The strategy for a non-toxic environment of the 7th Environment Action Programme

Sub-study g: Appendix
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APPENDIX 1. QUESTIONNAIRES FOR LITERATURE REVIEW

Environment; Literature source: https://eurl-ecvam.jrc.ec.europa.eu/databases/eas_database

1. What is the name of the system /registry/instrument?
   Endocrine Active Substances Information System (EASIS)

2. What is the goal of the system/method/instrument/database?
   EASIS is a database covering 428 substances suspected of having the potential for endocrine disruption. Although it has no normative or pre-normative implications, this database has proven useful in providing stakeholders with a significant amount of information on potential endocrine disrupters.

3. Is it aimed at identifying possible (new and emerging) risks? Or can it be used for that goal?
   Yes, the database in its current form is static in nature, and does not allow information to be introduced or updated. There are plans to build a new database into a Web Portal, so as to provide easy access to additional resources, such as other databases and modelling tools.

4. Which organization collects the information on possible (new and emerging) risks?
   Based on the output of four study contracts commissioned over the period 2000-2007, the Directorate-General for the Environment (DG ENV) developed the database.

5. Which language is used in the system? English

6. Is it publicly available or not? Yes,

7. What is the scope of the system/method/instrument?
   European Union; Both human and environment end points are covered

8. What definition is used for new or emerging risks? Not relevant

9. In which way are signals on possible (new and emerging) risks obtained?
   See information provided with question 3

10. Are possible (new and emerging) risks collected and stored in a someway (national database)? Is there some kind of registration procedure and does it work? Database

11. How is a first report of a possible (new and emerging) risks evaluated and what are the criteria used to evaluate reported signals?
    ED criteria have been established to evaluate studies and reported data.

12. Who evaluates a first report of a possible (new and emerging) risks?
    Study contracts have been commissioned to evaluate ED properties by experts

13. Is there a plan for communication of a (new and emerging) risk between the reporter/notifier and the evaluating body take place? Which evaluating bodies are in contact?
    Not relevant

14. How is the evaluation and start/set up of follow up actions of a possible (new and emerging) risks organised?
    Not relevant

15. What were the costs for setting-up or building the system? What does the maintenance and operation of the system cost?
    To be checked
Environment; Literature source: http://emm.newsbrief.eu/overview.html

1. What is the name of the system /registry/instrument? Europe Media Monitor (EMM)
2. What is the goal of the system/method/instrument/database? The EMM shows and explores current news reported by the world’s online media. It monitors thousands of news sources in over 70 languages, the system uses advanced information extraction techniques to automatically determine what is being reported in the news, where things are happening, who is involved and what they said. It provides a unique and independent viewpoint of what is being reported in the world right now. The EMM allows to track what is being said by people and organizations, follow news on a given topic (more than 500 predefined topics) and see what are the biggest stories that are happening right now in the world in a given language.
3. Is it aimed at identifying possible (new and emerging) risks? Or can it be used for that goal? It can be used to follow news on given topics and track signals concerning new and emerging risks of chemicals. The EMM is used for this purpose by the RIVM
4. Which organization collects the information on possible (new and emerging) risks? The Joint Research Centre produced the EMM
5. Which language is used in the system? English
6. Is it publicly available or not? Yes
7. What is the scope of the system/method/instrument? Worldwide, any topic
8. What definition is used for new or emerging risks? Not relevant
9. In which way are signals on possible (new and emerging) risks obtained? Automated procedure: NewsExplorer produces its results fully automatically every day, by applying a combination of various multilingual Language Technology tools to the news articles gathered automatically by the Europe Media Monitor EMM. NewsExplorer carries out the following tasks:
   - cluster all news articles of the day, separately for each language, into groups of related articles;
   - for each cluster, identify names of people, places, organisations;
   - apply approximate name matching techniques to all names found in the same cluster, in order to identify which name variants may belong to the same person;
   - link the monolingual clusters with the related clusters in the other languages;
   - identify the most typical article of each cluster and use its title for the cluster;
   - store the extracted information in a database, learning more about each person, etc. every day;
   - occasionally, the Wikipedia online encyclopaedia is automatically searched for images and for further multilingual name variants.

More information can be found at: http://emm.newsexplorer.eu/NewsExplorer/readme.html
10. Are possible (new and emerging) risks collected and stored in a someway (national database)? Is there some kind of registration procedure and does it work? NewsExplorer can export data for further computation and analysis. Currently supported formats.
11. How is a first report of a possible (new and emerging) risks evaluated and what are the criteria used to evaluate reported signals? Not relevant
12. Who evaluates a first report of a possible (new and emerging) risks? Not relevant
13. Is there a plan for communication of a (new and emerging) risk between the reporter/notifier and the evaluating body take place? Which evaluating bodies are in contact? Not relevant
14. How is the evaluation and start/set up of follow up actions of a possible (new and emerging) risks organised? Not relevant
15. What were the costs for setting-up or building the system? What does the maintenance and operation of the system cost? To be checked
1. **What is the name of the system/registry/instrument?** Generic framework for effective food safety management

2. **What is the goal of the system/method/instrument/database?** The goal is to provide a systematic framework for effective food safety management at the national government level. The framework is based on food safety risk analysis in order to oversee and manage the risk analysis process.

3. **Is it aimed at identifying possible (new and emerging) risks? Or can it be used for that goal?** Focus is on hazards that have long been recognised and addressed by food safety controls as well as new and emerging hazards.

4. **Which organization collects the information on possible (new and emerging) risks?**
   - Organisations involved in outlining a systematic framework for food safety are:
     - Codex (WHO and FAO): [http://www.who.int/foodsafety/areas_work/food-standard](http://www.who.int/foodsafety/areas_work/food-standard)/
       Specific work on Public health advice on food safety emergencies and outbreaks of foodborne disease which includes collaboration on international information sharing on foodborne diseases and food contamination via the International Food Safety Authorities Network (INFOSAN) and International Health Regulations (IHR) networks:
     - Food safety related to chemical risks: [http://www.who.int/foodsafety/areas_work/chemical-risks/en/](http://www.who.int/foodsafety/areas_work/chemical-risks/en/)

5. **Which language is used in the system?** Not relevant at it concerns a presentation of a generic framework.

6. **Is it publicly available or not?** Not sure whether there are actually systems running following this concept.

7. **What is the scope of the system/method/instrument?**

   The scope is food safety management at the national level, but food safety risk analysis is carried out by national, regional and international food safety authorities.

8. **What definition is used for new or emerging risks?**

   A food-borne hazard is defined by Codex as “a biological, chemical or physical agent in, or condition of, food, with the potential to cause an adverse health effect.”

9. **In which way are signals on possible (new and emerging) risks obtained?**

   - Automated procedure, expert judgement, expert panels, internet communication platforms
   - Type of sources consulted (News Letters, Databases, Digital Media, Scientific papers, symposia etc.)
   - The system exists of three basic components of risk analysis, that are risk management, risk assessment and risk communication.
   - Risk analysis is used to develop an estimate of the risks to human health and safety, to identify and implement appropriate measures to control the risks, and to communicate with stakeholders about the risks and measures applied.

10. **Are possible (new and emerging) risks collected and stored in some way (national database)? Is there some kind of registration procedure and does it work?**

   Identification is case by case based for instance on epidemiology, food source attribution where information is used from integrated systems in which data from public health surveillance and pathogen monitoring of foods of animal origin and animals at primary production and processing are routinely collected, collated and analysed by a single coordinating body are mentioned as examples.

   (At the EU level there is the Rapid Alert System food and feed (RASFF) system [http://ec.europa.eu/food/safety/rasff/index_en.htm](http://ec.europa.eu/food/safety/rasff/index_en.htm))

Environment; Literature source: [http://www.fao.org/docrep/012/a0822e/a0822e.pdf](http://www.fao.org/docrep/012/a0822e/a0822e.pdf)
11. **How is a first report of a possible (new and emerging) risks evaluated and what are the criteria used to evaluate reported signals?**

A lot of manual work and expert judgement is needed to collect the information and identify relevant issues (identification and hazard assessment).

12. **Who evaluates a first report of a possible (new and emerging) risks?**

Risk assessment by national or international coordinating bodies is the first step after identification of a possible food safety issue, see information presented with question 14.

13. **Is there a plan for communication of a (new and emerging) risk between the reporter/notifier and the evaluating body take place? Which evaluating bodies are in contact?**

Risk communication is the final step in the generic framework, see question 14. Some international or national coordinating bodies for contact are mentioned with question 4.

14. **How is the evaluation and start/set up of follow up actions of a possible (new and emerging) risks organised?**

The three main components of risk analysis have been defined by Codex as follows:

A) **Risk assessment**: A scientifically based process consisting of the following steps: i) hazard identification; ii) hazard characterization; iii) exposure assessment; and iv) risk characterization.

B) **Risk management**: The process, distinct from risk assessment, of weighing policy alternatives in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options.

C) **Risk communication**: The interactive exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions.

15. **What were the costs for setting-up or building the system? What does the maintenance and operation of the system cost?**

A generic concept is presented. There is no information about systems, based on this concept, that are currently running in this information source. Consequently, there is no information on costs.

16. **Additional comments**

**Concluding questions (A and B):**

A. **Criteria**

   a. The system ensures access to latest high quality information;
   b. It provides suitable support for the generation of data;
   c. It takes into account the different routing and triggers for specific targets (health or environment). Such triggers are used to start a follow-up process to further assess:
   d. Whether there is a risk;
   e. If so, which policy framework, regulatory body or actor is most suitable to address the risk?
   f. What kinds of actions are needed to ensure risks are controlled?
   g. It specifies the type of concerns to take into account (effect- or concentration based);
   h. It takes into account the needs to generate further CMR of PBT information;
   i. It fosters streamlining of the flow of information towards the risk managers;
   j. It highlights or provides linkages between the system and chemical policy.
   k. It can be used as a basis for prioritisation.

1. What is the name of the system/registry/instrument?
   IPCheM - the Information Platform for Chemical Monitoring

2. What is the goal of the system/method/instrument/database?
   IPChem is a single access point for discovering chemical monitoring data collections managed and available to European Commission bodies, Member States, international and national organisations and researchers. The Platform aims to support a more coordinated approach for collecting, storing, accessing and assessing data related to the occurrence of chemicals and chemical mixtures, in relation to humans and the environment. "This would help identify links between exposure and epidemiological data in order to explore potential biological effects and lead to improved health outcomes."

3. Is it aimed at identifying possible (new and emerging) risks? Or can it be used for that goal?
   It is not specifically aimed at identifying or tracing emerging chemicals. As mentioned with question two, one of the goals of IPChem is that it will host data on new, emerging and less-investigated chemicals that will be searchable and accessible through the platform;

   IPChem primary objective is focused on:
   - assisting policy makers and scientists to discover and access databases of chemical monitoring data covering a range of matrices and media;
   - hosting data currently not readily accessible (e.g. outcomes of research projects, off-line stored monitoring data, etc.) including data on new, emerging and less-investigated chemicals that will be searchable and accessible through the platform;
   - providing chemical monitoring information of defined quality concerning spatial, temporal, methodological and metrological traceability.

4. Which organization collects the information on possible (new and emerging) risks?
   IPChem is a joint effort initiated by the European Commission. Some of the organisations joining are JRC, EFSA, EEA and UBA.

   The IPChem platform is managed by the Joint Research Centre of the European Commission.

5. Which language is used in the system?
   English

6. Is it publicly available or not?
   Yes

7. What is the scope of the system/method/instrument?
   Scope is international, with focus on EU and its member states.
   Compartments covered are human biomonitoring, Environment (air, water, soil), Food and Feed, Indoor air and Consumer products

8. What definition is used for new or emerging risks?
   Not relevant

9. In which way are signals on possible (new and emerging) risks obtained?
   IPChem is an internet communication platform and is open for those who collect and handle chemical monitoring data across Europe and those who would like to share data with, promote activities and make data available for policymaking purposes.
   The type of sources that can be shared are Databases, Digital Media, Scientific papers and reports, watch lists etc.

10. Are possible (new and emerging) risks collected and stored in a someway (national database)? Is there some kind of registration procedure and does it work?
    Not relevant, emerging substances/risk are not specifically addressed.

