



**Scientific Committee on Health, Environmental and Emerging Risks
SCHEER**

**Emerging Issues and the Role of the SCHEER
Position Paper (2018)**



The SCHEER adopted this Position paper at its plenary meeting on 5-6 June 2018.

ABSTRACT

The early identification of emerging issues that may adversely affect human health and/or the environment is very important and may help to prevent or mitigate negative impacts through timely action.

The role of the SCHEER is to draw attention to and advise the European Commission on emerging issues. The primary purpose of this position paper is to describe how SCHEER draws the attention of the European Commission services to emerging issues in the non-food area.

The SCHEER debated two complementary approaches that enable the early identification of emerging issues. One is a proactive approach based on the committee's brainstorming sessions, held to identify emerging issues, characterise their development and prioritise them. The other is a more reactive approach based on the prior identification of indicators of change and the monitoring of these to detect emerging issues. The SCHEER have chosen the former approach and agreed on a suitable procedure for its application. It is recognised that the SCHEER needs to collaborate closely with other EU scientific committees and other international bodies to optimally fulfil this task.

Once emerging issues are identified, the decision to take appropriate action and/or to investigate possible risks related to these issues lies with the European Commission.

Keywords: SCHEER, emerging issues, emerging risks, newly identified health risks, health, environment, impacts

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Members of the SCHEER are acknowledged for their valuable contribution to this Opinion.

All declarations by Working Group members are available at the following webpage:
https://ec.europa.eu/health/scientific_committees/experts/declarations/scheer_en

About the Scientific Committees

Two 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.

The Scientific Committee on Consumer Safety (SCCS) and the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) review and evaluate relevant scientific data and assess potential risks. Each committee includes top independent scientists from all over the world who are committed to working in the public interest.

In the formulation of its policies and proposals, the Commission also relies on other Union bodies, such as the European Food Safety Authority (EFSA), the European Medicines Agency (EMA), the European Centre for Disease prevention and Control (ECDC) and the European Chemicals Agency (ECHA).

SCHEER

This Committee, on request of Commission services, provides Opinions on questions concerning health, environmental and emerging risks. The Committee addresses questions on:

- health and environmental risks related to pollutants in the environmental media and other biological and physical factors in relation to air quality, water, waste and soils.
- complex or multidisciplinary issues requiring a comprehensive assessment of risks to consumer safety or public health, for example antimicrobial resistance, nanotechnologies, medical devices and physical hazards such as noise and electromagnetic fields.

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SUMMARY

- i) The early identification of emerging issues that may adversely affect human health and/or the environment is very important. Early identification may help to prevent or mitigate negative impacts if timely action is taken.
- ii) Two complementary approaches have been identified that enable the early identification of emerging issues:
 - A proactive approach based on the committee's brain-storming sessions, held to identify emerging issues of principal concern, with discussion of procedures to detect and characterise their development.
 - A more reactive approach based on the prior identification of indicators of change and their monitoring to detect emerging issues.
- iii) The SCHEER 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.
- iv) An effective collaboration with other EU scientific committees and indeed other international bodies is necessary to ensure SCHEER's optimal performance in the fulfilment of this task.

The role of the SCHEER is to alert the European Commission to emerging issues and provide relevant advice. However, the decision to take appropriate action and/or to investigate possible risks from these issues lies with the Commission.

1. INTRODUCTION

The role of the SCHEER is to alert the European Commission to emerging issues and provide relevant advice. The primary purpose of this position paper is to illustrate the methodology followed by SCHEER to draw the attention of the European Commission services to emerging issues in the non-food area that have been identified by SCHEER members as potentially having significant negative impact on human health and/or on the environment. It is intended to supplement the information that is already accessible to the Commission services through other sources.

Identifying emerging issues early on can raise awareness, allowing authorities to take appropriate and timely action to ensure public safety and environmental protection. However, because it concerns *emerging* issues, the available data needed to correctly identify these issues and their impact are likely to be very limited. It is therefore important that each identified issue is regularly reviewed. The SCHEER therefore intends to consider any relevant new development at each plenary meeting and to update this position paper at least annually. When considering emerging issues, the SCHEER would like to work closely with other EU scientific advisory committees that are also mandated with identifying emerging issues. Furthermore, ongoing discussion and collaboration at EU and international level should foster global cooperation. (see Section 6.2).

The SCHEER recognises the need to establish a very flexible framework to aid the correct and timely 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 SCHEER has learned, from past successes and failures in the early identification of emerging issues, the importance of foresight and a sound understanding of scientific areas undergoing rapid change.

2. WORKING DEFINITIONS

The SCHEER's remit includes both emerging and newly identified issues that may have significant impacts on human health and/or on the environment.

For the purposes of the SCHEER'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 SCHEER has adopted the definition given in the working paper by the Chairs of Scientific Committees/Panels of Community bodies involved in risk assessment, namely: An ***emerging risk*** refers to an 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.

