

TECHNICAL REPORT OF EFSA

Report of the EFSA Scientific Cooperation (ESCO)

Working Group on Emerging Risks¹

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SUMMARY

The mission and tasks of the European Food Safety Authority (EFSA) include the responsibility to set up a system for identifying emerging risks. In 2007, the EFSA Scientific Cooperation (ESCO) Working Group (WG) on Emerging Risks received a mandate by the EFSA to propose an operational strategy to achieve this task. Since then, 11 meetings have been organised.

The mandate includes identification of priority indicators, identification of key sources of information and best practices for data collection and exchange, and development of procedures to collect, analyze and evaluate information.

The WG, building on the operational definition of “emerging risks” adopted by the EFSA in 2007, has developed an overall procedure for the collection, analysis and evaluation of the relevant data and information. The harvesting of data and information relevant to the identification of emerging risks relies principally on their detection through the use of indicators and signals. These should be considered as primary markers when screening appropriate sources electronically by means of a real-time central data collection facility. Eleven priority indicators have been identified in the areas of chemical, microbiological and nutritional hazards, with relevant examples of signals and key sources of data and information. In order to select the cases that deserve further assessment, either because there is clear indication of an emerging risk or because available data are suggestive of such a possibility, a filtering methodology of “emerging risk indicator data”, based on an “intelligence” approach and making use of available IT tools, has been foreseen. Such a methodology should be developed in the follow up of the current undertaking by paying careful consideration to filtering methodologies currently used by organizations working on emerging risk identification in all sectors as well as by making use of ad hoc documents already made available to the WG by some participants.

A number of different institutions/organizations currently aiming at identifying emerging risks in different sectors have been listed as potential key partners of the EFSA in such an undertaking. Although extensive information on these institutions/organizations has been gathered and reported, the work carried out so far has shown that it is quite difficult to clarify the specific methodologies used by each different body to identify emerging risks in the sector of specific competence and to report them. Information on existing procedures to identify emerging risks at national levels was collected using a survey submitted through the focal points. An inventory of selected research scientific articles and reports on emerging risks, populating an endnote database, has been initiated.

Objectives and strategies for the establishment of a collaborative network between the Emerging Risks Unit and the above-mentioned key partners in a sustainable platform to exchange information have been set. Harmonization of definitions and procedures among competent organizations would allow sharing experience and optimise resources.

The work carried out by the EFSA to identify emerging risks is promising. It should be continued and further intensified to complete and validate the overall methodological approach for emerging risks identification and communication, as well as by establishing a robust network between the EFSA, the European Union (EU) Member States and the other European and international partners.

Keywords: emerging risk, early warning system, horizon scanning, indicators, procedures, data sources, networks, intelligence, food and feed safety.

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BACKGROUND

The mission and tasks of the EFSA include the responsibility to set up a system for identifying emerging risks [EC, 2002].

The clear need to establish a structured, reliable, operational system to identify emerging risks was identified as a priority for the EFSA by the Scientific Committee soon after the establishment of the Authority [EFSA, 2003]. Subsequently, the EFSA Scientific Committee considered a report prepared under contract which outlined a comprehensive methodological approach for the implementation of a global system for the identification of food-related emerging risks [VWA, 2006]. Operational guidelines and recommendations for a practical implementation of such a system were then proposed by the EFSA Scientific Committee [EFSA, 2006] and an operational definition of “emerging risks” was adopted by the EFSA [EFSA, 2007a].

In the meantime, the early identification of an “emerging risk” has been selected as one of the subjects for cooperation between the EFSA and the EU Member States. To this end, a mandate was elaborated for the establishment of the ESCO WG on Emerging Risks. This WG, coordinated by the Emerging Risks Unit, has brought together members of the EFSA’s Scientific Committee and Panels together with experts nominated by the EU Member States. This document forms the report of that WG.

