooks; and,
- Clarify and demonstrate the importance of such research outlooks for EEA integrated assessments.

Relating to the first objective above, a workshop was organised on 14-15 May 2007 in EEA with the Scientific Committee and external experts. The workshop was structured around five main groups of drivers identified: Social, Technological, Environmental, Economical and Political (in accordance with the often used STEEP model in foresight studies), looking into mega trends of STEEP drivers, what are the uncertainties and how to "predict surprises". A second workshop is planned to be organised at a later stage.

The project will make a contribution to the Bridging-the-Gap conference that will be held on 14-17 May 2008 in Slovenia during their EU Presidency.

EEA European Environment Outlook Report (No 4/2005) is dedicated to outlooks.

It addresses a range of environmental concerns and their common driving forces in an integrated way, highlights the prospects for Europe's environment, exploring the consequences of our current expectations regarding socio-economic developments and, in some instances, points to options for a more sustainable future (http://reports.eea.europa.eu/eea_report_2005_4/en/#contents).

Innovation – the EEA work on innovation is visible in the following activities:

- Part of the economic chapter of LL2
- Involvement in development of analyses and databases of environmental technologies innovation

- Proposal for European award for green chemistry, in partnership with European Chemical Societies and based on the US award introduced in 1995. Proposal to run it from September 2007 with a view to introduce it in September 2008.

3.2. Other activities in which the Agency / EEA SC takes part

- Pharmaceuticals in the environment
- Link to European foresights projects
- FORESCENE - Development of a Forecasting Framework and Scenarios to Support the EU Sustainable Development Strategy, FP6
- SKEP ERA-NET (Scientific Knowledge for Environmental Protection) partnership - on the advisory board
- Converging Technologies for Improving Human Performance and Shaping the Future of European Societies, funded by DG RTD

4. EUROPEAN FOOD SAFETY AUTHORITY (EFSA)

4.1. Overview

The mission and tasks of EFSA are described in Regulation (EC) No 178/2002. These include the responsibility to set up a system for identifying the emerging risks. “The Authority shall establish monitoring procedures for systematically searching for, collecting, collating and analysing information and data with a view to the identification of emerging risks in the fields within its mission” (Art. 34.1). Regulation (EC) No 178/2002 also acknowledges that “Improved identification of emerging risks may in the long term be a major preventive instrument at the disposal of the Member States and the Community in exercise of its policy. It is therefore necessary to assign to the Authority an anticipatory task of collecting information and exercising vigilance and providing evaluation of and information on emerging risks with a view to their prevention”.

In February 2004 the Scientific Committee was requested by the European Food Safety Authority:

- To advise on a system to identify emerging risks within its area of responsibility.
- To advise on a procedure for evaluation and prioritisation of identified issues.
- To support the Authority in establishing a network of key sources from both within and outside the EU to systematically collect up-to-date relevant information on emerging risks.
- To advise on an operational system for maintaining appropriate contacts within such a network.

The Scientific Committee (SC) established a working group to draft an opinion in response to the request from EFSA. EFSA outsourced a project (see the EMRISK project[5]) to a consortium of scientists that already had completed an EU financed research project on emerging risks. The final report of the EMRISK Project was used as a major source of information when arriving at its conclusions. On 4th July 2006 the Scientific Committee adopted the opinion entitled "Opinion of the Scientific Committee on a request from EFSA related to the early identification of emerging risks" which was then published[6].

In order to establish an applicable system within EFSA, the Scientific Committee agreed at its 20th Plenary Meeting, in September 2006 to prepare an action plan in order to define priorities. To this end a reconstituted working group was set up.

4.2. Working Group on Emerging Risks

EFSA had a specific WG assigned to the identification of emerging issues.