3. POTENTIAL SOURCES AND CONTRIBUTORY FACTORS FOR EMERGING ISSUES

The term *emerging issue* embraces a range of different situations. The threats to the environment and to human health are normally not yet observable for emerging risks, which poses a great challenge. 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 supply of materials and commodities
- d) Changes due to alterations in legislation or public welfare measures
- e) A change in the use or operational conditions of a known stressor leading to a different exposure pattern
- f) Other socio-cultural or demographic elements
- g) Outcomes of research
- h) Large scale illegal activities
- i) Public/political concern

Emerging issues may involve both food and non-food areas, chemicals, human behaviour etc. Consequently, it is appropriate that, when feasible, the SCHEER should cooperate with EFSA, ECHA, ECDC and other European or international organisations (See Section 6.2).

4. POSSIBLE REASONS FOR FAILURE

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, effect and/or agent at an early stage.
- b) Failure to make important relevant information available to the risk assessors/risk managers in a timely manner.
- 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 sufficiently recognise the implications for human health and for the environment of a particular emerging issue at an appropriate time may have various consequences including:

- delayed action- limited effect in mitigating or managing the risk
- wrong action- no effect in mitigating or managing the risk
- loss of confidence in scientific risk assessment by the public/politicians of scientists and risk managers

- a combination of the above.

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

- The importance of the early identification and characterisation of emerging issues.
- 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 lack of sound scientific knowledge on a given issue, combined with the pressure of public opinion and the media, may lead risk managers to take inappropriate actions.
- The recognition that any risk management action taken in response to an emerging issue may itself give rise to new issues.

5. APPROACHES 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 SCHEER. This requires brain-storming sessions to identify emerging issues of principal concern followed by discussion to characterise their development and prioritise them.
- A more reactive approach based on the identification of indicators of change and their monitoring 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 issue.

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

Necessary components for effective emerging issue surveillance and an efficient monitoring system 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

Sources of information available to the SCHEER are:

- The active input of all members of the SCHEER in identifying emerging and newly identified health and environmental risks. It is expected that members will also utilise their own informal networks to aid the discussions.
- Periodic search of literature (*e.g.*, by JRC)

In addition, there are a number of additional potentially important sources of information:

- Input of the other scientific advisory committees of DG SANTE via the coordination group
- Feedback from other EU and member states scientific committees. Advice from other EU activities, e.g. DG SANTE Public Health Unit, CDC, JRC, EEA, EMCDDA, ECHA, etc.
- Early information from DG RESEARCH & INNOVATION funded projects
- Activities in Member States on emerging issues
- Use of the website to invite contributions
- Collaboration with other international bodies such as WHO, USEPA
- 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/International societies (e.g. SETAC, SOT, etcetera) through their Presidents or nominated representatives
- "search on search"; data mining
- Informal investigations by SCHEER members in their own scientific research fields

It is recognised that additional resources would be needed to utilise many of these other sources of information effectively. It is also appreciated that the more data provided, the greater the need for an appropriate filtering system in order to identify priorities.

5.2. International cooperation

With the exception of agriculture and food (EFSA), product use (SCCS), pharmaceutical development (EMA) and some other aspects of environmental changes, SCHEER has a lead role in the identification and signalling of emerging issues and risks to the European Commission. Cooperation with EFSA, SCCS and EMA on methods and tools, as well as on the issues and risks identified, is essential. EFSA reported on methods and tools, its Emerging Risk Exchange Network and international collaboration with FAO and WHO (Alfonso *et al.*, 2017). Human health or environmental concern may arise due to a change in one area which affects other areas as well. A survey of national and international methods and tools was recently compiled and critically examined and this survey also offers many opportunities for exchange of knowledge and information (EC, 2017). At a global level, the Network of Risk Assessment Institutes of WHO is also active in this area and close collaboration on methods and tools and on issues and risks identified is essential (<http://www.who.int/ipcs/network/about/en/>).

6. PRIORITISATION OF INDIVIDUAL EMERGING ISSUES

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

- facilitates the early identification of further emerging issues
- is applicable to food and non-food areas
- is of practical use to risk managers
- facilitates an interdisciplinary strategy

- is suitable to recognise potential impacts on both human health and on the environment

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:

- *Uniqueness or novelty.* What is the **potential** novelty (familiar risk with new exposure scenario or new risk)? Has the issue been addressed before?
- *Soundness.* Data verifiability what is the potential for verifiability (trusted source, more than one source, is reliable data available for prioritisation purposes)?
- *Urgency/imminence:* Estimated rate of change (what is the **potential** for rapid increases?). How soon is it estimated that the potential hazard will manifest?
- *Scale.* What is the spatial scale for **potential** exposure (local, regional, global, particularly vulnerable community/group)?
- *Severity.* Estimated severity for individual organisms or next generations (what is the **potential** to be life threatening?).
- *Interactions.* What **potential** is there for interaction, consequences, and knock-on effects, with other stressors?

The assessment of the potential of the emerging issue under each criterion will be scored on a 1-3 point scale, with 3 indicating high potential. Insufficient information to allow assessment will be categorised as *. The weighting of these criteria for any single issue indicates prioritisation in the importance of dealing with the issue and also allows the assessment of the relative priorities of multiple issues. It is recognised that prioritisation will be influenced by external variables, e.g. political factors and public concern.