11. How is a first report of a possible (new and emerging) risks evaluated and what are the criteria used to evaluate reported signals?
    Not relevant IPChem is an internet data sharing platform, there is not evaluation process involved
12. Who evaluates a first report of a possible (new and emerging) risks? Not relevant
13. Is there a plan for communication of a (new and emerging) risk between the reporter/notifier and the evaluating body take place? Which evaluating bodies are in contact? Not relevant
14. How is the evaluation and start/set up of follow up actions of a possible (new and emerging) risks organised? Not relevant
15. What were the costs for setting-up or building the system? What does the maintenance and operation of the system cost?
   To be done
Environment; Literature source: http://www.norman-network.net/

1. **What is the name of the system/registry/instrument?** The NORMAN network
2. **What is the goal of the system/method/instrument/database?**
   The goal of the NORMAN network is to enhance the exchange of information on emerging environmental substances, and encourages the validation and harmonisation of common measurement methods and monitoring tools so that the requirements of risk assessors and risk managers can be better met. It specifically seeks both to promote and to benefit from the synergies between research teams from different countries in the field of emerging substances.
3. **Is it aimed at identifying possible (new and emerging) risks? Or can it be used for that goal?**
   One of the primary aims of the NORMAN network is to assign priority action categories to emerging substances. This is done by the NORMAN Prioritisation Working Group.
4. **Which organization collects the information on possible (new and emerging) risks?**
   The NORMAN network became a permanent self-sustaining network of reference laboratories, research centres and related organisations for the monitoring and biomonitoring of emerging environmental substances. It is established as a non-profit association of all interested stakeholders dealing with emerging substances.
5. **Which language is used in the system?** English
6. **Is it publicly available or not?** Yes
   All interested stakeholders dealing with emerging substances could be part of the network.
7. **What is the scope of the system/method/instrument?**
   The focus of the network is the European Union and the compartments covered are water (fresh and marine), sediment and suspended matter and biota.
   The NORMAN network is addressed to aquatic ecosystems and human health via the aquatic environment, in line with the objectives of the WFD.
   Human health risks associated with drinking water exposure (i.e. via inhalation, skin contact and ingestion) are not considered in the present study.
8. **What definition is used for new or emerging risks?**
   "Emerging substances" can be defined as substances that have been detected in the environment, but which are currently not included in routine monitoring programmes at EU level and whose fate, behaviour and (eco)toxicological effects are not well understood.
   "Emerging pollutants" can be defined as pollutants that are currently not included in routine monitoring programmes at the European level and which may be candidates for future regulation, depending on research on their (eco)toxicity, potential health effects and public perception and on monitoring data regarding their occurrence in the various environmental compartments.
9. **In which way are signals on possible (new and emerging) risks obtained?**
   NORMAN has identified a list of the currently most frequently discussed emerging substances and emerging pollutants. These substances are selected by the NORMAN Prioritisation Working Group, based on citations in the scientific literature, and taking into account the definition of "emerging substances" and "emerging pollutants".
   Furthermore within the NORMAN network there are 8 different working groups with the focus on different topics related to emerging substances. Besides the working group on prioritisation of emerging substances there are working groups on:
   - WG2 Bioassays and biomarkers in water quality monitoring
   - WG3 Effect—directed analysis for hazardous pollutants identification
   - WG4 Nanomaterials
   - Cross-Working group on Passive sampling and monitoring of emerging contaminants
   - WG5 Wastewater reus and emerging contaminants
   - Cross-Working Group Activity Non-target Screening (NTS)
   - WG6 Emerging substances in the indoor environment
Information generated within these working groups bringing together existing knowledge on emerging substances and will generate signals on possible new or emerging risks. To facilitate the exchange between the various topics a cross working group was established. One of the goals is to set-up and maintenance of the Suspect Lists Exchange and the NormaNEWS initiatives to support identification of “unknowns”.

10. Are possible (new and emerging) risks collected and stored in a someway (national database)? Is there some kind of registration procedure and does it work?
NORMAN has identified a list of the currently most frequently discussed emerging substances and emerging pollutants (LIST OF EMERGING SUBSTANCES latest update February 2016):
http://www.norman-network.net/sites/default/files/files/Emerging_substances_list_Feb_16/NORMAN%20list_2016_FINAL.XLSX

11. How is a first report of a possible (new and emerging) risks evaluated and what are the criteria used to evaluate reported signals?
NORMAN systematically collects in the EMPODAT database monitoring data and information on effects and hazardous properties for these substances. On the basis of this information, the substances are assigned to priority action categories by the NORMAN Prioritisation Working Group. A set of criteria is used for the allocation of emerging substances to clearly pre-defined categories (substances for which e.g. there is not yet sufficient information about their toxicity, substances for which there is evidence of hazard but analytical performance is not yet satisfactory, etc.), and their subsequent prioritisation. Criteria used are frequency of occurrence, exceedance of environmental quality standards and hazard information. The information needed for the prioritisation is collected in a database (EMPODAT). For the prioritisation process a high degree of manual work and expert judgement is needed.

12. Who evaluates a first report of a possible (new and emerging) risks?
The NORMAN prioritisation Working Group

13. Is there a plan for communication of a (new and emerging) risk between the reporter/notifier and the evaluating body take place? Which evaluating bodies are in contact?
The NORMAN scheme is addressed to all water managers and competent authorities aiming to identify priority substances at national, river basin and European level. It provides decision-makers with a common framework for the creation and updating of the lists of chemical substances for which actions to reduce, monitor or gather scientific or technical data are to be undertaken as a matter of priority.
There is no clear communication plan to address the chemicals of with high concern. Putting forward the highly prioritised chemicals as candidates for watch list of possible relevant substances in the context of the WFD seems the most straight forward routes. The final goal would be to list of priority substance of the WFD.

14. How is the evaluation and start/set up of follow up actions of a possible (new and emerging) risks organised?
NORMAN systematically collects in the EMPODAT database monitoring data and information on effects and hazardous properties for these substances. On the basis of this information, the substances are assigned to priority action categories by the NORMAN Prioritisation Working Group. A set of criteria is used for the allocation of emerging substances to clearly pre-defined categories (substances for which e.g. there is not yet sufficient information about their toxicity, substances for which there is evidence of hazard but analytical performance is not yet satisfactory, etc.), and their subsequent prioritisation.
Criteria used are frequency of occurrence, exceedance of environmental quality standards and hazard information.

The information needed for the prioritisation is collected in a database (EMPODAT). For the prioritisation process a high degree of manual work and expert judgement is needed.

15. **What were the costs for setting-up or building the system? What does the maintenance and operation of the system cost?**

Information on costs are included in the yearly program reports:

Environment; Literature source: SCENIHR 2009, Emerging Issues and the Role of SCENIHR, Position Paper, 15 pages

1. What is the name of the system? Emerging Issues and the Role of the SCENIHR

2. What is the goal of the system/method/instrument/database?
   The early identification of emerging issues that may adversely affect human health and/or the environment in order to help to prevent negative impact by allowing earlier appropriate action

3. Is it aimed at identifying possible (new and emerging) risks? Yes.

4. Which organization collects the information on possible (new and emerging) risks?
   The members of the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR)

5. Which language is used in the system? English

6. Is it publicly available or not? Yes

7. What is the scope of the system/method/instrument?
   European scale
   Emerging issues in the non-food area having the potential for a significant impact on human health and/or the environment in the future

8. What definition is used for new or emerging risks?
   SCENIHR uses the following definitions:
   - 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.
   - 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)

9. In which way are signals on possible (new and emerging) risks obtained?
   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.

10. Are possible (new and emerging) risks collected and stored in a someway (national database)? Is there some kind of registration procedure and does it work?
    The primary sources of SCENIHR information is 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 and available sources to aid the discussions.

11. How is a first report of a possible (new and emerging) risks evaluated and what are the criteria used to evaluate reported signals?
    Suggestion (not active yet) of two judgement procedures
    - Decision tree approach using an algorithm for identifying priorities
    - Matrix system approach using a scoring/weighting system for each criterion.
    The used criteria are: (i) Uniqueness, (ii) Soundness, (iii) Scale, (iv) Severity, (v) Urgency,(vi) Severity, (vii) Interactions
12. **Who evaluates a first report of a possible (new and emerging) risks?**  
EC Commission Services

13. **Is there a plan for communication of a (new and emerging) risk between the reporter/notifier and the evaluating body take place? Which evaluating bodies are in contact?**  
SCENIHER and EC Commission Services

14. **How is the evaluation and start/set up of follow up actions of a possible (new and emerging) risks organised?** Not clarified

15. **What were the costs for setting-up or building the system? What does the maintenance and operation of the system cost?** Not clarified

16. **Additional comments**  
Position paper suggests a useful and comprehensive approach for identifying NERCs. However, no specific information is available about measures for identified NERCs and the costs of the proposed systems.  
The Commission decision 2008/721/EC concerns The setting up an advisory structure of Scientific Committees and experts in the field of consumer safety, public health and the environment.  
Annex II informs about rules of organization and indemnities (onkosten)
1. **What is the name of the system/registry/instrument?**
   Developing Ambient water quality criteria Under the United States Clean Water Act

2. **What is the goal of the system/method/instrument/database?**
   The purpose of the white paper is to provide general guidance on how criteria development for CECs could be facilitated through a supplemental interpretation of the Guidelines, with particular attention to PPCPs with an EDC mode of action (MOA). The white paper describes the Guidelines procedures and identifies several areas in which procedures could be modified to address potential limitations for deriving criteria for CECs. The focus of the paper is on the use of non-traditional endpoints in deriving water quality criteria especially related to endocrine disruption.

3. **Is it aimed at identifying possible (new and emerging) risks? Or can it be used for that goal?**
   No

4. **Which organization collects the information on possible (new and emerging) risks?**
   US EPA

5. **Which language is used in the system?**
   English

6. **Is it publicly available or not?**
   Yes

7. **What is the scope of the system/method/instrument?**
   Scope of the paper is water quality criteria in the USA.

8. **What definition is used for new or emerging risks?**
   The term “contaminant of emerging concern” is being used within the Office of Water to identify chemicals and other substances that have no regulatory standard, have been recently “discovered” in natural streams (often because of improved analytical chemistry detection levels), and potentially cause deleterious effects in aquatic life at environmentally relevant concentrations. They are pollutants not currently included in routine monitoring programs and may be candidates for future regulation depending on their (eco)toxicity, potential health effects, public perception, and frequency of occurrence in environmental media. CECs are not necessarily new chemicals. They include pollutants that have often been present in the environment, but whose presence and significance are only now being evaluated.

9. **In which way are signals on possible (new and emerging) risks obtained?**
   Not relevant

10. **Are possible (new and emerging) risks collected and stored in a someway (national database)?**
    Is there some kind of registration procedure and does it work? Not relevant

11. **How is a first report of a possible (new and emerging) risks evaluated and what are the criteria used to evaluate reported signals?**
    Not relevant

12. **Who evaluates a first report of a possible (new and emerging) risks?**
    Not relevant

13. **Is there a plan for communication of a (new and emerging) risk between the reporter/notifier and the evaluating body take place? Which evaluating bodies are in contact?**
    Not relevant

14. **How is the evaluation and start/set up of follow up actions of a possible (new and emerging) risks organised?**
    Not relevant

15. **What were the costs for setting-up or building the system? What does the maintenance and operation of the system cost?**
    Not relevant

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1. **What is the name of the system/registry/instrument?** Strategies in finding NERCs

2. **What is the goal of the system/method/instrument/database?**
   To develop a stepwise comprehensive strategy including follow-up measures, where needed, in the identification of NERCs for Workers, Consumers and Environment in order to manage, restrict or reduce the exposure of such compounds.

3. **Is it aimed at identifying possible (new and emerging) risks? Or can it be used for that goal?**
   Yes for Workers completed, for environment almost completed and for Consumers under development

4. **Which organization collects the information on possible (new and emerging) risks?**
   RIVM

5. **Which language is used in the system?** English

6. **Is it publicly available or not?** Yes

7. **What is the scope of the system/method/instrument?**
   To identify and evaluate NERCs for the three compartments Workers, Consumers and Environment

8. **What definition is used for new or emerging risks?**
   The definition of EU-OSHA (EU-OSHA, 2009) is used in this report for New or Emerging Risks of Chemicals (NERCs) involving both new and emerging risks:
   **New risks:**
   - the issue is new and caused by new types of substances, new processes, new technologies, new types of workplaces, or social or organizational change; or
   - a risk due to a change in social or public perceptions (e.g. stress, bullying); or
   - new scientific knowledge allows a longstanding issue to be identified as a risk (e.g. repetitive strain injury (RSI) where cases have existed for decades without being identified as RSI because of a lack of scientific evidence).
   **Emerging risks:**
   - number of hazards leading to the risk is growing; or
   - likelihood of exposure to the hazard leading to the risk is increasing, (exposure degree and/or the number of people exposed), or
   - effect of the hazard on the workers’ health is getting worse, or
   - More or new information becomes available.

9. **In which way are signals on possible (new and emerging) risks obtained?**
   Various sources, e.g. scientific literature, news sites, websites, electronic databases, stakeholder networks

10. **Are possible (new and emerging) risks collected and stored in a someway (national database)? Is there some kind of registration procedure and does it work?**
    A Risk Management Options Analysis (RMOa) under REACH will be carried out for identified NERCs.

11. **How is a first report of a possible (new and emerging) risks evaluated and what are the criteria used to evaluate reported signals?**
    For both Workers and Environment NERCs are identified by means of prioritization procedure

12. **Who evaluates a first report of a possible (new and emerging) risks?**
    Experts of the RIVM and of international Networks

13. **Is there a plan for communication of a (new and emerging) risk between the reporter/notifier and the evaluating body take place? Which evaluating bodies are in contact?**
    Identified NERCs will be transferred to responsible regulation bodies and/or ministries

14. **How is the evaluation and start/set up of follow up actions of a possible (new and emerging) risks organised?** System is under development
15. **What were the costs for setting-up or building the system? What does the maintenance and operation of the system cost?**

The estimated cost for the set-up the system are in the range of 500 kEUR

16. **Additional comments**

This still ongoing project has established a useful methodology to identify NERCs for Workers, an almost finished procedure for the Environment, and a strategy under development for Consumers.
1. **What is the name of the system/registry/instrument?** Addressing chemicals of potential concern within the context of the REACH Regulation and Prioritisation of substances of very high concern (SVHCs) for inclusion in the Authorisation List (Annex XIV) and the SVHC Roadmap.

2. **What is the goal of the system/method/instrument/database?**

   Uses of substances with certain hazardous properties can be of concern for human health and/or the environment. Those substances that potentially have such properties need to be identified and subsequently processed using relevant regulatory steps within the context of the REACH Regulation to make sure that the risks associated with their use are properly addressed. Priority lists of substances that result from the work of the national authorities and ECHA are published by ECHA on its website. There are different activities and regulatory processes such as hazard assessment, compliance check and substance evaluation when there is need for further information. When there is no need for further information is there is a concern a risk management analysis will be done from which the most appropriate option will follow such as harmonised classification, placement on the candidate list of substance of very high concern, inclusion in annex VII (restrictions), annex XIV application for authorisation or other legislation.