TERMS OF REFERENCE

The mandate for the ESCO WG on Emerging Risks was elaborated and approved by the Scientific Committee in July 2007 [EFSA, 2007b]. The terms of reference are:

“To define and list priority “indicators” considered relevant for the identification of emerging risks by making use of past and recent experience on significant risks timely assessed or gone undetected for a long time”;

“To identify key sources and best practices in Member States and in third countries, in the EFSA and internationally, to systematically collect and update relevant data and information on indicators”;

“To propose methodology and procedures to establish a network of the above-mentioned key sources”;

“To develop procedures and best practices to collect, analyze and evaluate the available data and information in order to identify emerging risks and to recommend, when necessary, additional investigations”;

“To review recently completed or ongoing projects related to emerging risks and, where possible, recommend research activities”.

The ESCO WG uses the definitions of emerging risk, indicator, and signal adopted by the EFSA [EFSA 2006, 2007a]:

“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.” Identifying emerging risks should not be confused with risk assessment under emergency conditions.

“An **indicator** is a component of risk assessment and is comprised of a focused selection of parameters, directly or indirectly related to the food chain that can be measured/calculated qualitatively and/or quantitatively”. Ideally, an indicator “should be reliable, sensitive, quantifiable, and should provide the information on the nature of the hazard (agent/process involved) and the source of the risk”.

“A **signal** is identified as a temporal or spatial trend in an indicator value”.

Further details, along with examples of indicators are presented in the Appendix.

ACKNOWLEDGMENTS

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1. INTRODUCTION

A number of recent events have demonstrated the importance of having robust systems in place to identify emerging food safety risks quickly thereby enabling risk managers to respond rapidly to limit the impact on consumers. Systems that seek to predict the occurrence of risks at their early inception must look at early changes in hazard, exposure or population susceptibility. Emerging hazards may be unknown new hazards, known hazards not yet seen in Europe or known hazards that have previously been controlled in Europe, but are once again becoming uncontrolled. Emerging exposure routes are usually existing exposure routes that have not previously led to disease, or new exposure routes brought about by changes in the environment, in the organisation of the food chain, or in consumption patterns of the population. Emerging patterns in susceptibility of the population can be brought about, for example, by an increased number of immuno-compromised people, possibly triggered by significant increases of the elderly population.

Identifying emerging risks is very important for public health protection as it makes it possible to plan and implement baseline surveys to produce relevant data to ensure that these risks are satisfactorily addressed. In fact, identification of emerging risks provides an opportunity for risk assessors, to undertake their full characterization; and for risk managers, to develop and implement appropriate measures to control and minimise their impact. It is, therefore, not surprising that identification of emerging risks is a priority issue in a number of different sectors, including: (i) food or feed chain; (ii) medicinal and consumer products; (iii) energy production and utilization; (iv) industrial and related activities; (v) use of natural resources; (vi) living environment; (vii) occupational settings; and (ix) plant protection products.

Emerging risks may depend on a variety of different factors and circumstances which, in some cases, are very difficult to predict. Moreover, a problem that might have remained largely localised in the past, can today quickly assume a global dimension, given the increasing complexity of the food supply chain and the extent of global food trade increasing year by year. Some current developments which are likely to have a major impact in terms of emerging risks include globalisation and other so-called “megatrends” such as ageing, innovation, migrations and the financial crisis.

One of the most obvious on-going megatrend is the increase in food, and feed and production prices. This is partly due to: (i) changing diets, with resulting increased demand for animal protein in wealthier developing countries; (ii) the impact of climate change on vegetable protein and cereal production; (iii) and the large scale diversion, for example, of cereals, into biofuel production. Possible consequences include, in developing countries, the potential for poor quality food products to be diverted into the supply chain, and the increased risk of hunger and malnutrition for those living at subsistence levels; whereas in the developed countries, the increase in food prices is likely to further stimulate the search for alternative food sources, including the importation of food into the EU from new sources.

