



**Opinion of the Scientific Committee on a request from EFSA related to
the early identification of emerging risks**

(Request No EFSA-Q-2004-018)

(adopted by written procedure on 4 July 2006)

SUMMARY

The mission and tasks of EFSA are described in Regulation (EC) No 178/2002. These include the responsibility to set up a system for identifying emerging risks. “The Authority shall establish monitoring procedures for systematically searching for, collecting, collating and analysing information and data with a view to the identification of emerging risks in the fields within its mission” (art. 34.1). An emerging risk (ER) for the purpose of this opinion is an issue that in the future may pose a risk to the health of the consumer, animals or the environment. The indication of an ER may relate (1) to a significant exposure to a hazard not recognized earlier, or (2) to a new/increased exposure to a known hazard (it is then called re-emerging risk).

To fulfill its task, EFSA will have to collect information from many different sources. The scientific literature is obviously an important but rather slow channel, while EFSA can very quickly make use of its internal sources of information; these sources are EFSA staff and members of the Scientific Committee and Panels who can bring in new knowledge from a wide environment, the Advisory Forum that has already established links with Member States to share information, and the Stakeholder Consultative Platform for a broad information exchange regarding emerging risks. Direct links with external sources of information such as relevant research projects, EU and international bodies should also be established over time.

In order to predict an emerging risk at a very early stage, parameters that are remotely and often indirectly connected to the food and feed chain have to be studied. In the outsourced project “Forming a global system for identifying food-related emerging risks – [EMRISK](#)” coordinated by the Food and Consumer Product Safety Authority (VWA), a large number of such parameters (indicators) were identified. The evaluation and validation of these indicators is very resource demanding and will be achievable by EFSA only in a long term perspective. As these indicators are of interest for several organisations, a close collaboration with others is essential to ensure complementary work. There are already some organisations that have established systems for identifying emerging risks (also called “early warning systems” or “horizon scanning systems”) and the development of IT tools used for these purposes is in an intensive phase. EFSA should as a first step exercise its vigilance to a limited number of key areas and direct its work towards the identification and validation of relevant indicators for these areas.

It is not recommended that EFSA should try to build one large network for the early detection of emerging risks, as different partners may need different arrangements regarding e.g. confidential information. A number of links and small networks that could be combined to address a given case are considered as being more useful. EFSA would have to establish contacts at an early stage and come to agreements with all partners, especially on a transparent policy for sharing, treating and releasing information.

EFSA will need to devote new internal resources for the work with emerging risks. A broad competence is needed for the initial assessment of the information potentially useful to identify a new issue. The relevant expertise of the scientific staff at EFSA would be involved to ensure a primary filter of signals. If the initial assessment indicates that the risk may be of concern, a more thorough assessment has to be done, either internally within EFSA Panels and Scientific Committee, or using external expertise, depending on the issue, the urgency, and the resources needed.

KEYWORDS

Emerging risk, early warning system, horizon scanning, food and feed safety.

BACKGROUND

The mission and tasks of EFSA are described in Regulation (EC) No 178/2002. These include the responsibility to set up a system for identifying emerging risks. “The Authority shall establish monitoring procedures for systematically searching for, collecting, collating and analysing information and data with a view to the identification of emerging risks in the fields within its mission” (art. 34.1).

Keeping in mind that risk is a function of hazard and exposure, emerging risks can be due to new or increasing hazards and/or exposure routes.

The mission includes the provision of scientific advice for the Community’s legislation and policies in all fields which have a direct or indirect impact on food and feed safety (art. 22.2). Some environmental and worker protection aspects should also be addressed (part 37 of the preamble).

TERMS OF REFERENCE

The Scientific Committee is requested by the European Food Safety Authority:

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

ASSESSMENT

1. Introduction

The Scientific Committee (SC) established a working group to draft an opinion in response to the request from EFSA. After some initial discussions within this group EFSA decided to outsource a project (in this opinion referred to as the EMRISK project) to a consortium of scientists that already had completed an EU financed research project on emerging risks called PERIAPT (VWA, 2005). The [final report](#) of the EMRISK Project is available on the EFSA website. That work was used as a major source of information in the development of conclusions for this opinion.