A work plan, based on the opinion published in July 2006, has been developed by the Scientific Committee working group in order to implement within EFSA an early detection system for (re)-emerging risks within EFSA. The work plan identified the resources required, the information sources to be accessed and the specific issues to be addressed in the first instance. In establishing the EFSA's system, considerations will be given to efficient interaction with institutions/countries that already have a working system in place or are carrying out the same type of exercise, as well as to the identification of key and manageable indicators and sources (internal and external) of information. The Working Group was also asked to develop a procedure for handling large amounts of information arriving from many different sources. Panel members and Member States are considered as a very valuable source for the identification and possible analysis of potential risks.

4.3. EFSA Scientific Cooperation Working Group (ESCO) on Emerging Risks

"Emerging Risks" has been identified as one of the subjects on which cooperation between the EFSA's Advisory Forum and the EFSA's Scientific Committee is highly desirable. To this end, a mandate has been elaborated to be carried out by the EFSA Scientific Cooperation Working Group (ESCO) on emerging risks. The working group is composed of experts from the EFSA Scientific Panels and Scientific Committee as well as experts identified by the Member States. The ESCO working group will report directly to the EFSA Executive Director and will carry out

[5] http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178638136476.htm

[6] http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620763427.htm, also in: EFSA Journal (2006) 375, 1-14.

preparatory work to be considered by the Unit on Emerging Risks that has been established within EFSA.

4.4. Unit on Emerging Risks

The Unit "Emerging Risks" has been established within EFSA[7] and it will be fully operational in January 2008. The Unit is responsible for the implementation and maintenance of monitoring procedures for systematically searching for, collecting, collating and analysing information and data with a view to the identification of emerging risks in the field within EFSA's mission.

5. EUROPEAN MEDICINES AGENCY (EMEA)

A system has been put in place some time ago by the pharmaceutical legislation for the surveillance of medicinal products. This system is the pharmacovigilance system that is looking at expected or unexpected adverse reactions related to medicinal products.

The system is based on a network of competent authorities in charge of the authorisation and surveillance of medicinal products in the EU whatever the procedure for granting the marketing authorisation. The European Medicines Agency (EMEA) is in charge of the coordination. The pharmacovigilance is performed at national level and the coordination is centralised. Separate, but similar, systems operate to monitor the safety of human and veterinary medicines.

The scientific committee for medicinal products for human use (CHMP) has established a Pharmacovigilance Working Party (PhVWP) to provide recommendations to the CHMP on all matters relating directly or indirectly to pharmacovigilance and to perform the tasks described below.

Upon request of National Competent Authorities (NCAs), the PhVWP provides recommendations for non-centrally authorised products. This dual reporting line gives a very specific status to this Working Party compared with other CHMP Working Parties that report exclusively to the CHMP.

The mission of the PhVWP is to provide advice on the safety of medicinal products authorised in the European Union (EU) and the investigation of adverse reactions to enable effective identification, assessment and management of risk, at any phase in the product life cycle. On the basis of such advice the PhVWP will provide, where applicable, recommendations for regulatory action to the CHMP/EMEA and/or NCAs. The advice given should be in a precise and operational format and in accordance with timeframes as defined, where applicable, in Community legislation.

[7] see http://www.efsa.europa.eu/EFSA/AboutEfsa/WhoWeAre/efsa_locale-1178620753812_EFSAStructure.htm

This should enable effective management and subsequent communication of risk. Best use of pharmacovigilance resources available in the EU will have to be considered when trying to achieve the above objectives. Effective utilisation of tools for information exchange will have to be applied in order to improve the access to and utilisation of pharmacovigilance information.

The key responsibilities of the PhVWP are:

- Evaluation of potential signals arising from spontaneous reporting, including those identified from the EudraVigilance database, and all other sources, including epidemiological databases, studies and published literature;
- Provision of advice on confirmation and quantification of risk and on regulatory options;
- Risk management by advising on risk management plans;
- Monitoring regulatory action and the outcomes of such action;
- Setting standards for procedures and methodologies to promote good vigilance practice;
- Promotion of communication and exchange of information between the EMEA and NCAs;
- International cooperation.

