



Scientific Committee on Emerging and Newly Identified Health Risks

SCENIHR

Emerging Issues and the Role of the SCENIHR Position Paper



The SCENIHR adopted this position paper at its 28th plenary on 19 January 2009

About the Scientific Committees

Three independent non-food Scientific Committees provide the Commission with the scientific advice it needs when preparing policy and proposals relating to consumer safety, public health and the environment. The Committees also draw the Commission's attention to the new or emerging problems which may pose an actual or potential threat.

They are: the Scientific Committee on Consumer Products (SCCP), the Scientific Committee on Health and Environmental Risks (SCHER) and the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) and are made up of external experts.

In addition, the Commission relies upon the work of the European Food Safety Authority (EFSA), the European Medicines Evaluation Agency (EMA), the European Centre for Disease prevention and Control (ECDC) and the European Chemicals Agency (ECHA).

SCENIHR

Questions concerning emerging or newly-identified risks and on broad, complex or multi-disciplinary issues requiring a comprehensive assessment of risks to consumer safety or public health and related issues not covered by other Community risk- assessment bodies.

In particular, the Committee addresses questions related to potential risks associated with interaction of risk factors, synergic effects, cumulative effects, antimicrobial resistance, new technologies such as nanotechnologies, medical devices, tissue engineering, blood products, fertility reduction, cancer of endocrine organs, physical hazards such as noise and electromagnetic fields and methodologies for assessing new risks.

Scientific Committee members

Anders Ahlbom, James Bridges, Wim De Jong, Philippe Hartemann, Thomas Jung, Mats-Olof Mattsson, Jean-Marie Pagès, Konrad Rydzynski, Dorothea Stahl, Mogens Thomsen

Contact:

European Commission
Health & Consumer Protection DG
Directorate C: Public Health and Risk Assessment
Unit C7 - Risk Assessment
Office: B232 B-1049 Brussels

Sanco-Sc1-Secretariat@ec.europa.eu

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(ISSN)

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http://ec.europa.eu/health/ph_risk/risk_en.htm

ACKNOWLEDGMENTS

This position paper is based on discussions that have taken place at a number of SCENIHR meetings over the past three years. It has also benefitted from interactions with the chairs of other EU-scientific committees and panels involved in risk assessment.

Keywords: SCENIHR, emerging issues, emerging risks, newly identified health risks

To be cited as:

SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks).
Emerging Issues and the Role of SCENIHR. 19 January 2009

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EXECUTIVE SUMMARY

- 1) The early identification of emerging issues that may adversely affect human health and/or the environment is very important. This approach may help to prevent negative impact by allowing earlier appropriate action.
- 2) Two complementary approaches have been identified to enable the timely identification of emerging issues:
 - A proactive approach based on 'brain storming' sessions by SCENIHR to identify the emerging issues of principal concern, followed by the introduction of procedures to detect and characterise their development.
 - A more reactive approach based on the prior identification of indicators of change and the monitoring of these to detect emerging issues.
- 3) SCENIHR recognises that in view of the limited resources anticipated to be available in the near future its primary contribution is through the proactive approach. A procedure has been identified for the operation of this approach which includes regular updates.
- 4) An effective collaboration with other European Union (EU) scientific committees/panels and other international bodies is necessary to ensure the optimal performance of the SCENIHR in order to fulfil this task.

The role of the SCENIHR is to draw the attention of and advise the Commission services on emerging issues. However, the decision to take appropriate action and/or to investigate possible risks of these issues lies with the European Commission.

1. INTRODUCTION

The primary purpose of this position paper is to draw the attention of the EU Commission Services to emerging issues in the non-food area that have been identified by SCENIHR members as having the potential for a significant impact on human health and/or the environment in the future. It is intended to supplement the information that is already accessible to the Commission services through other sources.

Early identification of emerging issues is of great potential value in order to ensure a high level of public safety and environmental protection. However, it must be recognised that often the data available to identify important emerging issues is likely to be very limited. It is therefore important that each issue that is identified is regularly reviewed. It is the aim of SCENIHR therefore, at each plenary meeting, to consider any relevant new developments and that this position paper will be updated at least annually. In considering emerging issues SCENIHR wishes to work closely with other EU scientific advisory committees that also have emerging issues as part of their mandate. Furthermore, the ongoing discussion and collaboration at EU- and international level should foster a global cooperation on this issue (see e.g. Global Risk Assessment Dialogue, 4th Meeting of the Chairs and Secretariats of Commission and Agency Scientific Committees and Panels involved in risk assessment).