Regulation (EC) No 178/2002 also acknowledges that “Improved identification of emerging risks may in the long term be a major preventive instrument at the disposal of the Member States and the Community in exercise of its policy. It is therefore necessary to assign to the Authority an anticipatory task of collecting information and exercising vigilance and providing evaluation of and information on emerging risks with a view to their prevention”.

A food and feed-related **emerging risk** (ER) for the purpose of this opinion is an issue that in the future may pose a risk to the health of the consumer, animals or the environment. The indication of an ER may relate (1) to a significant exposure to a hazard not recognized earlier or (2) to a new/increased exposure to a known hazard. Emerging risks can be the result of many factors, such as changed consumption patterns, new processes, and increased levels of pollutants.

In the context of the ER identification, an **indicator** is a component of risk assessment and is comprised of a focussed selection of parameters that can be measured/ calculated qualitatively and/or quantitatively. Indicators may be directly related to the food chain, or may also be connected to it via one or several links. Choosing the most relevant set of indicators and their data sources is an essential step in ensuring a functional ER identification system. A **signal** is identified as a temporal or spatial trend in an indicator value, and such a signal, or combination of several signals, may indicate an ER. A more detailed description of some parameters which could be helpful is given in the [report](#) (sections 5.3 and 5.4) and [annex 5](#) of the EMRISK project.

Both the accessibility and quality of the information are limiting factors for the identification of ERs. The amount of available information today is considerable, but relevant information of high quality can be difficult to access at an early stage. It is essential that EFSA gets access to relevant information from a number of sources, and that the quality of the data to be used is assessed.

The following section (2) describes possible partners and information sources as identified by the EMRISK project and the SC. The section after that (3) lists some ER identification projects already operating, and the final four sections (4 – 7) contain the SC response to the requests from EFSA.

2. Partners and sources of information relevant for ER identification

This section describes without priority order some of the existing capacities, which may be employed by EFSA to fulfill its ER mission. This mission could be very resource demanding and co-operation with other organizations active in the field will be essential. There are also a number of other channels, by way of example only and not in any order, that may act as sources of information, both within and outside EFSA.

2.1 Internal sources of information:

The EFSA Scientific Committee and Panels are valuable sources of information for the identification of potential problems in the different sectors of food/feed production, processing and distribution. Panel members represent many scientific disciplines covering a broad area. The Scientific Committee and the Scientific Panels are addressing emerging risks in the areas of their competence as part of their current activities. Identification of potential emerging risks is in most cases not the result of *systematic* screening of available sources, but is rather based on information reported by individual Panel members or supporting staff from current literature or other sources. If deemed relevant, identified hazards may further be characterized by the Panels or SC by means of self tasking activities.

The Advisory Forum (AF) has been established with the objective of building strong collaborative networks between EFSA and the national food agencies and other authorities working in the fields of risk assessment and risk communication. It can ensure close cooperation between EFSA and the competent bodies in the Member States. This forum also facilitates the sharing of information and collaboration between the national authorities themselves. Given its membership and mandate, the Advisory Forum plays an important role in the identification of emerging risks, in particular by providing access to information available within the national food agencies of the Member States.

EFSA has established a Stakeholder Consultative Platform composed of a wide range of stakeholder organisations engaged in the food chain. The members of the Platform are from organisations representing consumers, food operators active in the whole food chain, e.g. as farmers and other primary producers, the food industry, the food trade and NGOs. This consultative platform provides a forum for regular dialogue and exchanges on many issues, including the identification of emerging risks.

EFSA staff, especially the support teams of the Scientific Committee/Panels and the Scientific Expert Services, act as important antennae for the detection of the appearance of new risks in the food and feed chain, through their broad involvement with expanding networks and with the different stakeholders as well as the Scientific Panels and Scientific Committee. Their possible systematic role in signaling ERs and co-ordination of data retrieval and analysis requires further consideration within EFSA.