Food safety is likely to be challenged also by climate changes through the effects of droughts, floods or increasing temperatures that can modify the epidemiology of food-borne biological hazards. Other challenges are directly related to the increasing scarcity of water for irrigation, processing and drinking and the loss of farmland. Irrigation water of variable quality is one vehicle for introducing food-borne microbial hazards, including zoonotic agents, into the food chain through vegetables and fruits for instance. Little effort has been devoted to this issue.

The implications of these issues are further exacerbated by increasingly long global food chains which facilitate the introduction of food-borne hazards, previously considered as “exotic” into regions where measures for their surveillance and control are currently either rudimentary or absent.

Breeding for resistance to plant pathogens and pests has become international with reliance on the same source of resistance in many countries. Breakdown of resistance in one part of the world can endanger the crop in other continents by propagation of airborne inoculums and long-distance transport of seeds and other plant parts. Novel pests and plant pathogens frequently originate in wild flora and are efficiently disseminated by global trade in plant commodities. Expansion in host range of known pathogens and occurrence of new disease-causing agents and plant pests can have dramatic consequences on new hosts which did not co-evolve with the pathogen. Global pandemics and the spread of vector borne diseases to new areas all in part driven by climate changes are also likely to present new challenges for food safety.

On-going demographic trends in most of the EU Member States, mainly resulting in significant increase of the elderly population, who are particularly susceptible, among others, to specific pathogens, may also have a major role in the development of new emerging risks. Moreover, national food consumption habits are not stable over time and are subject to changes related not only to supply, but also to the direct cost to the consumer. Likewise, the changes in consumption habits, which include a move away from home-cooked meals to the consumption of industrially produced convenience foods and the marketing of novel foods, introduce new elements which need to be carefully considered. Immigration of people bringing with them their own consumption habits in completely new contexts could also increase the risk of food-borne illnesses inside and outside those communities.

The current trend towards mildly processed foods driven by nutritional health concerns, for example, reduction of salt and other preserving agents in foodstuffs, and new food processing technologies (e.g. nanotechnologies) and novel foods calls for a close scrutiny. Moreover, possible consequences of increased energy prices resulting in changes in the pattern of processing and storing foodstuffs (e.g. increased temperatures in cold storage and freezing as well as decreased time and temperatures of heat treatments) should also be carefully monitored.

Therefore, the early identification of a risk is made possible by the detection of specific related elements derived either from research, from monitoring programs or episodic observations. In particular, the use of reliable indicators and signals directly or indirectly related to the food chain has been identified by the EFSA Scientific Committee as a plausible valid approach to the identification of emerging risks [EFSA 2006, 2007a].