SCENIHR recognises the need to establish a very flexible framework to aid the correct identification of emerging issues and their potential impacts. The purpose of the framework is to help in the recognition and characterisation of trends pertinent to human health and environmental change (e.g. signals) but in a way that does not exclude the identification of issues for which there is no precedent. In establishing a suitable framework the SCENIHR has been informed by past successes and failures in the early identification of emerging issues. It has also considered the most likely trigger situation for an emerging issue i.e. the potential areas from which an emerging issue may arise and the factors that may initiate relevant changes.

2. WORKING DEFINITIONS

SCENIHR's remit includes both emerging and newly identified health risks.

For the purposes of SCENIHR's work:

An **emerging issue** may be defined as one that has very recently been identified and for which the available data base to conduct a risk assessment is very limited.

For an emerging risk the SCENIHR has adopted the definition of the working paper of the Chairs of Scientific Committees/Panels of Community bodies involved in risk assessment, namely: An **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.

A **newly identified health risk** is a new issue but one where sufficient data exists to conduct at least a preliminary risk assessment with a reasonable degree of confidence.

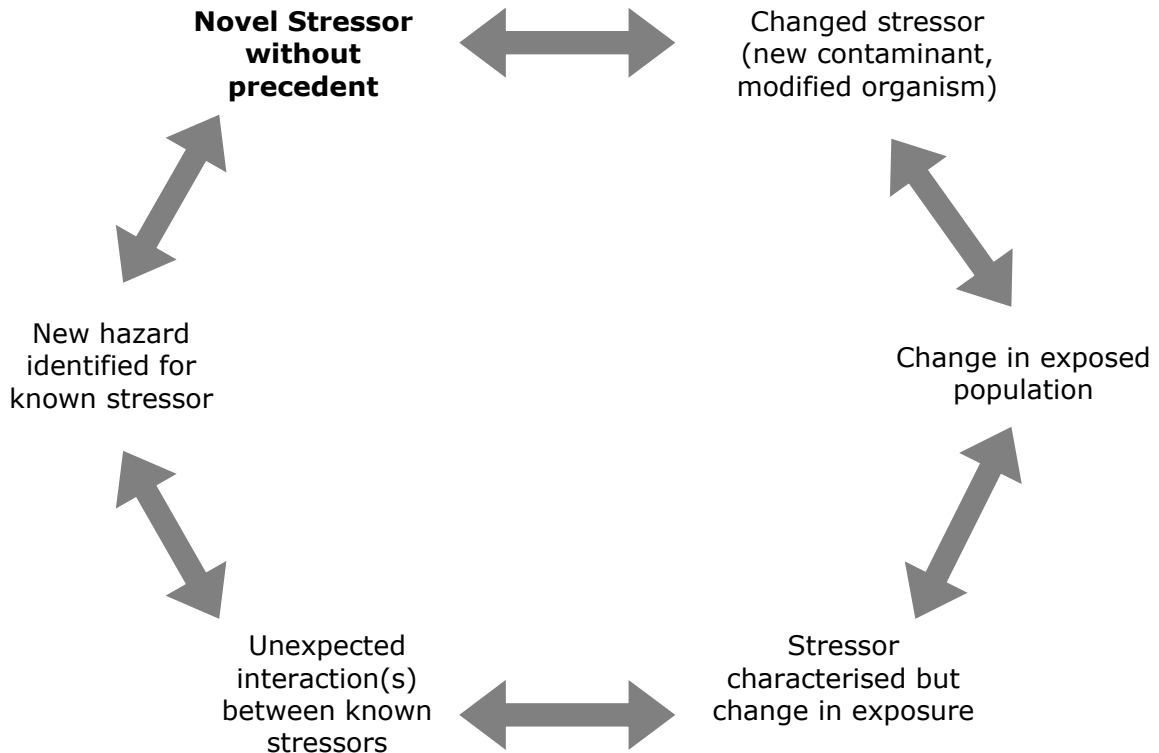
A **stressor** is a chemical, biological, or physical agent or process with the potential to cause (an) adverse effect(s)

3. POTENTIAL SOURCES AND CONTRIBUTORY FACTORS FOR EMERGING ISSUES

3.1. Types of emerging issues

The term emerging issue embraces a range of different situations. These situations and the relationship between them are set out in Figure 1.