2.2 External sources of information

According to Regulation EC No 178/2002 (Article 36), EFSA shall promote the European networking of organizations in the fields within the Authority's mission, with the aim of facilitating a scientific cooperation framework by the coordination of activities, exchange of information, development and implementation of joint projects, exchange of expertise, etc. A list has been drawn up of competent organizations, designated by the Member States, which

may assist EFSA among others in the collection of data and in the identification of emerging risks.

A new collaboration activity was initiated in 2005 involving the chairs of EFSA SC and Panels, other EU agencies and of the non-food scientific committees of the Commission. At its first meeting held in Brussels in December 2005, the identification of emerging risks was acknowledged as an important topic for forum exchange of information. This issue is proposed for discussion at the second meeting of the Chairs of the Commission and Agency Scientific Committees / Panels involved in risk assessment.

Co-operation with the three non-food scientific committees of the Commission viz. the Scientific Committee on Consumer Products (SCCP), the Scientific Committee on Health and Environmental Risks (SCHER) and the Scientific Committee on Emerging and Newly-Identified Health Risks (SCENIHR), can provide considerable assistance to EFSA regarding the early identification of emerging risks which may impact on food safety aspects of the food/feed production chains. The increasing awareness that health effects depend on the total exposure to a stressor (or several stressors) will increase the demand for co-operation between EFSA and the non-food scientific committees of the Commission.

The Rapid Alert System for Food and Feed (RASFF), as well as the project on information search in media and literature called “Risk-Watch” recently started and managed by DG SANCO, may provide useful information for the early identification and characterisation of ERs. The objective is to retrieve information from the databases available at the Commission or publicly accessible sources, using keywords that have been provided by the scientific secretariat and personnel of the unit dealing with the Commission non-food scientific committees. The members of those committees and Commission Services receive an overview list of subjects relevant to the non-food scientific committees’ activities with links to relevant articles twice a week.

EUROSTAT is monitoring a large number of parameters that may be useful for ER identification. The database “Food: from farm to fork” is a good example that holds a lot of information useful for the identification of trends that may be important signals for the identification of ERs relevant for EFSA.

Research is perhaps the most important source of information for the identification of hazards as yet unknown. There are well established methods for the retrieval of such findings when they have been published in journals or proceedings, but the time delay to publication is a problem. The Commission has, *via* DG RTD, the capacity to initiate, consolidate and sustain further research on emerging risks. In addition, it provides an opportunity to develop, establish and maintain a system whereby current findings emanating from such research can be rapidly drawn to the attention of interested parties. Also research at several Joint Research Centres generates a considerable amount of information of relevance to the detection of ERs.

Other EU agencies like the European Medicines Agency (EMA), the European Centre for Disease Control (ECDC), the European Environmental Agency (EEA) and the future Chemicals Agency are possible relevant partners for EFSA in the identification of emerging risks affecting food/feed production chains, and of future food safety related risks originating from these operations. EEA has published a report called “Late lessons from early warnings: the precautionary principle 1896-2000” (EEA, 2000) which describes the importance of the early identification of ERs.

The proposed forthcoming regulatory framework for the Registration, Evaluation and Authorisation of Chemicals (REACH) aims at improving the protection of human health and the environment through the better and earlier identification of the properties of chemical substances. The additional information that will be provided within this framework may be relevant for the early identification of emerging risks in the food and feed areas.

International bodies such as WHO, FAO and OIE, along with some non-European national bodies (e.g. Health Canada, US FDA, US EPA), represent not only a data resource for EFSA but are also bodies that currently conduct monitoring of parameters which may be useful for ER identification on a regional or worldwide scale. Several of these organisations and their work on the identification of ERs are further described in the EMRISK Report (section 5.6 of the [final report](#)).

A decision to collaborate with, or to engage the services of outside agencies could be made on the basis of the likely return of such engagement for ER. A global perspective however is an essential element to be maintained together with an appreciation of the need to adopt a holistic approach, engaging sources representing many disciplines and approaches, as the only way forward.

3. Examples of related systems for the identification of emerging risks

The EMRISK project identified many existing systems. The resources listed below without any priority order were considered by the Scientific Committee to be among those most likely to be relevant and accessible (at this time) for the ER work at EFSA. They should be more carefully considered and possible collaboration should be explored.