3. **Is it aimed at identifying possible (new and emerging) risks? Or can it be used for that goal?**

   Yes, the primary goal is to identify, address and regulate substances of very high concern. REACH does not include all uses of chemicals though. Only industrial chemicals (including cosmetics) with a volume of 1 ton or more placed on the market in the EU are covered. Many kinds of chemicals are outside the scope of REACH such as medicines, pesticides, biocides, food and feed additives and others. To some extent, new or emerging risk can be identified and dealt with but the scope is mainly limited to registered substances only. A screening and prioritisation approach is used to select the most relevant substances for amongst others placing on annex XIV, authorisation list.

4. **Which organization collects the information on possible (new and emerging) risks?**

   Primary source of information are the registration dossiers as well as the CLP-inventory and the SVHC in articles notification but also other data sources are used in the screening and prioritisation procedures. Registration dossiers are built by the registrants, industrial companies and submitted to ECHA. Besides the registration dossier database ECHA also manages the CLP-inventory and the SVHC in articles inventory.

5. **Which language is used in the system?** English

6. **Is it publicly available or not?** Yes, the information and the status of all the processes are publicly available to some extent at the ECHA website. Not all of the information in the registration dossiers is publicly available though.

7. **What is the scope of the system/method/instrument?**

   The REACH regulation covers the environment as well as consumers and worker health.

8. **What definition is used for new or emerging risks?**

   REACH regulatory processes conducted by ECHA and the EU member states focus on chemicals of concern and safe use of chemicals rather than finding new or emerging risks.

9. **In which way are signals on possible (new and emerging) risks obtained?**

   ECHA and the Member State competent authorities have developed a common screening approach to systematically screen available information for substances in the REACH registration dossiers and other databases to identify substances of concern. Substance of concern are those meeting the criteria for inherent properties as defined in article 57 and information as article 58 (3) of the REACH regulation. Groups of substances included are CMRs, sensitisers, PBTs, vPvBs, endocrine disruptors or substances with equivalent concern. The term “screening” process is used to identify and investigate substance (and dossiers) specific information, to make a...
preliminary assessment to support conclusion on how to proceed with the substance. The focus is on the criteria/properties defined in article 57 combined with criteria as defined in article 58 related to the use of a substance such as market volume, wide dispersive, professional and industrial use. Comparing structural similarity to substances on the Candidate List, to other substances is a way to identify new or emerging chemicals substances.

10. Are possible (new and emerging) risks collected and stored in a someway (national database)? Is there some kind of registration procedure and does it work?
There are several working lists of chemicals of concern depending on the evaluation phase they are in, such as lists of chemicals considered for compliance check, substance evaluation or chemicals going for risk management analysis that might be managed thru authorisation, restriction etc.

11. How is a first report of a possible (new and emerging) risks evaluated and what are the criteria used to evaluate reported signals?
   Article 57 and 58 (3) criteria and others, see question 9

12. Who evaluates a first report of a possible (new and emerging) risks?
   ECHA and EU member state competent authorities

13. Is there a plan for communication of a (new and emerging) risk between the reporter/notifier and the evaluating body take place? Which evaluating bodies are in contact?
   There is intensive communication through the ECHA website on the status of all chemicals addressed and the different regulatory processes ongoing.

14. How is the evaluation and start/set up of follow up actions of a possible (new and emerging) risks organised?
   There are different possibilities such a RMO analysis and follow up actions and regulatory processes such as the authorisation procedure, restriction and harmonised classification and labelling.

15. What were the costs for setting-up or building the system? What does the maintenance and operation of the system cost?
   Some information on costs might be available in different REACH functioning evaluation reports. REACH REFIT program. Operating Expenditure for REACH by ECHA covering the implementation of the REACH process is about 14 million Euros in 2017. Important to note that the activities included in this number go beyond the activities employed for the identification/screening for substances of concern. The budget for evaluation is 260 000 Euros and for Risk management 900 000 Euros. This excludes the expenditure by the EU member state authorities involved, see

1. What is the name of the system /registry/instrument?
   Expert forecast on emerging chemical risks related to occupational safety and health

2. What is the goal of the system/method/instrument/database?
   An expert forecast on emerging chemical OSH risks

3. Is it aimed at identifying possible (new and emerging) risks? Or can it be used for that goal? Yes

4. Which organization collects the information on possible (new and emerging) risks?
   The European Agency for Safety and Health at work.

5. Which language is used in the system? English

6. Is it publicly available or not? Yes

7. What is the scope of the system/method/instrument?
   Workers
   Scale (national, EU, Intercontinental) European
   Compartments (air, water, soil, consumers, workers, industrial chemicals, biocides, cosmetics etc.);
   Inhalation and dermal exposure of workers to industrial chemicals.

Six literature reviews explore in more depth the main emerging risks singled out in the forecast in terms of context, workers at risk, health and safety outcomes and prevention: nanoparticles; epoxy resins; man-made mineral fibers; dermal exposure to dangerous substances; dangerous substances in waste treatment activities; poor control of chemical risks in small and medium enterprises (SMEs).

8. What definition is used for new or emerging risks?
   An ‘emerging OSH risk’ is defined as any occupational risk that is both new and increasing. By ‘new’ it means that:
   - the risk was previously unknown and is caused by new processes, new technologies, new types of workplace, or social or organizational change; or
   - a longstanding issue is newly considered as a risk due to a change in social or public perceptions; or
   - new scientific knowledge allows a longstanding 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).

9. In which way are signals on possible (new and emerging) risks obtained?
   Automated procedure, expert judgement, expert panels, internet communication platforms
   Type of sources consulted (News Letters, Databases, Digital Media, Scientific papers, symposia etc.)
   A survey of European experts was undertaken to identify emerging occupational safety and health chemical risks. The Delphi method was used in order to reach a broad consensus and to avoid non-scientifically founded opinions A first exploratory survey round carried out in 2004 aimed to identify the risks which the experts reckoned to be emerging. A questionnaire with open-ended questions was developed to help the experts formulate their views as to the emerging OSH chemical risks of the next 10 years. The experts were invited to fill in the questionnaire electronically or on paper.
   A second questionnaire-based survey round was carried out in 2005 which aimed to validate and complement the results of the first round. The questionnaire presented a list, drafted from the first round responses and with an indication of the number of times each item was suggested. The
questionnaire invited participants to rate each item, independently from the others, on a five-point Likert scale (non-comparative scaling process). The scale ranged from ‘strongly disagree that the issue is an emerging risk’, through ‘undecided’ to ‘strongly agree that the issue is an emerging risk’. The experts could add new risks to the list.

The third questionnaire also consisted of a non-comparative scaling process whereby the respondents were asked to rate each issue independently from the others on the same five-point Likert scale used in the second round. The prioritised list of emerging risks established at the end of the third survey round formed the expert forecast on emerging OSH chemical risks.

10. **Are possible (new and emerging) risks collected and stored in a someway (national database)? Is there some kind of registration procedure and does it work?**

No, the registry is based on expert knowledge. The experts were proposed by members of the Topic Centre Research on Work and Health (TCWH) and the focal points of the Agency to ensure a broad coverage of qualified expertise across the EU. For their answers to be taken into consideration, the respondents had to have at least five years’ experience in the field of dangerous substances and related risks.

11. **How is a first report of a possible (new and emerging) risk evaluated and what are the criteria used to evaluate reported signals?**

   Level to which automated procedures, expert judgement, manual work is needed

   Not applicable since the Delphi method was used to identify a NERC. The Delphi method is based on expert judgement.

12. **Who evaluates a first report of a possible (new and emerging) risk?**

   Not applicable since the Delphi method was used to identify a NERC. The Delphi method is based on expert judgement.

13. **Is there a plan for communication of a (new and emerging) risk between the reporter/notifier and the evaluating body take place? Which evaluating bodies are in contact?**

   Communication between reporter/notifier and the evaluating body is not applicable because of the method chosen (Delphi method). Communicated to the public is done by ‘expert forecasts of emerging risks’ by the European Agency for Safety and Health at work.

14. **How is the evaluation and start/set up of follow up actions of a possible (new and emerging) risks organised?**

   The Delphi method is used to identify and evaluate possible NERCs. The results of this expert survey on emerging chemical risks are based on scientific expertise and should be seen as a basis for discussion among stakeholders to set priorities for further research and actions. Possible follow up actions mentioned are the derivation of occupational exposure limits for CRM.

15. **What were the costs for setting-up or building the system? What does the maintenance and operation of the system cost?**

   No information

16. **Additional comments**

**Concluding questions (A and B):**

A. **Does the measure support the development of an early warning system for chemical risks?**

   No, it depends on expert judgement of NERCs that already were identified in the past, and need to be controlled in a better way.

B. **Does the measure improve the knowledge of and access to information on chemical risks?**

   No

1. **What is the name of the system/registry/instrument?**
   Green jobs and occupational safety and health: Foresight on new and emerging risks associated with new technologies by 2020

2. **What is the goal of the system/method/instrument/database?**
   Develop scenarios of the future in order to anticipate new and emerging risks to occupational safety and health associated with a range of new technologies in green jobs. This foresight will be used by EU-OSHA to inform EU policymakers, Member States’ governments, trade unions and employers, so that they can make better decisions in order to shape the future of occupational safety and health (OSH) in green jobs leading to safer and healthier workplaces.

3. **Is it aimed at identifying possible (new and emerging) risks? Or can it be used for that goal?**
   Yes, it can be used for that goal

4. **Which organization collects the information on possible (new and emerging) risks?**
   European Agency for Safety and Health at Work

5. **Which language is used in the system?**
   English

6. **Is it publicly available or not?**
   Yes

7. **What is the scope of the system/method/instrument?**
   
   Scale (national, EU, Intercontinental)
   Compartments (air, water, soil, consumers, workers, industrial chemicals, biocides, cosmetics etc.)

   The subject of this report, was the identification of the key technological innovations that may be introduced in green jobs over the next ten years that may lead to new and emerging risks in the workplace or have a positive impact on workers’ safety and health. The decision to use a scenario-building approach project arose out of the workshop ‘Shaping the future of OSH — A workshop on foresight methodologies’ hosted by EU-OSHA’s European Risk Observatory (ERO) in October 2008. The ERO wished to build on earlier forecast exercises, comprising Delphi studies in four different risk areas, which had produced useful summaries and prioritization of key risks as assessed by experts. However, it was felt that in order to consider likely occupational health and safety risks further into the future, an alternative technique should be used. The scenario-building approach was selected as a suitable vehicle to provide a forward look. European scale Compartments: Inhalation and dermal exposure of workers

8. **What definition is used for new or emerging risks?**
   An ‘emerging OSH risk’ is defined as any occupational risk that is both new and increasing. By ‘new’ it means that:
   - the risk was previously unknown and is caused by new processes, new technologies, new types of workplace, or social or organizational change; or
   - a longstanding issue is newly considered as a risk due to a change in social or public perceptions; or
   - new scientific knowledge allows a longstanding 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).

9. **In which way are signals on possible (new and emerging) risks obtained?**
   Automated procedure, expert judgement, expert panels, internet communication platforms
Type of sources consulted (News Letters, Databases, Digital Media, Scientific papers, symposia etc.)

This two-year project was conducted between 2010 and 2012 over three phases and the methodology for each of these is described in Chapter 2 of the report.

Phase 1 was to select the key contextual drivers for new and emerging OSH risks associated with new technologies in green jobs by 2020. These drivers are the major forces or trends that will shape the future environment for workers in green jobs. Those that will have the greatest impact on the range of different future environments were used to define the scenarios. The drivers and the results of the selection process are set out in Chapter 3 of the report.

Phase 2 was to identify key new technologies that could contribute to creating new and emerging risks in green jobs by 2020. These were reviewed to select the nine key technologies where there would be the most significant new and emerging OSH risks. The data and results of this are contained in Chapter 4.

Phase 3 saw the development of the base scenarios using the key contextual drivers of change from Phase 1. These base scenarios were then used through a series of workshops to explore the respective development of the key technologies from Phase 2 and their impact on OSH in each of the scenarios. The information generated through this process was then integrated into the base scenarios to produce the full scenarios. The descriptions of the base scenarios, the process of their development and the technology developments and their OSH implications are set out in Chapter 5.

The scenarios were tested and consolidated in a consolidation workshop during which it was also demonstrated how the scenarios can be used to support OSH policymaking: the conclusions and the results of the consolidation workshop are in Chapter 6.

The final set of scenarios and guidance on their use are in Chapter 7. The conclusions are in Chapter 8.

10. Are possible (new and emerging) risks collected and stored in a someway (national database)? Is there some kind of registration procedure and does it work?
   Possible NERCs identified by expert judgement are collected and published in a report.

11. How is a first report of a possible (new and emerging) risks evaluated and what are the criteria used to evaluate reported signals?
   Level to which automated procedures, expert judgement, manual work is needed
   Not applicable; it is scenario buildings by expert judgement

12. Who evaluates a first report of a possible (new and emerging) risks? Not applicable; it is expert judgement

13. Is there a plan for communication of a (new and emerging) risk between the reporter/notifier and the evaluating body take place? Which evaluating bodies are in contact?
   Communicated to the public is done by ‘European risk observatories’ by the European Agency for Safety and Health at work.

14. How is the evaluation and start/set up of follow up actions of a possible (new and emerging) risks organised?
   Phase I: contextual drivers of change:
   - WP1.1: literature review
   - WP1.2: interviews with experts and internet based exercise to consolidate the list of drivers
   - WP1.3: Voting exercise to prioritise the drivers

   Phase II: key technologies
   - WP2.1: Review of existing material
   - WP2.2: Consultation (interviews and internet based survey) using expertise of key people who may be aware of important technological innovations not yet published
   - Selection of key technologies by invited experts

   Phase III: Scenarios
   - WP3.1: Scenario development. Technology workshops were held to explore the development pathways for each technology across the scenarios and the respective OSH
implications. Invitees included a mixture of technical experts and OSH experts as well as members of EUOSHA’s Prevention and Research Advisory Group

- WP3.2: testing and consolidating the scenarios in a workshop

15. What were the costs for setting-up or building the system? What does the maintenance and operation of the system cost? No information

16. Additional comments

**Concluding questions (A and B):**

A. Does the measure support the development of an early warning system for chemical risks?  
Yes, could be. Identification of the key technological innovations that may be introduced in green jobs over the next ten years may lead to new and emerging risks in the workplace

B. Does the measure improve the knowledge of and access to information on chemical risks?  
Yes. It may improve knowledge of key technological innovations that may lead to NERCs.