Figure 1: Scenarios of emerging issues



3.2. Classification of areas from which emerging issues may arise

As an aid to thinking about emerging issues it is helpful to consider potential sources and potential initiating factors. These are set out below:

- 1) Buildings and infrastructure
- 2) Energy and electronic communications
- 3) Disease evolution e.g. due to pathogen changes
- 4) Industrial and related activities
- 5) Waste processing and utilization
- 6) Use of natural resources
- 7) Transport and storage
- 8) Human behaviour (socioeconomic, lifestyle, perception)
- 9) Medical developments (technology, pharmaceuticals)
- 10) Environmental change
- 11) Product use/misuse
- 12) Agriculture and food.

With the exception of agriculture and food (role for the European Food Safety Authority - EFSA), product use (Scientific Committee for Consumer Products - SCCP), pharmaceutical development (European Medicines Agency - EMEA) and many aspects of environmental changes SCENIHR has a lead role in the identification of emerging risks.

A human or environmental health concern may arise due to a change in one area. More often the change involves changes in more than one area.

3.3. Causes/contributing factors

Emerging issues may be recognised as a consequence of:

- a) Technical advances opening up the prospect of new products and/or processes and/or raising concerns about waste treatment safety
- b) A consequence of changes in the natural environment
- c) Changes resulting from alterations in price, supply of materials and commodities
- d) Changes due to alterations in legislation or public welfare measures
- e) Other socio-cultural or demographic elements
- f) Outcomes of research
- g) Large scale illegal activities
- h) Public/political concern.

Typically emerging issues involve both food and non-food areas. Consequently, it is appropriate that SCENIHR should where possible work with EFSA and others.

4. LESSONS FROM PAST FAILURES

4.1. Reasons for past failures

There are a number of reasons why an emerging issue was not identified at an appropriate time or its potential effects were not properly considered, namely:

- a) Inadequate monitoring/surveillance resulting in a failure to detect the presence of a disease and/or agent at an early stage.
- b) Failure to make important relevant information available to the risk assessors/risk managers.
- c) Incorrect interpretation of the scientific information available by the risk assessors.
- d) Failure to extrapolate the information beyond a specific set of circumstances e.g. inadequate consequence analysis.
- e) Inability to communicate the risks effectively to the relevant risk managers.
- f) Inappropriate action/ inaction by risk managers.
- g) Misinterpretation of the risk assessment by risk communicators.
- h) Failure to anticipate the consequences of new technical developments or changes in legislation.

4.2. Consequences of failures and lessons learned

Failure to recognise the implications for human health and for the environment of a particular emerging issue sufficiently and at an appropriate time may have a variety of consequences:

- delayed action
- wrong action
- loss of trust among the public/politicians in the procedure for identifying emerging issues
- A combination of the above.

It is evident that a procedure needs to be established to enable SCENIHR to fulfil its mandate in respect of emerging issues. Key lessons that can be learned from the past are:

- The importance of the early identification and characterisation.
- The danger of the inappropriate categorisation of an emerging issue at an early stage. In particular, a need to think 'outside the box'.
- The need to assess the potential for an emerging issue in one domain to affect others.
- Poor communication between risk assessors and risk managers.
- The recognition that the risk management action in respect of an emerging issue may give rise to new issues.

5. PROCEDURES FOR THE IDENTIFICATION OF EMERGING ISSUES

There are two parallel and complementary approaches that may be used to identify emerging issues:

- A proactive approach by the SCENIHR. This requires 'brain storming' sessions to identify the emerging issues of principal concern followed by the introduction of procedures to detect and characterise their development
- A more reactive approach based on the identification of indicators of change and the monitoring of these to detect emerging issues.