- GOARN (Global Outbreak and Alert and Response Network) from WHO is a network intended to complement and support the existing WHO networks and includes a Chemical Alert and Response component. GOARN is a technical collaboration of existing institutions and networks which pools human and technical resources for the rapid identification, confirmation and response to outbreaks of international importance. The Network provides an operational framework to link this expertise and skills in order to keep the international community constantly alert to the threat of outbreaks and to be ready to respond.
- GLEWS (Global Early Warning and Response System) for major animal diseases is an instrument to be developed by FAO/OIE/WHO, aiming to assist in predicting and preventing livestock animal diseases.
- INFOSAN is a new International Food Safety Authorities Network launched by WHO to promote the exchange of food safety information and to improve collaboration among food safety authorities, both national and international. For further information see [Annex 7](#) of the EMRISK project report.

- GPHIN from the Public Health Agency of Canada is a secure, internet-based “early warning” system that gathers preliminary reports of public health significance in seven languages. This multilingual system gathers and disseminates relevant information on disease outbreaks and other public health events by monitoring global media sources such as news wires and web sites. The information is filtered for relevancy by an automated process, and then analyzed by Public Health Agency of Canada GPHIN officials. The output is categorized and made accessible to users. Notifications about public health events that may have serious public health consequences are immediately forwarded to users. Some more information on GPHIN is given in [Annex 6](#) of the EMRISK project report.
- An early warning support system for food safety risks has been developed in Japan (Maeda et al, 2005). The system is designed to provide support for the detection of signals of such risks from a variety of documents which are available on the Internet. This system consists of two parts, i.e. a clearinghouse and a Risk Path Finder®. The clearinghouse is a database of documents related to food safety risks. The Risk Path Finder® visualizes relationship between terms and documents and supports users to find paths from the sources to the risk events.
- Pathfinder is a scanning tool for electronic surveillance that has been adapted for the Centers for Epidemiology and Animal Health’s Centers for Emerging Issues (CEI) in USA.

4. The SC advice on a system to identify emerging risks within EFSA’s area of responsibility

A gradual development process is advisable as the techniques used for this purpose are in a phase of rapid development. As a first step it will be necessary for EFSA to establish an ER resource. However, it is unlikely that the dedicated resource will have the capacity to adequately assess all incoming information. It will probably prove necessary to recruit or identify additional expertise both from within EFSA and from other sources in a short term perspective. The SC does not consider it feasible to have all the available sources of information included in one network and would rather recommend using a number of smaller collaborating networks. Figure 1 proposes a structure for a short term approach linking with different organisations that are already active in terms of emerging risk detection in the food and feed sector.