1. What is the name of the system /registry/instrument?
Detecting emerging risks for workers and follow-up actions

2. What is the goal of the system/method/instrument/database?
Making an overview of new and emerging risks of chemicals for workers of the last decade.

3. Is it aimed at identifying possible (new and emerging) risks? Or can it be used for that goal?
Yes, it makes an overview of new and emerging risks identified by using different methods (clinical watch systems, periodic literature screening, data mining)

4. Which organization collects the information on possible (new and emerging) risks?
National Institute of Public Health and the Environment (RIVM)

5. Which language is used in the system? English

6. Is it publicly available or not? Yes

7. What is the scope of the system/method/instrument?
   Scale (national, EU, Intercontinental)
   Compartments (air, water, soil, consumers, workers, industrial chemicals, biocides, cosmetics etc.); International; Inhalation and dermal exposure of workers

8. What definition is used for new or emerging risks?
   An ‘emerging OSH risk’ is defined as any occupational risk that is both new and increasing.
   By ‘new’ it means that:
   - the risk was previously unknown and is caused by new processes, new technologies, new types of workplace, or social or organizational change; or
   - a longstanding issue is newly considered as a risk due to a change in social or public perceptions; or
   - new scientific knowledge allows a longstanding 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).

9. In which way are signals on possible (new and emerging) risks obtained?
   Automated procedure, expert judgement, expert panels, internet communication platforms
   Type of sources consulted (News Letters, Databases, Digital Media, Scientific papers, symposia etc.). Signals are obtained by expert judgement and expert panels
   Sources: literature search, symposia, notifications in early warning systems

10. Are possible (new and emerging) risks collected and stored in a someway (national database)? Is there some kind of registration procedure and does it work?
   Yes, they are collected in a database by the national institute of public health and environment (RIVM). At this moment RIVM together with National Centre of Occupational Disease (NCOD) are developing a bibliographic reference base for new and emerging occupational health risks. It is a new tool to facilitate the search for similar cases and report evidence from the literature. A reference database is currently built of case descriptions for new and emerging occupational health risks from different sources to be used within the MODERNET network. This online database can both be consulted and complemented by registered users.

1 MODERNET: Monitoring trends in Occupational Diseases and tracing new and Emerging Risks in a NETwork
11. How is a first report of a possible (new and emerging) risks evaluated and what are the criteria used to evaluate reported signals?
   Level to which automated procedures, expert judgement, manual work is needed

12. Who evaluates a first report of a possible (new and emerging) risks? Not applicable

13. Is there a plan for communication of a (new and emerging) risk between the reporter/notifier and the evaluating body take place? Which evaluating bodies are in contact? Not applicable

14. How is the evaluation and start/set up of follow up actions of a possible (new and emerging) risks organised?
   After prioritising the identified new and emerging risks (see Palmen and Verbist, 2014), a Risk Management Options Analysis identifies the best regulatory option to manage the risk for substances of very high concern, either in REACH (Authorisation, Restriction or Substance Evaluation) or outside of REACH (with another legislation).

15. What were the costs for setting-up or building the system? What does the maintenance and operation of the system cost? No information

16. Additional comments

Concluding questions (A and B):
   A. Does the measure support the development of an early warning system for chemical risks?
      No, the measure gives an overview of potential NERCs, which need to be evaluated further.
   B. Does the measure improve the knowledge of and access to information on chemical risks?
      Yes, RIVM together with NCOD is developing a bibliographic reference base for new and emerging occupational health risks.
Workers Literature source: Prioritization of new and emerging chemical risks for workers and follow-up actions, N.G.M. Palmen and K.J.M Verbist, RIVM report 2015-009

1. **What is the name of the system /registry/instrument?**
Prioritization of new and emerging chemical risks for workers and follow-up actions, N.G.M. Palmen and K.J.M Verbist, RIVM report 2015-0091

2. **What is the goal of the system/method/instrument/database?**
Prioritization of New and Emerging risks identified in Palmen et.al. (2013) and making an overview of measures already taken (information from EU databases).

3. **Is it aimed at identifying possible (new and emerging) risks? Or can it be used for that goal?**
No. It is aimed to prioritise new and emerging risks and check which measures are already taken to control the health risk.

4. **Which organization collects the information on possible (new and emerging) risks?**
National Institute of Public Health and the Environment (RIVM)

5. **Which language is used in the system?** English

6. **Is it publicly available or not?** Yes

7. **What is the scope of the system/method/instrument?**
Scale (national, EU, Intercontinental) Compartment (air, water, soil, consumers, workers, industrial chemicals, biocides, cosmetics etc.)/ International/ Inhalation and dermal exposure of workers

8. **What definition is used for new or emerging risks?**
An ‘emerging OSH risk’ is defined as any occupational risk that is both new and increasing.

By ‘new’ it means that:
- the risk was previously unknown and is caused by new processes, new technologies, new types of workplace, or social or organizational change; or
- a longstanding issue is newly considered as a risk due to a change in social or public perceptions; or
- new scientific knowledge allows a longstanding 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).

9. **In which way are signals on possible (new and emerging) risks obtained?**
Automated procedure, expert judgement, expert panels, internet communication platforms Type of sources consulted (News Letters, Databases, Digital Media, Scientific papers, symposia etc.); Not applicable

10. **Are possible (new and emerging) risks collected and stored in some way (national database)? Is there some kind of registration procedure and does it work?**

11. **How is a first report of a possible (new and emerging) risks evaluated and what are the criteria used to evaluate reported signals?**
Level to which automated procedures, expert judgement, manual work is needed

12. **Who evaluates a first report of a possible (new and emerging) risks?** Not applicable

13. **Is there a plan for communication of a (new and emerging) risk between the reporter/notifier and the evaluating body take place? Which evaluating bodies are in contact?** Not applicable

14. **How is the evaluation and start/set up of follow up actions of a possible (new and emerging) risks organised?**
After prioritization, a Risk Management Options Analysis is made to identify the best regulatory option to manage the risk for substances of very high concern, either in REACH (Authorisation, Restriction or Substance Evaluation) or outside of REACH (with another legislation).

15. What were the costs for setting-up or building the system? What does the maintenance and operation of the system cost? No information

16. Additional comments

Concluding questions (A and B):
A. Does the measure support the development of an early warning system for chemical risks?
   No, the measure prioritises potential NERCs, which need to be evaluated further

B. Does the measure improve the knowledge of and access to information on chemical risks?
   Yes, RIVM together with NCOD is developing a bibliographic reference base for new and emerging occupational health risks
Workers & Consumers

1. What is the name of the system / registry / instrument?
Position Statement on emerging and newly identified health risks to be drawn to the attention of the European Commission, Scientific Committee on Emerging and Newly-Identified Health Risks (SCENIHR), 2014.

2. What is the goal of the system / method / instrument / database?
Draw the attention of the EU Commission Services to emerging issues in the non-food area that have been identified by the SCENIHR members as having the potential to significantly impact human health and / or on the environment in the future.

3. Is it aimed at identifying possible (new and emerging) risks? Or can it be used for that goal?
No, it is aimed to address attention of the EU Cie to issues addressed by the SCENIHR members. SCENIHR members were free to suggest issues to be evaluated.

4. Which organization collects the information on possible (new and emerging) risks?
Not applicable

5. Which language is used in the system?
Not applicable

6. Is it publicly available or not?
Not applicable

7. What is the scope of the system / method / instrument?
Scale (national, EU, Intercontinental)/ Compartments (air, water, soil, consumers, workers, industrial chemicals, biocides, cosmetics etc.)/ Not applicable

8. What definition is used for new or emerging risks?

1) Exposure categories:
- Agriculture and food, drinking water (chemicals, pesticides, nanomaterials, microorganisms ….)
- Consumer products (chemicals, pesticides, nanomaterials, microorganisms ….)
- Energy and energy transmission
- Environmental changes
- Evolution of diseases and microbial pathogens
- Medical technology
- Pharmaceuticals (excluding drugs: vaccines, DNA & synthetic biology, blood ….)
- Social and lifestyle activities
- Urban engineering

2) Suggested hazard categories:
A. New origin of risk
   - Development and implementation of new technologies
   - Newly identified pathogens
B. 'New modifier with pre-existing Origin'
   - Emerging issue related to a change in collective human behaviour
   - Emerging issue related to changing environmental factors
C. Change in 'scientific knowledge'
D. Risk perception by the Society

9. In which way are signals on possible (new and emerging) risks obtained?
Automated procedure, expert judgement, expert panels, internet communication platforms/ Type of sources consulted (News Letters, Databases, Digital Media, Scientific papers, symposia etc.)/ Not applicable

10. Are possible (new and emerging) risks collected and stored in a someway (national database)? Is there some kind of registration procedure and does it work? Not Applicable

11. How is a first report of a possible (new and emerging) risks evaluated and what are the criteria used to evaluate reported signals?
Level to which automated procedures, expert judgement, manual work is needed/ Not Applicable

12. Who evaluates a first report of a possible (new and emerging) risks? Not Applicable

13. Is there a plan for communication of a (new and emerging) risk between the reporter/notifier and the evaluating body take place? Which evaluating bodies are in contact? Not Applicable

14. How is the evaluation and start/set up of follow up actions of a possible (new and emerging) risks organised? Not Applicable

15. What were the costs for setting-up or building the system? What does the maintenance and operation of the system cost? No information

16. Additional comments

Concluding questions (A and B):
   A. Does the measure support the development of an early warning system for chemical risks?
      No, it is based on expert judgement of NERCs that were identified already and need the attention of the European Commission.
   B. Does the measure improve the knowledge of and access to information on chemical risks? No
Workers Literature source: Early warning systems to detect new and emerging risks in Europe, RIVM Letter report 2016-0022

1. **What is the name of the system/registry/instrument?**
The publication gives an overview of available early warning systems used in European countries:
- Clinical watch systems
- Databases
- Biomarkers

2. **What is the goal of the system/method/instrument/database?**
Identification, evaluation and control of potential NERCs

3. **Is it aimed at identifying possible (new and emerging) risks? Or can it be used for that goal?**
Yes, several early warning systems were identified specifically designed for that purpose

4. **Which organization collects the information on possible (new and emerging) risks?**
It depends on the system; see the report.

5. **Which language is used in the system?**
It depends on the system. This question is not answered in the report.

6. **Is it publicly available or not?**
It depends on the system; see the report.

7. **What is the scope of the system/method/instrument?**
Scale (national, EU, Intercontinental)
Compartments (air, water, soil, consumers, workers, industrial chemicals, biocides, cosmetics etc.)
Most systems are national systems. One system (OccWatch designed by ANSES, France) is international.
Compartments: Inhalation and dermal exposure of workers

8. **What definition is used for new or emerging risks?**
It depends on the system; this question is not answered in the report.

9. **In which way are signals on possible (new and emerging) risks obtained?**
Automated procedure, expert judgement, expert panels, internet communication platforms
Type of sources consulted (News Letters, Databases, Digital Media, Scientific papers, symposia etc.)
It depends on the system; this question is answered in the report.

10. **Are possible (new and emerging) risks collected and stored in a someway (national database)? Is there some kind of registration procedure and does it work?**
It depends on the system; this question is answered in the report.

11. **How is a first report of a possible (new and emerging) risks evaluated and what are the criteria used to evaluate reported signals?**
Level to which automated procedures, expert judgement, manual work is needed
It depends on the system; this question is answered in the report.

12. **Who evaluates a first report of a possible (new and emerging) risks?**
It depends on the system; this question is answered in the report.

13. **Is there a plan for communication of a (new and emerging) risk between the reporter/notifier and the evaluating body take place? Which evaluating bodies are in contact?**
It depends on the system; this question is answered in the report.

14. **How is the evaluation and start/set up of follow up actions of a possible (new and emerging) risks organised?**
It depends on the system; this question is not answered in the report.

15. **What were the costs for setting-up or building the system? What does the maintenance and operation of the system cost?**
No information

16. **Additional comments**

**Concluding questions (A and B):**
A. **Does the measure support the development of an early warning system for chemical risks?**
   Yes, this report gives an overview of available early warning systems in Europe.

B. **Does the measure improve the knowledge of and access to information on chemical risks?**
   Yes, it will give information on health effects of chemicals that were not identified already.

1. What is the name of the system/registry/instrument?

Wild cards and weak signals (WI-WE) analyses used in foresight and horizon scanning could be applied to emerging risks identification, so as to support strategic processes aimed to anticipate changes, build resilience and prevent undesirable food safety surprises. Through the application of foresight and horizon scanning, potential emerging risks can be identified systematically by:

1. Identifying and analysing drivers of change, as underlying causes of emerging risks.
2. Developing scenarios (including wild cards) associated to the drivers of change.
3. Identifying, characterising and interpreting weak signals linked to potential scenarios.

2. What is the goal of the system/method/instrument/methodology/database?

A number of areas of concern were identified across the agro-food industry and some challenging issues to be addressed by policy-makers were identified. These include: (1) the harmonisation of national agricultural laws and policies which differ between EU members and other countries regarding, for example, the usage, typology and quantity of pesticides; (2) the promotion of more stringent controls for external factors affecting food products such as: export, terrorism, sabotage, hygiene, cross-contamination, etc.; (3) the monitoring and assessment of new technologies and novel foodstuff with uncertain impacts on health, such as Genetically Modified Foods and radiation, among others; (4) the implementation of effective internal risk analysis within businesses using better tools and methods to detect critical control points and other hazards; and (5) the Maintenance of a good communication and dialogue with all stakeholders in the food supply chain.