The former is much less resource intensive than the latter but may suffer from the disadvantage that it may miss an unexpected emerging issue. The latter approach needs very extensive resources and has the potential danger that it may focus on well established types of emerging issues.

Both approaches require the participation of both scientists and non scientists across the globe. The reactive approach in particular also demands a well coordinated activity rather than the piece meal approach that has characterised this area in the past.

Necessary components for effective emerging issue surveillance and monitoring systems are:

- Reliable background data and data on the nature of any changes and the rate of changes.
- Appropriate indicators of changes in exposure and/or public health and environmental quality.

5.1. Sources of information

The primary sources of information available to the SCENIHR are:

- The active input of all members of SCENIHR in identifying emerging and newly identified health risks. It is expected that members will also utilise their own informal networks to aid the discussions.

- Involvement of the reserve list¹ appointed in the non-food area

There are a number of additional potentially important sources of information:

- Input of the other scientific advisory committees of DG SANCO via the coordination group.
- Feedback from other EU and Member States scientific committees (e.g. those responsible for emerging issues for EFSA)
- Advice from other EU activities e.g. DG SANCO Public Health Directorate, Centers for Disease Control and Prevention (CDC), Joint Research Centre (JRC), European Environmental Agency (EEA) etc.
- Early information from projects funded by DG Research (RTD) under the framework contract.
- Activities in the Member States on emerging issues
- Use of the web site to invite contributions
- Collaboration with other international bodies such as World Health Organization (WHO), US Environmental Protection Agency (EPA)
- Views from a stakeholder forum established for a specific issue (which could include an electronic consultation system such as a 'scientific chat room')
- Dialogue with major European societies through their Presidents or nominated representatives.

Additional resources will be needed, both to establish effective interactions with these potential data sources, and to ensure that the additional data provided is properly assessed. .

5.2. Indicators of change

EFSA has given considerable attention to the identification of appropriate indicators relevant to food and feed. Further discussion is needed in SCENIHR regarding the suitability of these or other indicators in the non-food areas.

6. PRIORITISATION OF INDIVIDUAL EMERGING ISSUES

A categorisation system for emerging issues needs to be established that:

- aids identification of further emerging issues,
- is applicable to food and non-food issues,
- is of practical use to risk managers,
- facilitates an interdisciplinary strategy,
- is effective in the recognition of potential impacts on both human health and on the environment.

¹ to be replaced by pool of advisors/database of experts (see Commission Decision 2008/721/EC: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:241:0021:0030:EN:PDF>)

A rigid framework is not appropriate for emerging issues because by definition information about any individual emerging issue is rather limited. Nonetheless, resources are inevitably limited and therefore a structured framework is needed in order to rank them to inform on priorities for detailed follow up. The criteria to be used for this purpose are the following:

1. *Uniqueness*
2. *Soundness*: Data verification (trusted source, more than one source)
3. *Scale*: Estimated scale local, regional, global; consideration of vulnerable community/group; capacity to disseminate (spread)
4. *Severity*: Estimated severity for individual organisms (priority for life threatening)
5. *Urgency*: Estimated rate of change (priority for rapid increases)
6. *Interactions*: Potential for interaction, consequences, and knock on effects, with other stressors.

The weighting of these criteria indicates prioritization from a health/environmental impact perspective in dealing with these issues. It is recognized that final prioritization by the Commission Services may be influenced by political factors such as socio-economic considerations and public concern.