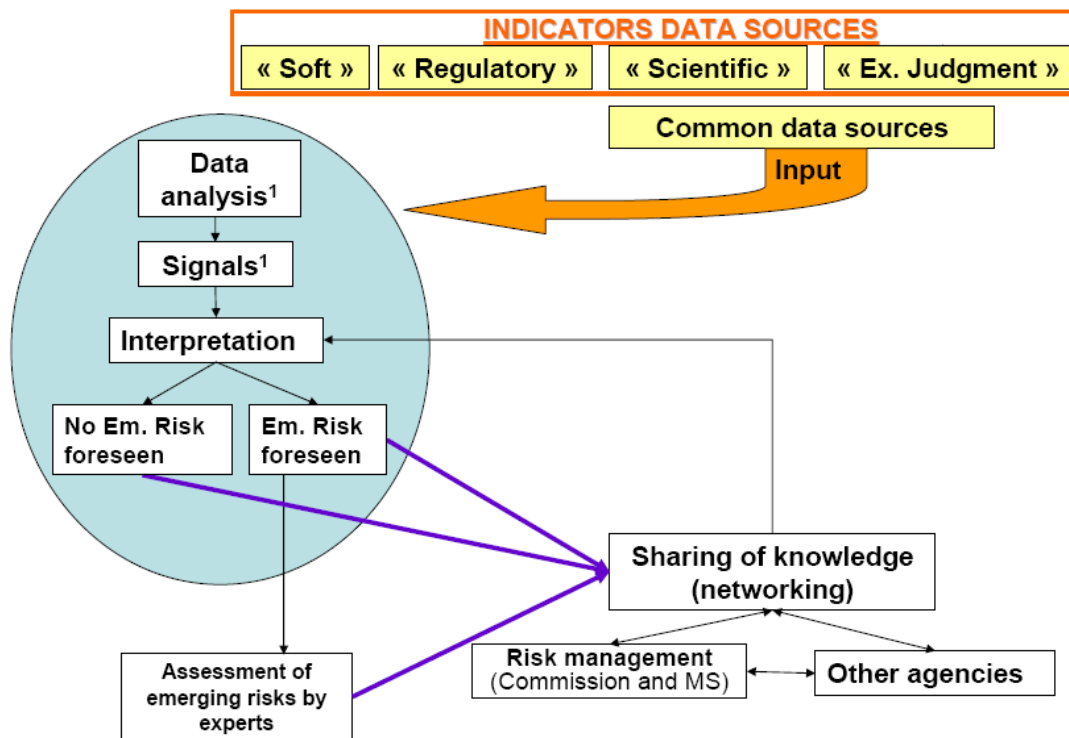
A number of competent bodies that address emerging risk issues, along with some network systems designed to identify emerging risks in different sectors including food, already exist. The absence of collaboration and harmonization among these bodies and other agencies, and specifically the lack of knowledge as to how emerging risk identification is carried out in different sectors, makes it difficult to address emerging risks at a regional or global, level, in a coordinated manner. The real challenge is, therefore, to better harmonise aims and procedures and to develop a network system involving key partners from all interested European, (inter-)national institutions and organizations, and stakeholders, sharing relevant information on emerging risks in real time.

Within this general framework, the WG has endeavoured to identify a preliminary practical approach for the establishment and operation of a global system for emerging risk identification, at all times aware of the many uncertainties and new challenges that are likely to arise in the course of its operation.

2. GENERAL PROCEDURE FOR EMERGING RISKS IDENTIFICATION

The basic challenge of an emerging risk identification system is to find, combine, filter and assess available data and information in an optimal way. The type and quality of available data and information can be extremely variable, ranging from observations among stakeholders, to precise quantitative data from monitoring or surveillance programs, such as disease registries. Thus, identifying emerging risks requires the early recognition of reliable data and information sources and a standardised system that ensures that an objective assessment can be conducted. As data leading to a correct identification of risks at their early inception are likely to be, in general, characterised by considerable limitations and uncertainties, it is not surprising that the identification of emerging risks requires a “structured intelligence approach” based on a high level of organization and expertise in the relevant sector. The overall aim is to develop a framework of a conceptual model that can deal with various kinds of information sources at different levels of detail so as to ensure an efficient analysis, quantification and validation of the indicator’s relevant signals for the early identification and assessment of emerging risks.

This section describes the overall procedure for the collection, analysis and evaluation of the relevant data as designed by the WG (Figure 1). The harvesting of data and information relevant to the identification of emerging risks will rely principally on their detection through the use of signals of indicators as primary markers when screening appropriate sources electronically by means of a real-time central data collection facility.



¹ including relevant single events

Figure 1. General procedure for emerging risk identification.

Note: Indicator Data Sources: « soft » = e.g. media, grey literature; « regulatory » = e.g. data from the RASFF, compulsory reporting/monitoring; « scientific » = e.g. published papers, proceedings, research findings, documented reports; « expert judgment » = the EFSA’s Panels, committees DG-Health and Consumers, conferences, stakeholders platforms etc...