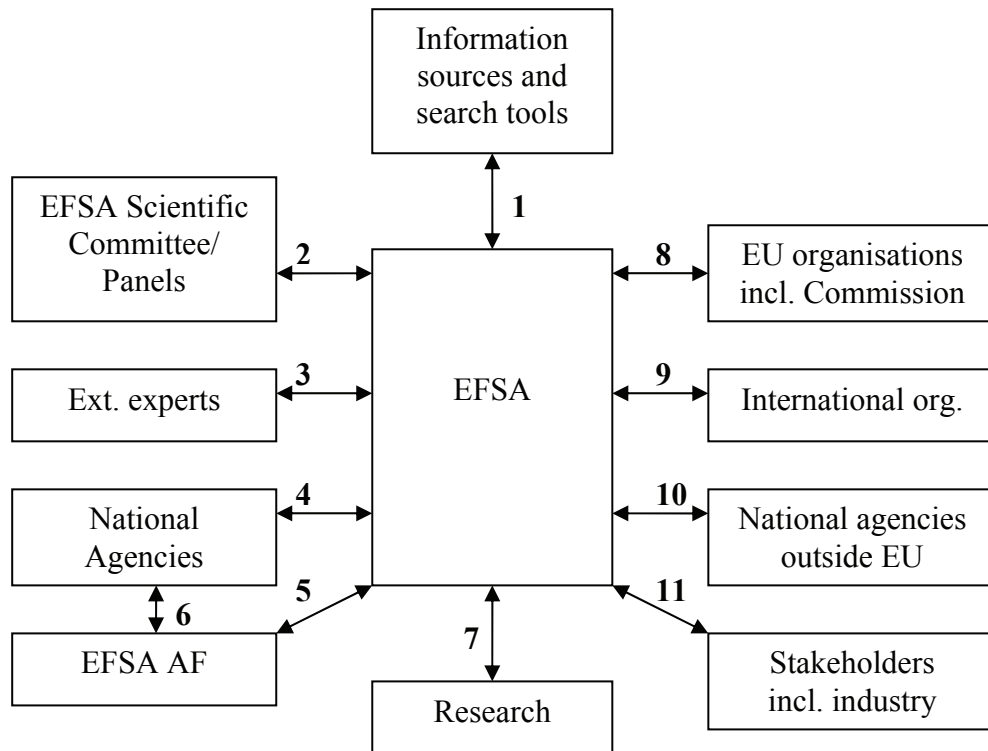


Figure 1. A possible structure outlining the most important links between EFSA and relevant internal and external bodies regarding information on emerging risks.

Adjustments to the structure proposed in Figure 1 would evolve gradually over time. It is not possible today to predict how it will work in the distant future as IT and other techniques are rapidly being developed. The links / interactions between the agencies and other bodies indicated in the boxes can be different in character, from formal agreement to less-binding arrangements within a network. The SC recommends EFSA the following activities:

- **Establish a programme within the organisation and allocate adequate resources to initiate and ensure the co-ordination of ER activities.**
- **Build links** (numbered 2 and 5 in Figure 1) **to internal EFSA Resources** (SC, Panels and AF) initially to inform those involved about the new activity and possible contributions expected from the partners, who later will be important sources of information and resources in the evaluation of signals. Links should also be established with the EFSA Scientific Expert Services that are in charge, on behalf of the European Commission, of the surveillance and reporting work in areas such as zoonoses and pesticide residues.
- **Involve Member State National Agencies** (link 4).
- Form an *ad hoc* working group under the umbrella of the Stakeholder Consultative Platform with the mandate to **suggest a stakeholder network** for the purpose of facilitating information exchange regarding emerging risks.

- **Establish bilateral contacts and co-operations**, through direct contact and by other means, **with some of the institutions that already are active in the ER field** (links 8 – 11).
- **Arrange a workshop** with interested parties, and include presentations on active systems currently in use and discussions on future networking.
- **Establish** (in co-operation with possible partners) **transparent rules concerning how information is to be treated and released**.
- **Establish contacts with food related research activities** (link 7). Information from on-going research projects needs to be made available to bodies such as EFSA faster and more effectively than in the present system.
- **Build an interactive database to store and retrieve the evaluated information**. This would provide a facility to validate the outcome of the process and possibly also to detect repeated signals that may have to be re-interpreted after a number of repetitions. This database will also be very useful for the refinement of computer-based filters in the future.
- **Identify useful information sources and tools** (link 1) based on experiences of other organisations and information in this opinion and in the EMRISK Project [final report](#).
- **Initially a limited number of the most useful indicators would be used**. The selection of those indicators has to be done in expert consultations, where trigger values would also be recommended, if possible. The use of a larger number of indicators, as suggested in the EMRISK Project ([Annex 5](#) of the report), is resource-demanding and will be a long term aim.
- **Create a roster of experts willing to support the EFSA ER Resource in the assessment and judgement of new information** (link 3).

5. The SC advice on a procedure for the scoping and evaluation of identified issues

The SC regards the system proposed in the EMRISK project ([Annex 3](#) of the report) as being worthy of further assessment by EFSA in a long term perspective. In the shorter term, the focus should be on a system based more on direct expert judgement than the system suggested in that report.

Initially, information indicating an ER will be picked up by the EFSA ER Resource. Inevitably, in order to avoid losing relevant information there will be a lot of ‘noise’ in the incoming material. The ER resource needs to be able to carry out an initial filtering procedure to remove obvious noise and other apparently less relevant repetitive signals. It is therefore essential that there is a broad scientific competence available within the resource or its immediate environment. This initial assessment of the incoming information is probably the most difficult part of the process. EFSA staff will often need to consult other experts before discarding incoming information as irrelevant. A false negative means a lost opportunity to recognise an ER, while a false positive can in the worst case give rise to unnecessary concern or alarm. Both cases are to be avoided where possible and therefore the initial treatment of new information will be critical. An outline of a possible process is given in Figure 2.