The PhVWP will give advice to the national Heads of Medicines Agencies on implementation of recommendations. Such advice will also address the communication strategy and documents.

Where relevant, the PhVWP will prepare a report which summarises the main advice on the issues discussed for which the assessment has been finalised, together with proposals for action. Such report will be communicated to the national Heads of Medicines Agencies.

The PhVWP is involved in the development of principles, procedures, and guidelines for regulators and pharmaceutical industry:

- Development of common principles and procedures on the different elements of the European Risk Management Strategy, for agreement by the CHMP/EMEA/European Commission and the NCAs;
- Development and revision of European guidance documents for regulatory authorities and pharmaceutical industry at the request of the CHMP/EMEA/European Commission and the NCAs;
- Contribution to the process of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH);
- Contribution to the preparation and revision of Community legislation, at the request of the European Commission.

The PhVWP is composed of experts selected from the European experts list according to their specific expertise and of 8 co-opted members providing expertise in the fields of pharmacoepidemiology, statistics, biotechnology, paediatrics, risk management and communication.

The PhVWP meets 11 times per year, in parallel with the meetings of the CHMP in order to allow interaction between PhVWP representatives and the CHMP.

A parallel system exists for monitoring the safety of veterinary medicinal products involving the CVMP and its Pharmacovigilance Working Party (Veterinary) and EudraVigilance Veterinary. In the case of veterinary medicines the system collects data to identify actual or potential risks not only to the target animal but also to the consumer, through monitoring residues of veterinary drugs in food, to the user and to the environment. Any party that suspects that a veterinary medicinal product has exerted a suspected adverse reaction may report this suspicion into the scheme.

In addition to this well-established system of pharmacovigilance that deals with the products authorised in the Community, there is also the legislation on medicinal products for human use studied in (interventional) clinical trials. The EU legislation on interventional clinical trials contains also provisions concerning adverse reactions occurring during these clinical trials in particular for serious and unexpected adverse reactions. The regulation of (interventional) clinical trials is performed at the level of each EU Member States and does not involve the PhVWP. A database (EudraCT) containing a registry of all the interventional clinical trials started since 1 May 2004 is hosted by the EMEA. This database is fully accessible by all Member States National Competent Authorities. The Agency has also created a specific module of the EU Pharmacovigilance database (EudraVigilance) specifically dedicated to the surveillance of serious unexpected adverse reactions observed in interventional clinical trials.

Finally, in the context of the development of new therapies, the CHMP and its Working Parties is assessing the established or theoretical safety issues potentially associated with the use of emerging therapies (e.g. gene therapy, cell therapy). This scientific assessment is conducted more in a prospective context.

6. EUROPEAN AGENCY FOR SAFETY AND HEALTH AT WORK (OSHA)

Working environments are continuously changing with the introduction of new technologies, substances and work processes, changes in the structure of the workforce and the labour market, and new forms of employment and work organisation. New work situations bring new risks and challenges for workers and employers, which in turn demand political, administrative, technical and regulatory approaches to ensure high levels of safety and health at work.

In 2000, the Lisbon summit identified specific objectives to create quality jobs and increase workforce participation. Improving working conditions to keep people in work is necessary if these objectives are to be achieved. In this context, the Community strategy on health and safety at work 2002–06 called on the European Agency for Safety and Health at Work (the Agency) to ‘set up a risk observatory’. One of its priorities would be to ‘anticipate new and emerging risks, whether they be linked to technical innovation or caused by social change’. The strategy emphasized that this should be done by ‘ongoing observation of the risks themselves, based on the systematic collection of information and scientific opinions’, as part of the development of a ’genuine culture of risk prevention’.

The Agency, therefore, took the first step towards establishing a Risk Observatory, commissioning its Topic Centre Risk Observatory (TCRO) — the former Topic Centre Research on Work and Health (TCWH), which included some of the principal OSH institutions in Europe — to identify emerging risks related to OSH. To do so, two types of activities have being carried out: the collection of published information from reliable sources — still ongoing — and the production of expert forecasts.