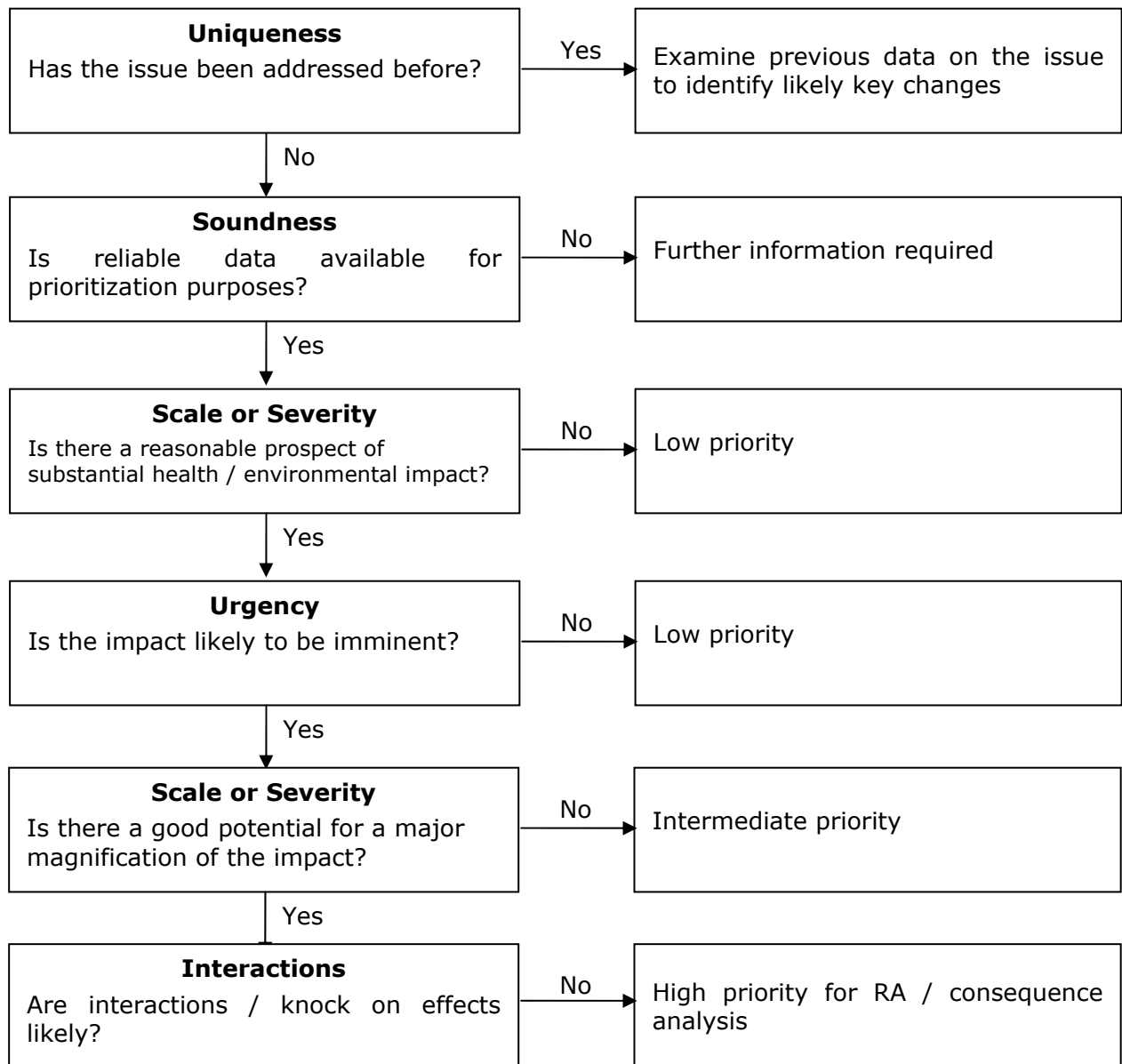
Two simple approaches can be considered for this purpose:

- A decision tree system
- A matrix system based on simple scoring of each of the key parameters.

6.1. Decision tree approach

The decision tree approach (see Figure 2), is designed to be easy to use, however, it inevitably prioritises some criteria over others. This may be a problem if the data for a particular decision point are inadequate. As experience is gained in its use it may require further sophistication.

Figure 2: Algorithm for identifying priorities



6.2. Matrix system approach

The advantage of a scoring system is that the weighting system for each criterion can be applied in a more flexible way. In view of the likely limited sophistication of much of the initial data available and the inevitable judgmental element that needs to be applied to it, a four point scoring system is proposed:

- 3 = high priority
- 2 = medium priority
- 1 = low priority
- * = information inadequate

The proforma might be along the following lines:

Human health

Parameter	Score (1,2,3,*)	Overall profile
Uniqueness		
Soundness		
Scale		
Severity		
Urgency		
Interactions		

Environmental protection

Parameter	Score (1,2,3,*)	Overall profile
Uniqueness		
Soundness		
Scale		
Severity		
Urgency		
Interactions		

It is important that in scoring attention is focussed on the potential health and environmental impact potential and that issues such as scientific interest are put to one side.