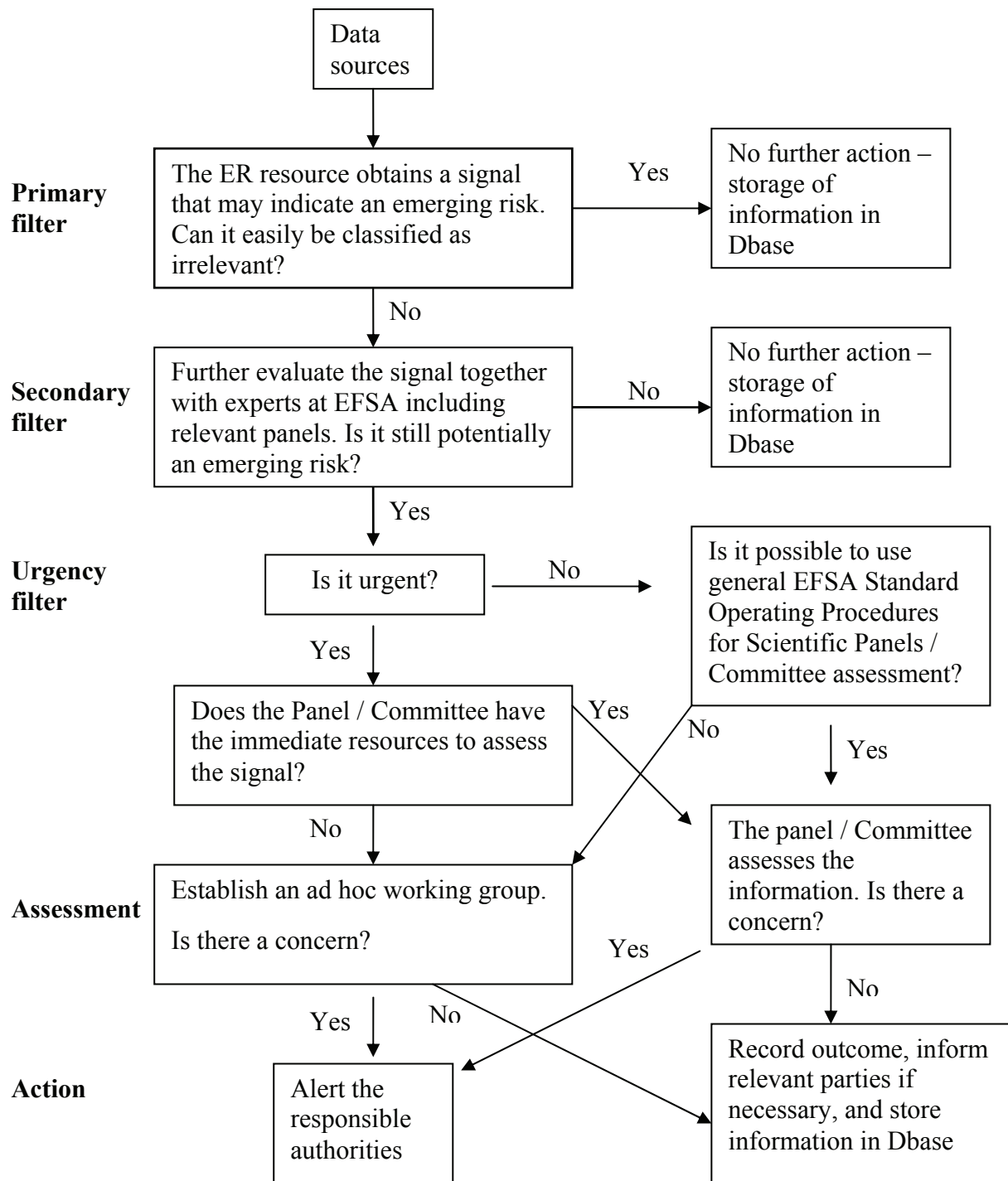


Figure 2. A possible process for the handling of a signal indicating an emerging risk. Further data collection, or initiation of further studies, may be needed at all levels of the process.