The expert forecasts on emerging OSH risks were reached through questionnaire based surveys following the Delphi method. Four Delphi surveys have been carried out: on physical risks; psychosocial risks; chemical risks; and biological risks. This division into four themes was neither meant to indicate fixed boundaries between the areas nor to exclude combinations of them. Quite the opposite: many OSH issues are multifactorial and have been mentioned in several of the surveys. In total, 520 experts from 27 countries and one international organisation were invited to participate in the surveys. Answers were received from 188 experts from 24 countries and one international organisation, giving a response rate of 35%.

This report is the second of a series of risk observatory reports dedicated to emerging risks. It sets out an expert forecast on emerging biological OSH risks. The results of this forecast have also been used as a basis for discussion among representatives from major European OSH research institutes and from UNICE, ILO, DG Research and DG Employment in a seminar organised by the Agency aimed at promoting occupational safety and health research in the EU (Bilbao, Spain, 1st and 2nd December 2005). Several of the emerging issues identified in the forecast have been included in a summary list of top OSH research priorities drawn up at the seminar and consolidated in a broader consultation process among the Agency's stakeholders. Using this list, the OSH research community can present a clear message during the seventh framework programme (FP7) consultation to promote the inclusion of OSH issues.

The "Expert forecast on Emerging Biological Risks related to Occupational Safety and Health" contains a forecast of emerging biological risks related to occupational safety and health (OSH) based on an expert survey and a literature review. The Agency also worked on forecasts and literature reviews on physical, chemical, and psychosocial risks in order to paint as full a picture as possible of the potential emerging risks in the world of work.

These results are linked to other Risk Observatory work, which aim to examine OSH trends in Europe and to anticipate emerging risks and their likely consequences for safety and health at work. This should help with better targeting of resources and lead to more timely and effective interventions.

Method:

Within the scope of this project, an 'emerging OSH risk' has been defined as any occupational risk that is both new and increasing.

By new, it is meant that:

- the risk was previously unknown and is caused by new processes, new technologies, new types of workplace, or social or organisational change; or

- a long-standing issue is newly considered as a risk due to a change in social or public perceptions; or
- new scientific knowledge allows a long-standing issue to be identified as a risk.

The risk is increasing if:

- the number of hazards leading to the risk is growing; or
- the likelihood of exposure to the hazard leading to the risk is increasing (exposure level and/or the number of people exposed); or
- the effect of the hazard on workers' health is getting worse (seriousness of health effects and/or the number of people affected).

For the formulation of the expert forecast on emerging OSH biological risks, a questionnaire-based survey was run in three consecutive rounds following the Delphi method. This method was chosen to avoid individual, non-scientifically founded opinions, and to verify whether a consensus could be reached among the respondents. Some 109 experts in the first survey round and 95 experts from each of the second and third rounds were invited to participate in the survey following their nomination by the Agency's focal points and Topic Centre Research. Thirty-two valid questionnaires from the first round, 42 from the second and 36 from the third were returned from 58 organisations in 18 Member States, as well as Bulgaria, Romania and Switzerland. The response rates were 29% (first round), 44% (second) and 38% (third). Participating experts were required to have at least five years'experience in the field of OSH and biological risks. Respondents were mainly involved in research, consulting or teaching and training activities, followed by labour inspection and policy development.

The 'top' emerging biological risks identified:

- Occupational risks related to global epidemics (biggest emerging issue identified in this forecast);
- Emergence of drug-resistant organisms;
- Risks resulting from poor risk assessment (as the second most important of the emerging issues);
- Lack of information on biological risks in the workplace, and inadequate provision of OSH training to workers;
- Poor maintenance of water and air systems;
- Combined exposure to biological agents and chemicals;
- Endotoxins;
- Indoor moulds and subsequent health issues;
- Occupational risks linked to waste treatment.