The identification of potential emerging risks often involves the combination of creative activities (i.e. brainstorming and scenarios workshops) with other activities interconnecting knowledge based on evidence (e.g. indicators from RASFF5 database), expertise (e.g. interviews) and interaction of key players (e.g. conferences). The identification of emerging risks also requires a structured and forward-looking intelligence approach, whereby networking plays a key role in the analysis and communication of emerging risks and drivers of change. To ensure that not only emerging risks but also potential opportunities in food safety are captured, it is important to promote foresight and horizon scanning processes, as they often involve multidimensional reasoning.

3. Is it aimed at identifying possible (new and emerging) risks? Or can it be used for that goal? Yes it can, but the methods are not described in the current summary report.

4. Which organization collects the information on possible (new and emerging) risks?

Information is collected by an interactive community.

5. Which language is used in the system? English

6. Is it publicly available or not?

   a. Scale (national, EU, Intercontinental)
   b. Compartments (air, water, soil, consumers, workers, industrial chemicals, biocides, cosmetics etc.)
   c. The system is available at world scale. Policy/research trends are being collected. Novel ways for risk analyses are used such as wild cards and weak signals (WI-WE) analyses.

7. What definition is used for new or emerging risks?

Foresight is a systematic, participatory, prospective and policy-oriented process which, with the support of environmental and horizon scanning approaches, is aimed to actively engage key stakeholders into a wide range of activities “anticipating, recommending and transforming” (ART) “technological, economic, environmental, political, social and ethical” (TEEPSE) futures. Horizon Scanning (HS) is a structured and continuous activity aimed to “monitor, analyse and position” (MAP) “frontier issues” that are relevant for policy, research and strategic agendas. The types of issues mapped by HS include new/emerging: trends, policies, practices, stakeholders, services, products, technologies, behaviours, attitudes, “surprises” (Wild Cards) and “seeds of change” (Weak Signals).
8. *In which way are signals on possible (new and emerging) risks collected?*
   Automated procedure, expert judgement, expert panels, internet communication platforms
   Type of sources consulted (News Letters, Databases, Digital Media, Scientific papers, symposia etc.)/ NA

9. *Are possible (new and emerging) risks collected in a someway (national database)? How is the registration done?NA*

10. *How is a first report of a possible (new and emerging) risks evaluated and what are the criteria used to evaluate reported signals?*
    a. Level to which automated procedures, expert judgement, manual work is needed/ NA

11. *Who evaluates a first report of a possible (new and emerging) risks? NA*

12. *Is there a plan for communication of a (new and emerging) risk between the reporter/notifier and the evaluating body take place? Which evaluating bodies are in contact? NA*

13. *How does the evaluation and start/set up of follow up of a possible (new and emerging) risks take place?NA*

14. *What has costed the set-up building of the system? What does the Maintenance of the system cost? NA*
1. **What is the name of the system/registry/instrument?**
   Emerging Risks Identification: an appraisal of the approaches trialled by EFSA/EMRISK

2. **What is the goal of the system/method/instrument/methodology/database?**
   EFSA has a legal basis on the identification of emerging risks.
   Article 34 of the food and feed safety directive says the following:
   1. The Authority shall establish monitoring procedures for systematic searching for, collecting, collating and analysing information and data with a view to the identification of emerging risks in the fields within its mission.
   2. Where the Authority has information leading it to suspect an emerging serious risk, it shall request additional information from the Member States, other Community agencies and the Commission. 3. The Authority shall use all the information it receives in the performance of its mission to identify an emerging risk.
   4. The Authority shall forward the evaluation and information collected on emerging risks to the European Parliament, the Commission and the Member States.

3. **Is it aimed at identifying possible (new and emerging) risks? Or can it be used for that goal?**
   Yes, this system is built for the identification of new problems (not necessarily incidents or crises), to better anticipate risk assessment needs. It investigates:
   - New and emerging hazard or drivers
   - New research issues
   - New risk assessment methodologies

4. **Which organization collects the information on possible (new and emerging) risks?**
   The key players for data collection are:
   - EU Member States and Norway and observers from the European Commission, EU pre-accession countries, the FDA and FAO.
   - StaCG-ER is composed of EU-wide stakeholder organisations working in areas related to the food chain. The selection of members for StaCG-ER was based on the individual expertise of the nominees, and to ensure a balanced representation of both industry and consumers.
   - The SC’s SWG on Emerging Risks was created in 2013 and includes representatives from EFSA Panels.
   - EC.

5. **Which language is used in the system? English**

6. **Is it publicly available or not?**
   a. Scale (national, EU, Intercontinental)
   b. Compartments (air, water, soil, consumers, workers, industrial chemicals, biocides, cosmetics etc.)

   It is outcasted by EFSA. The focus is the EU but global signals are being screened.

7. **What definition is used for new or emerging risks?**
   The definition is a mixture between certain areas of focus being:
   - New hazard
   - New exposure
   - Increased susceptibility
   - Differentiation between
   - Emerging issue = suspicious of a serious risk
   - Emerging risk: “an emerging risk to human, animal and/or plant health is understood as a risk resulting from a newly identified hazard to which a significant exposure may occur or from an unexpected new or increased significant exposure and/or susceptibility to a known hazard” (Statement of the Scientific Committee, 10 July 2007).

8. **In which way are signals on possible (new and emerging) risks collected?**
a. Automated procedure, expert judgement, expert panels, internet communication platforms
b. Type of sources consulted (News Letters, Databases, Digital Media, Scientific papers, symposia etc.)

The following steps are part of the system as applied by EFSA:

a. Identification of priority issues: performed by SCER and Scientific Committee WG
   (Emerging issues are identified though e.g. Consultations with experts, MS Network, Stakeholders), Prioritization based on a set of agreed criteria, including the EFSA definition of ER.

Output 1: first priority list

b. Identification of Data Sources and Data collection. This is performed by the EMRISK Unit of EFSA. The data collection focuses on selected emerging issues identified and takes the available resources into account. It is a prioritization based on a set of agreed criteria, including the EFSA definition of ER.
   i. Output 2: first priority list

   ii. Output 2: first priority list

   c. Final Evaluation: Emerging Risks are Identified. This step is performed by the EMRISK Unit and the Scientific Committee WG.
      i. Output 3: emerging risks and recommendations for possible actions

During the data processing the following items are of importance for EFSA:

i. Medisys customization (search terminology using the European Media Monitor)
ii. Evaluation of a system for the scanning of Eurostat’s data to detect trends in trade
iii. Omics technologies in risk assessment
iv. Pilot study for the identification of emerging biological risks
v. A procedure for the identification of chemical risks
vi. Modern methodologies for human chemicals hazard assessment
vii. Chemical mixtures
viii. A framework for the risk assessment of chemical mixtures

9. Are possible (new and emerging) risks collected in someway (national database)? How is the registration done? NA

10. How is a first report of a possible (new and emerging) risks evaluated and what are the criteria used to evaluate reported signals?
    a. Level to which automated procedures, expert judgement, manual work is needed
    Emergent Risks Identification (ERI) is done by:
    b. Develop methodology and procedures (e.g. best practices for ERI);
    c. Data collection and tool development (e.g. Sc. Lit,RASFF, Media, Experts);
    d. Evaluation and prioritisation;
    e. Exchange of information (e.g. MS-Network, Stakeholders,Experts);


12. Is there a plan for communication of a (new and emerging) risk between the reporter/notifier and the evaluating body take place? Which evaluating bodies are in contact? NA

13. How does the evaluation and start/set up of follow up of a possible (new and emerging) risks take place? NA

14. What has costed the set-up building of the system? What does the maintenance of the system cost?
   As such the cost of this system is not mentioned in the report. Costs have however been predicted on a project basis and is mentioned below. This could be of support in the estimation of the costs of an EU side Early Warning System.
1. What is the goal of the system/method/instrument/methodology/database?


2. Is it aimed at identifying possible (new and emerging) risks? Or can it be used for that goal?

This report discusses (1) how CPSC’s authorities and other factors may affect the time it takes CPSC to respond to new and emerging risks and (2) proposed options that may be available to improve CPSC’s ability to respond to new and emerging risks in a timely manner and trade-offs associated with those options.

3. Which organization collects the information on possible (new and emerging) risks?

US Consumer Product Safety Commission (CPSC)

4. Which language is used in the system? English

5. Is it publicly available or not? NA

6. What is the scope of the system/method/instrument?

a. Scale (national, EU, Intercontinental) International literature is investigated but focus is on US
b. Compartments (air, water, soil, consumers, workers, industrial chemicals, biocides, cosmetics etc.)/ Consumers

7. What definition is used for new or emerging risks? NA

8. In which way are signals on possible (new and emerging) risks collected?

a. Automated procedure, expert judgement, expert panels, internet communication platforms
b. Type of sources consulted (News Letters, Databases, Digital Media, Scientific papers, symposia etc.)

To address both objectives, we reviewed our prior work on CPSC’s authorities, CPSC standard operating procedures, performance and accountability reports, and agency budget documentation in order to obtain information on the resources currently available to CPSC and how those resources may impact the agency’s ability to respond to new and emerging consumer product safety hazards. In addition to our document review, we interviewed cognizant CPSC officials, knowledgeable staff, and three current and three former CPSC commissioners, including CPSC’s acting Chairman, regarding CPSC’s ability and authority to identify, assess, and address new and emerging risks in a timely manner. 2 To gather perspectives on the sufficiency of CPSC’s current statutory authority and specific factors affecting its ability to respond to emerging risks and to seek opinions on potential options that may be available to CPSC to address these risks in a more timely manner, we interviewed representatives from four consumer advocate groups and representatives from seven industry organizations that represented manufacturers for various consumer products, including juvenile products, clothing and home goods, chemical production, and general consumer goods. We also interviewed six consumer safety experts, three of which were legal experts in the consumer product safety field regarding CPSC’s existing statutory and regulatory authorities for addressing new and emerging risks and other potential options available to CPSC.

9. Are possible (new and emerging) risks collected in a someway (national database)? How is the registration done? NA

10. How is a first report of a possible (new and emerging) risks evaluated and what are the criteria used to evaluate reported signals?

a. Level to which automated procedures, expert judgement, manual work is needed

To address objective one, we reviewed and analyzed relevant federal laws that authorize CPSC to both promulgate and enforce consumer product safety standards, as well as those that authorize
the agency to take corrective action necessary to remove a potentially hazardous product from the consumer market. We then examined CPSC rulemaking procedures as stipulated in relevant sections of the Consumer Product Safety Act, the Federal Hazardous Substances Act, and the Flammable Fabrics Act. We identified additional administrative and statutory requirements that may impede CPSC’s implementation of corrective action, and we reviewed CPSC’s ability to issue mandatory standards and enforce voluntary standards designed to address new and emerging consumer product safety hazards.

To address objective two, we conducted a literature review of scholarly articles using Proquest, Nexis.com, and law review databases. Some of the search terms we used to identify articles on options available to respond to new and emerging risks were “consumer safety,” “new and emerging risks,” “precautionary principle,” “premarket model,” and the “Consumer Product Safety Commission” either in combination or alone with geographic delimiters such as “European Union,” or “United States,” and a date boundary of “after 2007”. After removing duplicate articles, we selected 96 scholarly articles and legal reviews from the thousands that were identified based on the extent to which they discussed (1) advantages and disadvantages of the precautionary principle approach or premarket approval or (2) the regulation of relevant policy areas such as consumer product safety, public health, or the environment. Two team members independently reviewed these articles for relevance and found that 18 were relevant for our study. We reviewed these articles more closely for background information on CPSC’s authorities and factors that affect timeliness of responding to new and emerging risks and also to identify trade-offs for any options the article discussed. Similarly, we also searched for additional material on the Internet using search terms such as “United States,” “precautionary principle,” and “premarket approval” and identified an additional 4 articles that we used for contextual purposes.