Primary filter: It is assumed that the ER resource will be able to perform an initial filtering of the incoming signals to remove obviously irrelevant and repetitive information. It will also combine signals with similar messages to support the initial evaluation. The staff of the ER resource will also have to assess the quality of the signals. The development of some kind of quality index may be necessary so as to communicate uncertainties in the information. This index may be a function of the reliability of the source, the number of independent sources, quality control in the data production and other similar parameters.

Secondary filter: Signals that the ER resource does not eliminate will need further evaluation; it is assumed that this will first be done through consultation with primarily the EFSA scientists coordinating the Panels and Scientific Committee or by involving the Scientific Expert Services, and secondly by consultations with appropriate Panels and Scientific Committee, and available experts externally.

Urgency filter: The urgency and seriousness of the indicated emerging risk will set the time frame necessary for its assessment. This process will probably often be part of the first and second filtering.

Assessment: In urgent cases it will be necessary to establish whether the relevant Panel(s) or Scientific Committee has the capacity in term of resource and expertise to assess the signal immediately. If not, an *ad hoc* working group would be created. Such a group will probably consist of members of the EFSA staff involved in the primary and secondary filtering processes, along with scientists from the Scientific Committee and Panels, as well as external experts. In less urgent cases it is suggested to try to incorporate the assessment (as a self task) in the workload of the relevant Panel. If the Panel does not have the capacity to do the assessment, then an *ad hoc* group should be established also in this case.

Action: If the outcome of the assessment does not exclude a risk of concern, relevant action has to be taken. The initial step would be to inform the European Commission and Member States of the character of the issue. It may also be necessary to initiate further action to improve the database used for the assessment, and other measures. Also if the outcome of the assessment is that there is no concern, this should be documented in a transparent way, and the relevant bodies should be informed. In order to prevent an overload of information, the transfer of information to relevant bodies will only occur if the signal reaches the assessment step.

6. Support the Authority in establishing a network of key sources from both within and outside the EU to systematically collect up-to-date relevant information on emerging risks

The SC does not recommend one single network for this purpose. There are so many different conditions in the relationships between EFSA and other organisations that a single network will be unlikely to be effective. A progressive build-up of linkages with individual bodies or with small networks of similar bodies elsewhere would be more effective, as the specific needs, as they arise, can then be addressed in different ways.

7. The SC advice on an operational system for maintaining appropriate contacts within such networks

A decision to collaborate with, or to engage the services of outside agencies could be made on the basis of the likely return of such engagement for ER identification. **A global perspective however, is an essential element** to be maintained together with an appreciation of the need to adopt a holistic approach, engaging sources representing many disciplines and approaches.

There are two very important key words to keep in mind during the ER activities, and those are ‘trust’ and ‘incentives’. One way to increase both trust and incentives is to ensure that EFSA gives a quick response to any signals coming from the partners in the ER work.

Trust between partners is a prerequisite for a working co-operation. EFSA will need to be as open as possible to its partners and may sometimes be obliged to reveal information that is not yet in the public arena, in order to be able to get some “early warnings” back in return. EFSA must also be able to deal properly with confidential information; in some cases this may be difficult as the Authority is required to be transparent. Clear rules should be provided as to how to address this type of information.

The partners in a network will have different ‘incentives’ for making available current information on ERs. The major incentive is likely to be the degree of reciprocity and mutual cooperation.

In this context a key source of relevant information is current research. In the case of small research projects, funding is a very important incentive. When a possible problem is identified there is often an acute need for further studies to be conducted immediately to verify the initial findings. The normal funding process is slow, and **a resource for support to further studies** could be ring-fenced for this purpose. This would give benefits both to the scientists and the authorities, who together could decide which further studies would be necessary so as to enable EFSA to decide how best to make use of the findings in assessing whether or not an emerging risk is present or imminent.

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