Judgment of these tables should be based on the overall profile rather than simply addition of scores; thus if most of the scores are 3 and the remainder are * this would indicate a high priority.

It is suggested that in the first instance the two approaches are run in parallel for comparison purposes.

7. SCENIHR PROCEDURE FOR THE IDENTIFICATION OF EMERGING ISSUES

7.1 Very urgent situations

Very urgent issues are most likely to be first identified by the Commission Services. The role of SCENIHR members in very urgent situations has yet to be spelled out by the Commission Services. To date, in the uncommon situation that a very urgent issue has arisen, SCENIHR members have been involved on an individual basis according to their expertise and ready accessibility

7.2 Other emerging issues

The following procedure for non-emergency issues should be trialled:

- 1) At the start of the autumn session each SCENIHR member should be requested to identify new and review any previous suggestions for emerging issues that they feel are particularly important in terms of potential impact on human health and/or the environment. These issues should be presented in the form of summary reports in line with the format above. Members of the pool of scientific advisors might also be requested to contribute their suggestions.
- 2) These summary reports should be considered initially by a plenary meeting of SCENIHR. On the basis of the SCENIHR deliberations an *Emerging Issues Working Paper* should be produced. This should recommend priorities to the Commission services. Individual emerging issues will hence fall into one of two categories:

- those for which there is a formal request from the Commission services for further assessment (see a)
- others (see b)

a) Emerging issues involving formal requests by Commission services

- i) Once the Commission initiates a request for work on a specific emerging issue, in line with current and, presumably, future procedures, a working group of SCENIHR will be established including some SCENIHR members, experts from the pool of scientific advisors or database of experts plus other experts where needed. The working group is responsible for the development of a draft opinion.
- ii) The draft opinion of the working group then needs to be discussed at a plenary session of SCENIHR who would approve/adopt the committee's opinion. Following consultation with Commission services the SCENIHR opinion should, where appropriate, put the agreed opinion on the internet for external comment (public consultation). The time for response should normally be at least one month.
- iii) If there are substantive comments the working group should meet to consider them and how they influence the opinion. This might lead to a proposal for the revision of the opinion or a recommendation to the SCENIHR plenary that the opinion should stand in its original form.
- iv) The SCENIHR would then adopt the final opinion in the plenary or by written procedure.

b) Other emerging issues

- i) At each SCENIHR Plenary meeting any new developments relevant to the *Emerging Issues Working Paper* should be discussed.
 - ii) Once a year 1 or more of the emerging issues that are not already being addressed in depth by SCENIHR in the form of an opinion should be discussed in detail at a plenary meeting/special meeting of SCENIHR with external invited participants. This should include at least some members of the pool of scientific advisors/database of experts as well as commission officials from a number of DG's. The output of this meeting should be used to update the emerging issues report and to raise awareness of commission officials.
- 3) At the end of the mandate of the SCENIHR the *Emerging Issues Working Paper* should, along with the consideration of the various published opinions by SCENIHR, be the basis for a *SCENIHR Position Paper on Emerging Issues*. This position paper should include recommendations on the future process for identifying and following up emerging issues.

The role of SCENIHR is, inter alia, to draw the attention of and advise the Commission services to emerging issues. However, the decision to take appropriate action and/or to investigate possible risks of these issues lies with the Commission.

8. FORMAT FOR SUMMARY REPORTS (DESCRIPTION OF AN EMERGING ISSUE)

A common format is needed to describe emerging issues. The following is proposed:

- Title
- Brief description of the background to the issue in scientific terms
- Likely sources and causative factors
- The nature of the hazard, its uniqueness, soundness, severity, scale, urgency and interactions
- Parallels with past emerging issues (if any)
- Ranking of importance
- One or two key references where possible

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Working paper on emerging risks, developed 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) (see http://ec.europa.eu/health/ph_risk/committees/ev_20061024_en.htm).

4th Meeting of the Chairs and Secretariats of Commission and Agency Scientific Committees and Panels involved in risk assessment, Parma, 4-5 November 2008 (see http://ec.europa.eu/health/ph_risk/ev_20081104_en.htm)