2.1. Emerging risk indicators and signals

2.1.1. Priority indicators and signals

Under the EFSA definitions for emerging risks, indicator and signal [EFSA, 2007a], the WG focussed on specific indicators (Table 1) for which relevant signals could be provided using information derived from existing databases and other accessible sources (see Section 5.2). A list of indicators was developed using selected criteria (e.g. relevance for the EFSA, influential sector, proximity with the food chain, measurability, interpretability, and potential impact on public health). Table 1 gives the list of indicators and examples of signals identified. The overall approach underlying Table 1 and Figure 1 is that once an indicator is triggered through a change in the specific signal implying a clear or possible identification of an emerging risk, the competent unit at EFSA will gather any other relevant information in a very short period of time, making this available to an expert group for an initial risk assessment (Figure 1).

Eleven different indicators have been identified so far (Table 1). The first two indicators relate to emerging risks concerning new chemical hazards. These are based upon new research data indicating a previously unknown toxic activity of a specific chemical that has a potential to occur in food and feed, and on analytical results showing unexpected detection of a potentially toxic or radioactive chemical in food/feed. The other indicators listed concern emerging risks relating to new or already recognised biological hazards. These indicators deal with the emergence of new zoonotic and other foodborne pathogens, and with the emergence of new or exotic biological agents, pathogenic to animals or plants. An additional indicator is related to the emergence of increased resistance to antimicrobials and plant protection products. The signals considered relevant to these indicators are in the first instance the occurrence of zoonotic or other human or animal disease outbreaks, as well as laboratory and diagnostic data. Mortality/morbidity data, health activity (e.g. output records from hospitals) and monitoring of prescription data relating to infectious and other diseases are also considered as relevant signals for new zoonotic and other foodborne pathogens.

Table 1 takes into account not only newly identified hazards, but also unexpected new or increased significant exposures to a known hazard (i.e. re-emerging risks). In this case the relevant indicators are increased virulence of known pathogens, and unexpected evidence of increased exposures of human/animal population groups to particular hazardous chemical/biological/radioactive contaminants and other agents. In relation to these indicators the aim is not to deal with episodic findings indicating lack of compliance of specific food batches with existing regulations (that obviously should be removed from food/feed chain), or fraud, but rather to investigate the occurrence and relative time trends regarding hazardous agents which may be accumulating for whatever reason in the food or feed chain. Relevant signals for such indicators include analytical results from food and feed samples, and results from outbreak surveillance and investigations.

A third kind of indicator is the unexpected increase in susceptibility of human/animals (sub)population groups to known contaminants and other hazardous substances. Relevant signals in this case include clusters of specific diseases and data from studies in human beings (e.g. allergenicity tests on populations or monitoring results of individuals exposed to pesticides or radioactivity fallouts).

The last indicator in Table 1 is related to dietary changes and unbalances caused by modification of food consumption patterns or habits. In this case signals are mainly related to

increases in diseases related to specific food components (e.g. celiac disease, and diseases related to inadequate or excessive consumptions of specific nutrients).

The main difference between the overall approach described above to identify emerging risks and the approach normally adopted in risk assessment is the early retrieval of data and information in a systematic manner in order to activate an early evaluation process under the coordination of, and with the assistance of, the relevant EFSA's units and the Panels. The objective here is to provide guidance to risk managers in advance of a risk developing into a real event such as an outbreak of disease in persons, animals or plants, as mandated to the EFSA.

2.1.2. Limitations of indicators

The list of indicators in Table 1 can not be considered comprehensive and definitive. Rather, this list attempts to facilitate the systematic gathering of relevant data and information. It should remain open to the addition of unexpected indicators (e.g. detection of clusters of neurological disorders in a slaughterhouse) identified through expert judgement. Moreover, data sources on megatrends (e.g. globalisation, trade, travel, migration and innovation), which may not be very helpful for risk assessment on specific issues, could be of a major importance when trying to identify emerging risks in a wider context; to this end, a specific analytical approach should be developed. In this respect the fact that the EFSA is considering the establishment of an ad hoc "observatory" is very important.