11. Who evaluates a first report of a possible (new and emerging) risks? NA
12. Is there a plan for communication of a (new and emerging) risk between the reporter/notifier and the evaluating body take place? Which evaluating bodies are in contact?
   US Consumer Product Safety Commission (CPSC), experts, legal experts, consumer advocate groups and representatives from industry organizations.
13. How does the evaluation and start/set up of follow up of a possible (new and emerging) risks take place? NA
14. What has costed the set-up building of the system? What does the Maintenance of the system cost? NA
Consumers literature source: European Association of Poisons Centres and Clinical Toxicologists (EAPCCT)

1. What is the name of the system /registry/instrument? NA
2. What is the goal of the system/method/instrument/ methodology/database? NA
3. Is it aimed at identifying possible (new and emerging) risks? Or can it be used for that goal? NA
4. Which organization collects the information on possible (new and emerging) risks? NA
5. Which language is used in the system? NA
6. Is it publicly available or not?
   a. Scale (national, EU, Intercontinental) NA
   b. Compartments (air, water, soil, consumers, workers, industrial chemicals, biocides, cosmetics etc.) NA
7. What definition is used for new or emerging risks? NA
8. In which way are signals on possible (new and emerging) risks collected?
   a. Automated procedure, expert judgement, expert panels, internet communication platforms
   b. Type of sources consulted (News Letters, Databases, Digital Media, Scientific papers, symposia etc.) NA
9. Are possible (new and emerging) risks collected in a someway (national database)? How is the registration done?
10. How is a first report of a possible (new and emerging) risks evaluated and what are the criteria used to evaluate reported signals?
    a. level to which automated procedures, expert judgement, manual work is needed NA
11. Who evaluates a first report of a possible (new and emerging) risks?
    NA
12. Is there a plan for communication of a (new and emerging) risk between the reporter/notifier and the evaluating body take place? Which evaluating bodies are in contact?
13. How does the evaluation and start/set up of follow up of a possible (new and emerging) risks take place? NA
14. What has costed the set-up building of the system? What does the Maintenance of the system cost? NA
Consumers literature source: EFSA (2006). Forming a Global System for Identifying Food-related Emerging Risks, EMRISK

1. **What is the name of the system/registry/instrument?** EMRISK
2. **What is the goal of the system/method/instrument/methodology/database?** Identifying Food-related Emerging Risks
3. **Is it aimed at identifying possible (new and emerging) risks? Or can it be used for that goal?**
4. **Which organization collects the information on possible (new and emerging) risks?** EFSA, specific Unit
5. **Which language is used in the system?** English
6. **Is it publicly available or not?** NA
7. **What is the scope of the system?**
   a. Scale (national, EU, Intercontinental); Global, EU
   b. Compartments (air, water, soil, consumers, workers, industrial chemicals, biocides, cosmetics etc.)
8. **What definition is used for new or emerging risks?** No clear conclusion was mentioned in this document. In short, the document describes that the emerging character of the hazard that could give rise to a risk may be at different phases of the risk assessment process. It is essential that the system to be developed is adept at identifying and evaluating each step of a trajectory: from the early origins of a new hazard to its final consequences for a given adverse effect in human beings or animals. Therefore, the pre-early warning system should ensure the needed coherence with all steps of the risks assessment process including phase zero, but to different extents.
9. **In which way are signals on possible (new and emerging) risks collected?** In 2006 EFSA was in the process to set up a system. At that time it was thought to collect signals incorporating the following points:
   - Food information sources-European Union’s Rapid Alert System on food and feed (RASFF).
   - Rapid Alert System for Biological and Chemical Attacks and Threats (RAS-BICHAT)
   - USDA-FSIS/HHS-FDA CARVER+Shock method
   - Expert networks
   - Stakeholders
   - Consumer concerns
   - Conferences and symposia
   - Anticipatory systems
   - Several predictive instruments exist in different domains, such as IPCC/CRU, OECD/IEA, CDIAC, FDA/CRED, UNCHS/Habitat, GEMSFOOD, EMPRES (FAO), GRI (UNEP).
   a. Automated procedure, expert judgement, expert panels, internet communication platforms
   b. Type of sources consulted (News Letters, Databases, Digital Media, Scientific papers, symposia etc.)
10. **Are possible (new and emerging) risks collected in a someway (national database)? How is the registration done?** In order to be able to identify an emerging hazard as early as possible it is necessary to use indicators that are able to provide signals that indicate (directly or indirectly) the (possibility of) occurrence of this emerging hazard. According to the holistic vision these indicators should be sought in various influential sectors. In order to obtain the necessary information, related to these indicators, from various sources like databases or scientific experts it is important to ask the right questions in order to obtain the (most appropriate) answers, i.e. the predictive signals. Subsequently, evaluation of these signals may lead to a proactive alert that in turn will lead to actions analysing whether an emerging hazard gives rise to a risk. Summarised, the proposed blueprint of the pre-early warning system consists of the following key elements: influential sectors, indicators, questions, information sources and signals.
   Key sources of information: Sources related to the prioritised indicators are: veterinary and wildlife surveillance networks, outbreak management reports, human illness registration systems,
Apart from recognised sources like databases on morbidity/mortality, scientific publications, regular press and databases on food consumption surveys, it is stressed that no central databases exist on abnormal / atypical clinical findings in farmed and wild animals.

11. How is a first report of a possible (new and emerging) risks evaluated and what are the criteria used to evaluate reported signals?
   a. Level to which automated procedures, expert judgement, manual work is needed
   The starting point of the EMRISK project was to draw the information necessary for the identification of emerging risks from a combination of knowledge both from inside as well as from outside the food supply chain (i.e. covering the fork to farm continuum and its host environment). This holistic vision was used to identify the various influential sectors (areas of disciplines), which are more or less related to the food production chain.

12. Who evaluates a first report of a possible (new and emerging) risks? EFSA Unit

13. Is there a plan for communication of a (new and emerging) risk between the reporter/notifier and the evaluating body take place? Which evaluating bodies are in contact? NA

14. How does the evaluation and start/set up of follow up of a possible (new and emerging) risks take place? NA

15. What has costed the set-up building of the system? What does the Maintenance of the system cost? NA
1. **What is the name of the system /registry/instrument?** NA

2. **What is the goal of the system/method/instrument/ methodology/ database?** Identification of emerging risks and safeguarding food and feed of EU citizens

3. **Is it aimed at identifying possible (new and emerging) risks? Or can it be used for that goal?** Yes

4. **Which organization collects the information on possible (new and emerging) risks?** EFSA

5. **Which language is used in the system?** English

6. **Is it publicly available or not?**
   a. Scale (national, EU, Intercontinental)
   b. Compartments (air, water, soil, consumers, workers, industrial chemicals, biocides, cosmetics etc.) All compartments of food and feed

7. **What definition is used for new or emerging risks?** “An emerging risk to human, animal and/or plant health is understood as a risk resulting from a newly identified hazard to which a significant exposure may occur or from an unexpected new or increased significant exposure and/or susceptibility to a known hazard”.

8. **In which way are signals on possible (new and emerging) risks collected?**

   In general, the framework consists of a multi-step selection procedure that starts from a list of chemical substances (referred to as “entry point”) to which a sequence of selection (inclusion/exclusion) criteria is applied to identify the chemicals of potential concern in the present context. The selection criteria take into account volumes of production or import, persistence in the environment, bioaccumulation, dispersive uses, toxicity, and any available risk assessment. The procedure is discussed in terms of: (i) main entry points in the selection procedure (e.g. list of chemicals to be screened, such as industrial chemicals registered under the REACH Regulation or chemical contaminants consistently found in the environment) with a subset of more specific entry points depending on particular objectives characterising the application of the procedure and relevant data availability; (ii) several selection (inclusion/exclusion) criteria, including production volume, dispersive use, persistence, bioaccumulation, toxicity, evidence from existing Regulations or previous risk assessments; and (iii) selection process for the chemicals: multi-step procedure with a varying number of steps in which the outcome of each step becomes the entry point for the next step, and the last leads to the identification of emerging risks. The proposed procedure includes two main entry points - industrial chemicals registered under the REACH Regulation, and the non-intentionally produced or natural chemicals detected in different environmental compartments (e.g. water, soil and biota).

9. **Are possible (new and emerging) risks collected in a someway (national database)? How is the registration done?** EFSA uses numerous databases for the screening of signals. It can be assumed that signals are archived but a specific name of database was not found.

10. **How is a first report of a possible (new and emerging) risk evaluated and what are the criteria used to evaluate reported signals?** The first main entry point is the REACH Registered Substances Information of industrial chemicals produced or imported in the EU. The first two main procedural steps aim at selecting those chemicals which are produced in high volumes (first step) and used with dispersive modalities (second step). The third step of the procedure consists of parallel selection of: (i) high volume industrial chemicals characterised by highly dispersive use modalities, high persistence and tendency to bioaccumulate; and (ii) high volume industrial chemicals characterised by highly dispersive use modalities and high toxicity. The fourth step consists of a probabilistic combination of these two criteria and results in the selection of industrial chemicals characterised by highly dispersive use modalities, high persistence and...
tendency to bioaccumulation or high toxicity. The fifth procedural step is intended to exclude from the selected chemicals those that are already regulated as food contaminants, as undesirable substances in feed, or authorised or prohibited for specific uses in the food chain. The sixth procedural step, aiming at the exclusion of chemicals already assessed by EFSA and other scientific bodies, identifies chemicals classified as emerging issues (i.e. unregulated toxic chemicals likely to occur in the food chain). The seventh, and last, procedural step, consists of the selection of chemicals classified as constituting emerging risks according to the EFSA operational definition (i.e. toxic chemicals likely to occur in the food chain that have not been regulated in food/feed and have neither been evaluated by the European Commission or EFSA, nor authorised for use in food/feed).

The second main entry point aims at identifying chemicals, not included in the REACH register, using several different databases, including the Norman Network. This entry point includes, for example, chemicals of natural origin (e.g. mycotoxins, phytotoxins), or substances detected in specific environmental compartments (e.g. water, soil, sediments, biota or wildlife) which may be contaminants of the food/feed chain. After the exclusion of industrial chemicals included in the REACH Registered Substances Information, the previously-described procedure from step three to step seven applies.

The experience gained by EFSA indicates that the evaluation of the seriousness of an emerging risk should be based on expert judgement given the considerable data gaps generally characterising such risks. In fact, reliable data on health effects of and exposure to new agents are not generally available at short times since the inception of exposure. Therefore, establishing a clear threshold for the seriousness of an emerging risk may not always be feasible on pure scientific grounds. An “emerging serious risk” may thus have to be defined in dialogue with risk managers.

11. Who evaluates a first report of a possible (new and emerging) risks? EFSA, network and stakeholders EFSA established in 2010 EREN to exchange information with MS on possible emerging risks for food and feed safety. The Network is currently composed of delegates from 21 MS and an EFTA country (Norway) designated through the Advisory Forum of EFSA and observers from the EC, EU pre-accession countries, the Food and Drug Administration of the USA (FDA) and FAO. EREN members are requested to provide information on the issues identified. The first report of EREN was published in 2011 (EFSA, 2011c).

12. Is there a plan for communication of a (new and emerging) risk between the reporter/notifier and the evaluating body take place? Which evaluating bodies are in contact? NA

13. How does the evaluation and start/set up of follow up of a possible (new and emerging) risks take place? NA

14. What has costed the set-up building of the system? What does the Maintenance of the system cost? NA
1. What is the name of the system /registry/instrument? NA
2. What is the goal of the system/method/instrument/ methodology/database? Recognising the critical need for exposure-based prioritization approaches on par with those for toxicity, the U.S. Environmental Protection Agency (EPA) has initiated the ExpoCastTM program to better evaluate and prioritise chemicals based on biologically relevant human exposures.
3. Is it aimed at identifying possible (new and emerging) risks? Or can it be used for that goal? The research program employs systematic and comprehensive approaches to consolidate existing exposure information and generate new tools to inform chemical design, evaluation, and risk management. Current research seeks robust approaches that use human exposure data, product use information, and modeled human behavior to systematically prioritise potential for exposure, based on chemical properties, product life cycle, and individual and population characteristics (Cohen Hubal et al., 2010). Exposure is influenced not only by the physical and chemical properties of the chemical but also by a multitude of factors, including human activities, acting jointly to produce or control emissions along the entire life cycle. Further, characteristics of the environment and of the individual/organism (e.g., the life stage-related exposure vulnerabilities) influence exposures. This review has identified eleven currently available tools for exposure-based prioritization. Only three (CEPST, ConsExpo, and GExFRAME) rely purely on exposure as the basis of prioritization; the remainder incorporate hazard and employ risk as the basis.
4. Which organization collects the information on possible (new and emerging) risks? US EPA
5. Which language is used in the system? English
6. Is it publicly available or not? NA
7. What is the scope of the system? Scale (national, EU, Intercontinental); Compartments (air, water, soil, consumers, workers, industrial chemicals, biocides, cosmetics etc.)
8. What definition is used for new or emerging risks? NA
9. In which way are signals on possible (new and emerging) risks collected? NA
10. Are possible (new and emerging) risks collected in a someway (national database)? How is the registration done? NA
11. How is a first report of a possible (new and emerging) risks evaluated and what are the criteria used to evaluate reported signals? NA
12. Who evaluates a first report of a possible (new and emerging) risks? NA
13. Is there a plan for communication of a (new and emerging) risk between the reporter/notifier and the evaluating body take place? Which evaluating bodies are in contact? NA
14. How does the evaluation and start/set up of follow up of a possible (new and emerging) risks take place? NA
15. What has costed the set-up building of the system? What does the Maintenance of the system cost? NA

1. **What is the name of the system/registry/instrument?** A Guide for national food safety authorities

2. **What is the goal of the system/method/instrument/methodology/database?** Ensuring food safety to protect public health and promote economic development. This remains a significant challenge in both developing and developed countries.

3. **Is it aimed at identifying possible (new and emerging) risks? Or can it be used for that goal?** Not as such, it is a manual to guide authorities to identify and manage food safety risks by the following risk management activities:
   - Step 1: Identify and describe the food safety issue
   - Step 2: Develop a risk profile
   - Step 3: Establish broad risk management goals
   - Step 4: Decide whether a risk assessment is necessary
   - Step 5: Establish a risk assessment policy
   - Step 6: Commission the risk assessment
   - Step 7: Consider the results of the risk assessment
   - Step 8: Rank food safety issues and set priorities for risk management

4. **Which organization collects the information on possible (new and emerging) risks?** International (FAO) and national organizations and (competent) authorities dealing with food safety issues.

5. **Which language is used in the system?** English

6. **Is it publicly available or not?** Yes

7. **What is the scope of the system?**
   a. Scale (national, EU, Intercontinental)/Global
   b. Compartments (air, water, soil, consumers, workers, industrial chemicals, biocides, cosmetics etc.)/Global

8. **What definition is used for new or emerging risks?** This document described new risks in terms of new hazards: “A new or emerging potential hazard constitutes an unknown level of risk”.

9. **In which way are signals on possible (new and emerging) risks collected?** NA

10. **Are possible (new and emerging) risks collected in a someway (national database)?** How is the registration done? NA

11. **How is a first report of a possible (new and emerging) risks evaluated and what are the criteria used to evaluate reported signals?** Safety problems may be identified by domestic and international (point of entry)inspection, food monitoring programmes, environmental monitoring, laboratory, epidemiological, clinical and toxicological studies, human disease surveillance, food-borne disease outbreak investigations, technological evaluation of novel foods and difficulties in achieving compliance with regulatory standards, among other ways. Sometimes academic or scientific experts, the food industry, consumers, special interest groups or the media expose food safety problems. At other times, food safety issues that are not necessarily driven by concerns about food-borne risks to consumers become apparent through legal action and disruptions to international trade.