Simple scoring of each of the criteria and then a weighting of the criteria (based mainly on scientific judgement) will provide a prioritisation of an issue. The prioritisation is a weight-of-evidence process based on a subjective judgement of all criteria.

A decision-tree approach was considered but it inevitably prioritises some criteria over others and follows a linear decision-making track. This is a problem if the data for a particular decision point are inadequate.

The advantage of a scoring system is that the weighing for each criterion can be applied giving a judgement on the overall weight of the emerging issue at stake. In view of the likely limited evidence available and the inevitable judgmental element that needs to be applied, a three-point scoring system is proposed: for each criterion, the assessor addresses its potential as identified in the criterion description:

3 = high

2 = medium 1 = low * = information inadequate to allow assessment

The overall assessment then is also on a 3-point scale, with 3 being high priority and * indicating that the information is inadequate to allow assessment. The approach might be along the following lines:

Human health

Parameter	Score (potential) (1,2,3,*)
Uniqueness	
Soundness	
Urgency	
Severity	
Spatial scale	
Interactions	
Profile and Overall priority	

Environmental protection

Parameter	Score (potential) (1,2,3,*)
Uniqueness	
Soundness	
Urgency	
Severity	
Spatial scale	
Interactions	
Profile and Overall priority	

It is important that in scoring, attention is focussed on the potential impact to health and/or the environment and that issues such as scientific interest are put aside. It may be that an issue is only relevant for either human health or the environment.

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

7. SCHEER PROCEDURE FOR THE IDENTIFICATION OF EMERGING ISSUES

Separate procedures are clearly needed for urgent highest priority issues, i.e. those that have an immediacy that requires a rapid risk assessment versus those of lower priority. A “rapid risk assessment (RRA)” procedure has now been installed within the SCHEER to address highest priority, urgent situations.

The following procedure applies to the identification of the less-urgent emerging issues:

- i) At the start of the autumn session each SCHEER member is requested to identify new issues and review the previous suggestions for emerging issues that they feel are of high priority in terms of potential impact on human health and/or the environment. These issues should be summarised (summary reports) in line with the format in the next section. Members of the pool of scientific advisors might also be requested to contribute their suggestions.
- ii) These summary reports should be considered initially by a plenary meeting of the SCHEER which should recommend priorities to the European Commission services in an emerging issues report at least twice during the five-year term of the Committee. One or more of the emerging issues that are not already being addressed in-depth by the SCHEER in the form of an Opinion (see iii) should be discussed in detail at a plenary meeting/special meeting of the SCHEER with external invited participants. This may include consultation with members of the reserve list of experts as well as European Commission officials from a number of DGs. The output of this meeting should be used to update the emerging issues report and to raise the Commission officials' awareness.
- iii) Once the European Commission initiates a request for work on a specific emerging issue, a working group of the SCHEER is established that may also use experts from the reserve list plus other experts where needed. The working group is responsible for the development of a draft Opinion. The recommendations of the working group then need to be discussed at a plenary session of the SCHEER, who would agree on the committee's emerging issue Opinion. Following consultation with Commission services, the SCHEER should, where appropriate, publish the agreed Opinion on the internet for external comment. The time for response should normally be only one month.
- iv) If there are substantive comments, the working group should meet to consider them and discuss how they influence the Opinion. This might lead to a proposal for the revision of the Opinion or a supplement, or a recommendation to the SCHEER plenary that the Opinion should stand in its original form.
- v) At each SCHEER plenary meeting, developments in regard to the report should be discussed.

At the end of the SCHEER's mandates, a review of progress on the work on the emerging issues listed should be carried out by the SCHEER to make recommendations on the process for identifying and following up emerging issues.

The role of the SCHEER is to draw the European Commission services' attention to emerging issues and provide relevant advice. Procedures may be adapted according to the urgency of the 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 DESCRIBING AN EMERGING ISSUE

A common format is needed to describe emerging issues, containing the following information:

- 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 previous emerging issues, if any.
- Profile of potential and prioritisation of the issue, with one or two key references where possible.

The full template is included as Annex I.

9. REFERENCES

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10. Annex I: TEMPLATE FOR DESCRIBING AN EMERGING ISSUE

EMERGING ISSUES AND POTENTIAL NEW TOPICS IDENTIFIED BY SCHEER MEMBERS

Potential sources and potential initiating factors:

- 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.

Causes / Contributing factors:

- 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

Empty template:

Topic	
Initiator(s)	
Sources Causative factors (see p. 1 of this document)	
Hazard (provide the potential score (as 1,2,3 or *) for the following criteria -uniqueness, - soundness -severity, -scale - urgency - interactions	
Parallels with past emerging issues. Potential interactions with other stressors)	
Preliminary Estimation of prioritisation (*, 1, 2 or 3 where *=uncertain and 3 is high)	
Background including reliability of data, a key reference if possible any other reasons for concern.	