12. **Who evaluates a first report of a possible (new and emerging) risks?** NA

13. **Is there a plan for communication of a (new and emerging) risk between the reporter/notifier and the evaluating body take place?** Which evaluating bodies are in contact? NA

14. **How does the evaluation and start/set up of follow up of a possible (new and emerging) risks take place?** NA

15. **What has costed the set-up building of the system?** What does the Maintenance of the system cost? NA
1. **What is the name of the system /registry/instrument?** NA
2. **What is the goal of the system/method/instrument/ methodology/database?** Gather information on incidents and the circumstances of exposure to hazardous mixtures marketed in soluble packaging
3. **Is it aimed at identifying possible (new and emerging) risks? Or can it be used for that goal?** Goal is not described.
4. **Which organization collects the information on possible (new and emerging) risks?** NA
5. **Which language is used in the system?** English
6. **Is it publicly available or not?** NA
7. **What the scope of the system?** Scale is international, EU; Compartments (air, water, soil, consumers, workers, industrial chemicals, biocides, cosmetics etc.)
8. **What definition is used for new or emerging risks?** NA
9. **In which way are signals on possible (new and emerging) risks collected?** NA
10. **Are possible (new and emerging) risks collected in a someway (national database)?** How is the registration done? NA
11. **How is a first report of a possible (new and emerging) risks evaluated and what are the criteria used to evaluate reported signals?** NA
12. **Who evaluates a first report of a possible (new and emerging) risks?** NA
13. **Is there a plan for communication of a (new and emerging) risk between the reporter/notifier and the evaluating body take place?** Which evaluating bodies are in contact? NA
14. **How does the evaluation and start/set up of follow up of a possible (new and emerging) risks take place?** NA
15. **What has costed the set-up building of the system? What does the Maintenance of the system cost?** NA
1. What is the name of the system/registry/instrument? NA
2. What is the goal of the system/method/instrument/methodology/database? To perform exposure prioritization facilitating high-throughput risk assessment.
3. Is it aimed at identifying possible (new and emerging) risks? Or can it be used for that goal? This article is not presented as a system to identify new and emerging risks. It however, could be used as a tool for the identification and strengthening of signals leading to potential risks.
4. Which organization collects the information on possible (new and emerging) risks? NA
5. Which language is used in the system? NA
6. Is it publicly available or not? NA
7. What is the scope of the system? Scale (national, EU, Intercontinental). The focus is on consumer products
8. In which way are signals on possible (new and emerging) risks collected? The methodology for building the CPCP db can be broken down into three major steps:
   - Building and curating a database for consumer product ingredients and percent compositions using available MSDSs.
   - Identifying and annotating product use categories for all products in the database.
   - Evaluating data quality.
9. Are possible (new and emerging) risks collected in a someway (national database)? How is the registration done? MSDS information on the presence of chemicals in consumer products and use categories are stored in a database. Using chemical space analysis exposure based prioritization is being facilitated.
10. How is a first report of a possible (new and emerging) risks evaluated and what are the criteria used to evaluate reported signals? NA
11. Who evaluates a first report of a possible (new and emerging) risks? NA
12. Is there a plan for communication of a (new and emerging) risk between the reporter/notifier and the evaluating body take place? Which evaluating bodies are in contact? NA
13. How does the evaluation and start/set up of follow up of a possible (new and emerging) risks take place? NA
14. What has costed the set-up building of the system? What does the Maintenance of the system cost? NA
1. What is the name of the system /registry/instrument? iNTeg-Risks
2. What is the goal of the system/method/instrument/methodology/database? Improving management of emerging risks, related to ‘new technologies’ in European Industries (in the area of “Nano-sciences, Nano-technologies, Materials and new Production Technologies). Improving early recognition and monitoring of emerging risks and decrease reaction times if major accidents involving emerging risks happen.
3. Is it aimed at identifying possible (new and emerging) risks? Or can it be used for that goal? It can be sued to identify new and emerging risks due to new materials and technologies, within the next 15 years.
4. Which organization collects the information on possible (new and emerging) risks? EU Industries and renowned R&D institutions coordinated by the European Virtual Institute for Integrated Risk Management
5. Which language is used in the system? English
6. Is it publicly available or not?
7. What is the scope of the system? Worldwide/New technologies
8. What definition is used for new or emerging risks? When iNTeg-Risk project was proposed in 2008, the definition of emerging risks proposed by OSHA in 2005, adapted to major accident risk, was stipulating that a risk was to be considered new and emerging if:
   - the risk was previously not recognised and is caused by new processes, new technologies, new ways of working, or social or organizational change (e.g. risks linked with nanotechnology, biotechnology, ICT technologies, new chemicals, effects of globalization etc.) or
   - a long-standing issue is newly considered as a risk due to a change in social or public perceptions (e.g. stress, bullying) or
   - a new scientific knowledge allows a long-standing issue to be identified as a new risk, e.g. in the situations where cases have existed for many years without being identified as risk because of, e.g., lack of scientific knowledge.
   The risk was considered to be 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
   - effect of the hazard is getting worse (e.g. seriousness of health effects and/or the number of people affected).
Current OSHA definition of emerging risks stipulates that an emerging risk is any risk that is new and/or increasing. In this context (and adapted to major accident and technological risk) "new" means that the risk did not previously exist and is caused by new processes, new technologies, new types of workplace, or social or organizational change; or that a long-standing issue is newly considered as a risk due to a change in social or public perception; or that 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 if the exposure to the hazard leading to the risk is increasing, or that the effects/impacts of the hazards are getting worse (e.g. seriousness of health effects and/or the number of people affected). In iNTeg-Risk project the above definition applies generally, and is taken as a starting reference point.
On the governance side, the definition of emerging risks provided by IRGC is [21]: "[…] a risk that is new, or a familiar risk that becomes apparent in new or unfamiliar conditions. Of particular interest to IRGC are emerging risks of a systemic nature, which typically span more than one country, more than one economic sector, and may have effects across natural, technological and social systems. These risks may be relatively low in frequency, but they have broad ramifications
for human health, safety and security, the environment, economic well-being and the fabric of societies.”

An emerging risk is any risk that is new/and/or increasing (OSHA definition).

9. *In which way are signals on possible (new and emerging) risks collected?* Screening signals, consultation with experts, relevant organizations

10. *Are possible (new and emerging) risks collected in a someway (national database)? How is the registration done?* The signals are stored in the Active Risk Spark in Risk Database The implementation of iNTeg-Risk ERMF relies largely on the iNTeg-Risk 1StopShop and the tools contained in it. The main elements are:

a. RiskRadar
b. (1StopShop main) Tools
   - RiskEars
   - RiskAtlas
   - MCDM Tools
   - New Technologies Acceptance Tools
   - Notion clustering (S-RDI) Tools
c. Specific Tools (of iNTeg-Risk project)
d. Background Tools
   - Safetypedia
   - KPI Library
   - MethodsMart & Glossary
   - iNTeg-Risk Education
   - ENISFER
   - Survey Tool

The StopShop is organised as a “system of systems”, managing

- Data
- Information
- Knowledge
- Meta-information
- Analyses/work
- Communication

11. *How is a first report of a possible (new and emerging) risks evaluated and what are the criteria used to evaluate reported signals?*

   The step-wise criteria used are:
   - the systemic nature of emerging risks;
   - link of emerging risks to high-impact-low-probability-events (HILP events, HILPs);
   - multidisciplinary character;

12. *Who evaluates a first report of a possible (new and emerging) risks? Experts*

13. *Is there a plan for communication of a (new and emerging) risk between the reporter/notifier and the evaluating body take place? Which evaluating bodies are in contact?* When a risk is identified it is communicated to experts for consultation. This is considered as important throughout the entire process.

14. *How does the evaluation and start/set up of follow up of a possible (new and emerging) risks take place?* NA

15. *What has costed the set-up building of the system? What does the Maintenance of the system cost?* EU funded project
1. What is the name of the system/registry/instrument? Proactive governance of emerging risks

2. What is the goal of the system/method/instrument/methodology/database? Proactive governance of emerging risks aims to enhance anticipation and forward-looking capabilities. Projecting managers into their possible future operating context helps highlight decision opportunities and provides them with additional lead time to prevent risks from emerging or to manage their consequences.

3. Is it aimed at identifying possible (new and emerging) risks? Or can it be used for that goal? This guidance explains how an organization can identify emerging risks that are of stake for the organization. The principles can be used for the identification of an EU wide early warning system.

4. Which organization collects the information on possible (new and emerging) risks? The guidance described an approach inspired by existing ER units like within EFSA. A risk conductor is among the advices given.

5. Which language is used in the system? English

6. Is it publicly available or not? Yes

7. What is the scope of the system? NA

8. What definition is used for new or emerging risks? Emerging risks are characterised mainly by uncertainty regarding their potential consequences and/or probabilities of occurrence. This can be due to a lack of knowledge about causal or functional relationships between new risk sources and their environment or to the insufficient application of available knowledge to the case in question.

9. In which way are signals on possible (new and emerging) risks collected? NA

10. Are possible (new and emerging) risks collected in a someway (national database)? How is the registration done? NA

11. How is a first report of a possible (new and emerging) risks evaluated and what are the criteria used to evaluate reported signals? NA

12. Who evaluates a first report of a possible (new and emerging) risks? A risk conductor

13. Is there a plan for communication of a (new and emerging) risk between the reporter/notifier and the evaluating body take place? Which evaluating bodies are in contact? Stakeholders/experts

14. How does the evaluation and start/set up of follow up of a possible (new and emerging) risks take place? NA

15. What has costed the set-up building of the system? What does the maintenance of the system cost? NA
1. What is the name of the system /registry/instrument? NA

2. What is the goal of the system/method/instrument/methodology/database? The goal is prioritise chemicals on the basis of their exposure potential. A model is presented in which chemicals are evaluated based on inherent chemical properties and behaviorally-based usage characteristics over the chemical’s life cycle. These criteria are assessed and integrated within a decision analytic framework, facilitating rapid assessment and prioritization for future targeted testing and systems modeling. A case study outlines the prioritization process using 51 chemicals. The results show a preliminary relative ranking of chemicals based on exposure potential. The strength of this approach is the ability to integrate relevant statistical and mechanistic data with expert judgment, allowing for an initial tier assessment that can further inform targeted testing and risk management strategies.

3. Is it aimed at identifying possible (new and emerging) risks? Or can it be used for that goal? Yes, it can be used for this goal. It is aimed to prioritise chemicals on the basis of the exposure potential. This paper demonstrates how analytical tools, such as LCA and MCDA, can offer a versatile and transparent approach to exposure-based prioritization utilising results from several approaches evaluated in the EPA ExpoCast model challenge.

The criterias used are:
- assessment of chemical properties
  - Bioaccumulation
  - Bioconcentration factor (BCF)
  - Log kow
  - Molecular weight
  - Persistence
  - ADME
  - Absorption
  - Metabolism
  - Physical hazard potential

- The potential for human exposure is by assessing three main life cycle phases of manufactured chemicals:
  - Production
  - Projected average annual number of production sites
  - Regional geometric mean production quantity (MQR)

- Consumer use
  - Number of potential exposure sources
  - Projected average annual number of individual consumers
  - Projected average annual number of industrial consumers
  - Projected average annual quantity consumed per individual/industrial consumer.
  - Susceptible populations
  - Disposal: Number of potential exposure sources Projected average annual number of disposal events.
  - Projected average annual quantity disposed.

The proposed methodology allows for structured and transparent analysis of chemical exposure potential through integration of heterogeneous metrics used to evaluate exposure risk-related information associated with both chemical properties and life cycle phases.
4. Which organization collects the information on possible (new and emerging) risks?
   - Biosystems & Agricultural Engineering, Michigan State University, East Lansing, Michigan, United States of America,
   - Physics Department, Carnegie Mellon University, Pittsburgh, Pennsylvania, United States of America,
   - Environmental Laboratory, Engineer Research and Development Center, United States Army Corps of Engineers, Concord, Massachusetts, United States of America,
   - Office of Research and Development, United States Environmental Protection Agency, Research Triangle Park, North Carolina, United States of America
5. Which language is used in the system? English
6. Is it publicly available or not? Yes
7. What is the scope of the system? USA/Human exposure, not a specific compartment.
8. What definition is used for new or emerging risks? NA
9. In which way are signals on possible (new and emerging) risks collected? NA
10. Are possible (new and emerging) risks collected in a someway (national database)? How is the registration done? NA
11. How is a first report of a possible (new and emerging) risks evaluated and what are the criteria used to evaluate reported signals? NA
12. Who evaluates a first report of a possible (new and emerging) risks? NA
13. Is there a plan for communication of a (new and emerging) risk between the reporter/notifier and the evaluating body take place? Which evaluating bodies are in contact? NA
14. How does the evaluation and start/set up of follow up of a possible (new and emerging) risks take place? NA
15. What has costed the set-up building of the system? What does the maintenance of the system cost? NA

1. What is the name of the system/registry/instrument? NA
2. What is the goal of the system/method/instrument/methodology/database? To characterise potential risks to human health and the environment associated with manufacture and use of thousands of chemicals.
3. Is it aimed at identifying possible (new and emerging) risks? Or can it be used for that goal? It can be used for this purpose. It is a framework for high-throughput exposure assessment.
4. Which organization collects the information on possible (new and emerging) risks? USEPA
5. Which language is used in the system? English
6. Is it publicly available or not? Yes
7. What is the scope of the system?
   It is primarily focused on the US. It consists of:
   - Fate and Transport Models,
   - Chemical Selection
   - Model Parameterization
   - Chemical Use Information
   - Biomonitoring Data
   - Statistical Analysis.
8. What definition is used for new or emerging risks? NA
9. In which way are signals on possible (new and emerging) risks collected? The ExpoCast exposure prioritization framework here is intended to be sufficiently flexible to incorporate new models as they become available. To rapidly screen a set of chemicals for exposure, we used linear regression to evaluate the predictive power of multiple exposure models.
10. Are possible (new and emerging) risks collected in a someway (national database)? How is the registration done? NA
11. How is a first report of a possible (new and emerging) risks evaluated and what are the criteria used to evaluate reported signals? Intake fractions are predicted (kilograms exposed to the population per kilograms emitted) via exposure factors that translate predicted environmental media concentrations into human exposure metrics.
12. Who evaluates a first report of a possible (new and emerging) risks? NA
13. Is there a plan for communication of a (new and emerging) risk between the reporter/notifier and the evaluating body take place? Which evaluating bodies are in contact? NA
14. How does the evaluation and start/set up of follow up of a possible (new and emerging) risks take place? NA
15. What has costed the set-up building of the system? What does the maintenance of the system cost? NA
1. What is the name of the system /registry/instrument aimed at identifying possible (new and emerging) risks? All activities of the Dutch National Poisons Information Center (NVIC) are relevant to signaling of emerging risks. Especially the 24/7 information supply to medical healthcare personnel (44000 questions per year) provides us with valuable information on the epidemiology of intoxications and poisoning incidents in the Netherlands. Toxicologische Informatie & Kennisdatabank (Toxicological Information and Knowledge Bank, TIK)

Note. This system contains only information in Dutch.

2. Which organization collects the information on possible (new and emerging) risks? The DPIC uses information received from producers (requirement in CLP, article 45 product notification) on ingredients in products, like household and DIY products, Biocidal and Plant Protection Products, Cosmetic products and industrial chemicals. The NVIC also has broad knowledge on medicines (human/animal), drugs of abuse and plant/animal toxins

With regard to possible NERCs.

NVIC (and TIK) is set-up to inform and help professionals. While doing that, requests for information on what to do when for example a kid has swallowed household cleaning agent, is registered. This information on cases comes from physicians/general practitioners. NVIC is only meant for professionals, which can also be the emergency response services as fire brigade, ambulance personal, police

3. What is the goal of the system/method/instrument? The goal of the TIK is to support the NVIC professionals in their everyday task to inform physicians how to act upon emergency situation during which contact with potentially toxic substances or mixtures (all chemicals, radiation, biological toxins) took place. The scale of TIK is the Netherlands focusing on the citizen including man indirect, workers and consumers. Only with regard to acute toxicity! All the compartments mentioned are relevant in the questions to the DPIC.

4. What definition is used for new or emerging risks? No definition is used. Criteria that trigger closer investigation are: increasing number of intoxications with a certain product or product group, unusual symptoms in relation to the intoxication or poisoning severity that is much worse than expected, based on the exposure.

Requests and responses are based on acute toxicity. To facilitate signaling of increasing numbers of certain intoxications, TIK is extended with a Business Intelligence tool used for (annual, specific ad hoc) reporting purposes, early warning and trend analysis, potentially leading to the detection new risks (e.g. liquid caps).

5. In which way are signals on possible (new and emerging) risks collected? NVIC collects all signals (44000 calls) from the parties specified in the answer of question 2. During the calls information on exposure (quantify, etc.) is collected and inserted into a system. Apart from the telephone service, where it is clear if exposures did actually occur, the DPIC also operates a website for professionals, with 51000 visits in 2015. For the website consultations it is unknown whether exposure actually occurred or the user is just looking for information.

TIK is updated when necessary, based on continuous literature research and the consultations to the DPIC. Up-to-date dose-response information facilitates dose-response modeling. Using detailed exposure information more precise information can be provided on how to intervene during the emergency situations.

The information that is screened is scientific literature, Poisindex database, pubmed, and via a world-sharing database on current awareness in toxicology. This database is maintained by the European Association of Poisons Centres and Clinical Toxicologists(society via membership contributions) and provides monthly highlights.
6. **How is a first report of a possible (new and emerging) risk evaluated and what are the criteria used to evaluate reported signals?** With regard to the providing of information, the level of automization is relatively high compared to many other EU poison centres that frequently rely on the expert judgement of the physician of person providing the emergency responds. With regard to the registration, NVIC registers all calls (cases) when something deviates from the normal situation (e.g. more emergency situations from a single product in several months) a signal on a potential new of emerging risk could exist. Based on discussion and expert judgment this is followed-up.

7. **Who evaluates a first report of a possible (new and emerging) risks?** Based on three criteria the signal is evaluated by scientific experts (at NVIC/DPIC)
   - **Type of signal**
   - **Causality** (where, how, what substance(s) are involved, did exposure occur and to what dose of toxin, can the reported symptoms be attributed to the exposure)
   - **External factor influences**, like seasonal variations in exposures, like the use of certain products, availability of plants, etc.

When a new product (for example the liquid washing caps) is introduced the number of intoxications with the product always increases, all signals are new and this is something else than a new signal concerning a new or emerging risk. Only after several months this could lead to some kind of indication. Comparison to intoxications with similar product(groups) are used to evaluate the risk posed by new products.

With regard to drugs of abuse, TRIMBOS does follow-up which drugs of abuse are causing more visits to hospital emergency rooms.

VeiligheidNL researches the number of emergency room visits (Letsel Informatie Systeem, LIS) nationwide and evaluates emerging risks (not only chemical, but also accidents, trauma, mechanical safety, etc).

8. **Are possible (new and emerging) risks collected in a someway (national database)?** All calls are stored in the TIK system.

9. **How does the communication of a (new and emerging) risk between the reporter/notifier and the evaluating body take place?** This depends on the type of signal. Feedback is given to the experts dealing with the source of the signal. This could be e.g. the advisory body on medicines (college beoordeling geneesmiddelen), the Inspectorate (NVWA or IGZ or CTGB), etc. Sometimes feedback is also given to the DPIC-caller, especially if follow-up of the case is performed.

10. **How does the evaluation and start/set up of follow up of a possible (new and emerging) risk take place?** Within the DPIC the DPIC-experts decide whether to upscale an emerging risk or not. Depending on the product group in which the emerging risk is signaled, the DPIC informs the competent authority and they decide for themselves what actions they find appropriate. The competent authorities contact the producers to find suitable solutions (like smaller packaging, etc.), DPIC can act as expert/advisor.

Collaboration is also important with laboratory facilities, for analysis of possibly contaminated products (RIVM, hospital pharmacies, NVWA (Dutch Consumer Safety Authority). Examples of competent authorities with which DPIC collaborates: IGZ (medication), NVWA (consumer product, food & non-food), CTGB (pesticides).

11. **Could you give an indication of the costs of maintaining your system?** The activities of the DPIC are tightly intertwined: without giving poisons information, to healthcare providers, we wouldn’t be able to generate signals about poisoning risks.

The TIK system is primarily made to facilitate the information supply to healthcare providers. The poisoning information supply helps to lower health care costs by tailored care; no overtreatment of mild or non-poisoning and quick adequate treatment of moderate or severe poisonings in order to reduce health damage. It efficiently supports the
task of the NVIC professional for an adequate response to an intoxication. The Dutch database is more advanced compared to many other EU countries. Differences exist in both the systems for registering the CLP notification information (because EU member states are free to interpret the Directive according to their own desired, discussions ongoing in Brussels on an EU system). But they also differ in how they contain the knowledge and expertise at their poison center to be able to provide information and help physicians. The way in which case-information is recorded also differs, but most Poisons Centres (including NVIC) do record information on the following subjects:

- patient characteristics (e.g. age, bodyweight, sex)
- exposure (e.g. substance(s), product(s), dose, route of exposure (ingestion, inhalation, skin, eye, etc.))
- symptoms actually observed in the patient and poisoning severity (e.g. estimated severity, Poisoning Severity Score (PSS), symptoms, measures taken (e.g. therapies, hospitalization yes/no).

Included in the DPIC total budget, the Inspectorate NVWA requests for 70k several trend analyses on the observed new and emerging risks (with regard to consumer products) of their choice. That can be executed because of the existing system.
## Cost related information

In general, existing information sources relevant for the three above-mentioned sectors are preferred for the short-term.

a) Technology. Use existing search engines, databases and thesauri already utilised within the sectors agriculture, health & welfare and environment & energy. Technical systems using a worldwide information input are preferred, whether they are used by international (e.g. WHO/FAO) or national (Health Canada) bodies. Although early warning and rapid alert systems are usually responsive systems (see paragraph 4.2.1), available systems in sectors like health & welfare and environment & energy could be used to anticipate a possible transfer of hazards into the feed and food supply chain.

b) Experts. On a European level experts or expert networks operating at the national food authorities/agencies within the EU can be used. Scientific experts or expert networks operating within European research projects (e.g. within FP6 and FP7) are useful. However, these expert networks tend to dry up when the research projects finish and effort is needed to keep them in operation (see also paragraph 6.2.1).

c) Stakeholders. Organised stakeholders like European product boards, commodity organisations, retailer organisations and NGO’s can provide valuable input. But also large food producing companies operating in the EU are important suppliers of information. Effort is needed to organise their input to fulfil EFSA’s information needs.

### Short-term options (2006-2007)

#### Estimated costs

Much of the initial work is to organise existing information sources in such a way that they meet the specific demands of a system for the identification of ERs. This means: a) using or subscribing to publicly available technical systems supplying information; b) co-operating with organisations that manage existing technical systems; c) organising working groups of experts operating in the sectors agriculture, health & welfare and environment & energy to develop the pre-early warning system.

It is envisaged that a budget of ≈ 200 k€ is necessary for activities b) and c). The costs of subscription per year vary enormously (from free up to 250 k€).

Apart from the pilot studies, the work mentioned under the EFSA management will have to be carried out by EFSA personnel. In the beginning this work could be carried out by at least three full-time employees but heading for the mid-term this could easily increase to a larger number of employees. Especially in the first phase and when no decisions have been made yet on a definite establishment of an ER-unit within EFSA, the introduction and employment of secondments seems to be a flexible possibility.

The estimated costs for one or two pilot studies are ≈100 or 250 k€. Therefore, excluding personnel, overhead costs and subscriptions, the total costs could amount up to 450 k€.

### Mid-term options (2007-2008)

#### Estimated costs

The use of existing information sources (IT, experts and stakeholders) is comparable to that of the short-term period. Organising working groups of issue and sectoral experts operating in the sectors economy & finance, industry & trade and science and technology can probably be carried out at the same costs as calculated for the short-term period (≈ 200 k€). Additional costs for updating the first three primary sectors and/or integrating all primary sectors are foreseeable: ≈ 50 k€.

Apart from contract work, much of the work mentioned under EFSA activities will have to be carried out by EFSA personnel. Independent of scenario A or B the management of the various activities will have to be carried out by a team of full-time employees. The size of the team depends on how much work will or can be subcontracted, a minimum of 4 full-time employees is envisaged, however.

The estimated costs for a cost-benefit analysis are ≈ 50 k€. Therefore, excluding overhead costs and subscriptions, the total costs could amount up to ≈ 400 k€. It must be emphasised that, independent of scenario A or B, the overhead costs increase substantially after the first year.

### Long-term options (2008-2010)
Estimated costs

The extension with existing information sources (IT, experts and stakeholders) is comparable to the mid-term period. Organising working groups of experts operating in the sectors government & politics, population & social conditions and information & communication can probably be carried out at the same costs as calculated for the previous periods (≈100 k€). Additional costs for the integration of all sectors are foreseeable: ≈50 k€. Furthermore, the extension of the worldwide activities may involve additional costs: ≈ 200 k€. This adds up to a subtotal of 350 k€.

At the beginning of the long-term period the nature of the chosen scenario will have a distinct impact on the composition and workload of the ER-unit of EFSA employees. Scenario A will not affect the number of the employees involved. The estimated costs for the optimalisation and Maintenance, excluding overhead costs, of the adapted system (scenario A) are estimated to be ≈ 500 k€ per year.

Scenario B will mean that the ER-unit’s expertise and skills will have to be enlarged, because the workload and the number of tasks will increase. The costs for the development of a new system are difficult to estimate because it depends very much on the features of a more or less sophisticated system. Moreover, costs for Maintenance usually increase if technical possibilities increase. The project team proposes to implement the required additional expertise including search engine development by means of outsourcing on a three years basis. Thereto following budget estimations can be envisaged in order to build a system fitted to the purpose of EFSA. Within the project to be outsourced a linguist team member (80 k€ per year) is needed for basic multi-lingual ontological research in this area, and needed to adopt contents to mathematical modelling. A mathematician should develop and advance search algorithms in this field (80 k€ per year), whereas two programmes (160 k€ per year) should construct the frame for the search engine technology. A food scientist (100 k€ per year) should be responsible for identifying key sources and is responsible for the judgment of the relevance of the obtained results (project leader). A sociologist (80 k€ per year) should explore the influence of human’ behaviours in relation to available information with respect to human health issues and indicators etc. Additionally an amount of ≈ 150 k€ per year will be needed to cover operational expenses.

Therefore, estimated costs for scenario B may easily reach the level of ≈ 1,000 k€ per year (i.e. ≈ 650 k€ for search engine development and of ≈ 350 k€ for integrating sectors and worldwide activities) for the next three years, excluding Maintenance and EFSA staff costs. If firsthand information is essential to EFSA’s purposes, it might add substantially to the total costs.

Summarised, the total costs of scenario A, excluding overhead costs and subscriptions, will be approximately 500 k€ per year. The total costs of scenario B, excluding overhead costs and subscriptions, may amount to 1,000 k€ per year. After three years of development the costs of scenario B will be comparable to those of scenario A.
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