Several factors should be taken into account in the evaluation and validation of specific indicators and signals as useful tools for the identification of emerging risks. They can be heterogeneous with regard to origin, quality (i.e. accessibility, completeness, reliability, relevance, format, time-lag), and type (e.g. qualitative or quantitative). Thus, the development of a standardised approach for identification, evaluation, signal detection and interpretation will present, particularly at the start, some difficulties. Moreover, the relevance of an indicator and signal may be strongly influenced by its inherent sensitivity and specificity (e.g. number of false negatives/positives emerging risks identified), and also by the impact on changes related to a pre-determined baseline or threshold value, i.e. parameters that have not been quantified. Reporting or surveillance biases need to be taken into account when establishing baseline levels. In particular, for indicators used to monitor changes in the patterns of incidence of specific diseases, it is important to take into account that certain trends can be spurious, due to the use of new detection methods or increased reporting.

2.2. Data and information sources and gathering tools

2.2.1. Data and information sources

Development of a systematic approach for the screening and evaluation of all the useful sources of relevant data and information for validation of the selected indicators was not feasible by the WG in the period of time and with the resources available. Therefore, the suggested sources of data and information dealt with in the present section should be considered as a starting point.

A preliminary list of main data and information sources identified as relevant to different emerging risks indicators is reported in Table 1. Obviously, some data sources may serve several different purposes and are frequently accessed independently in the course of emerging risks identification. However, as some data sources are very specific (e.g. network monitoring releases of radioactive contaminants), caution is needed to ensure a detailed identification of the most relevant data sources. Moreover, for example, data sources on megatrends (e.g. globalisation, trade, travels, migrations and innovations), which may not be necessarily helpful for risk assessment on specific issues, could be of major importance when trying to identify emerging risks more widely. Moreover, in the process of setting up a system to identify emerging risks, it is important to rely not alone on traditional approaches to the reporting of diseases or other adverse events, but also to avail of alternative sources of information.

There are four main types of data sources to be considered: (i) “soft” including those generated by the media and grey literature; (ii) “regulatory” including data from rapid alert systems and compulsory reporting/monitoring of foodborne illness; (iii) “scientific” including published papers, proceedings, research findings and documented reports and, lastly, (iv) “expert judgement”. The main specific data and information sources identified so far are as follows:

- Soft data from web monitoring systems

Among the many systems in place that can be used to retrieve so called soft data (e.g. news from the media), the Europe Media Monitoring (**EMM**) by the Join Research Centre (**JRC**) and the Global Public Health Intelligence Network (**GPHIN**) system by Public Health Agency of Canada were considered by the WG to be among those most likely to be relevant and accessible. These focus on systems designed in order to facilitate the monitoring of the media or established surveillance systems. These tools have been, at least in part, tested and possible collaboration with the developers has been preliminarily explored.

- Regulatory data

A large number of official reports and other potentially useful sources of information have been considered by the WG. Regulatory data include information that can be retrieved from official bodies at a Community, national or international level such as the RASFF.

- Eurostat

A very important information source has been identified in the Eurostat that is monitoring a large number of parameters, some of which related to the food chain, and potentially useful for emerging risk identification. The Eurostat is developing a database called “Food: from farm to fork” that will hold information useful for the identification of trends that may be important signals for the identification of emerging risks. In order to understand the extent to which the information collected and stored by the Eurostat can be useful for the Emerging Risks Unit, it is advisable that the Unit makes direct contact with the Statistical Office of the European Community. One potential area of interest to focus on is the (il)legal trade of food

commodities. The WG has collected limited, but useful information on the work programme on statistics on control and monitoring activities of the Eurostat.

- European Community Health Indicators Monitoring

European Community Health Indicators Monitoring (**ECHIM**) is a project funded by the EU through the Programme of Community Action in the Field of Public Health (2003-2008). ECHIM is a three-year project to develop and implement health indicators and health monitoring in the EU and all the EU Member States.

- EFSA's Focal Points

Focal Points have been established in the EU Member States who act as an interface between the EFSA and the different national food safety authorities, research institutes, consumers and other EFSA-related stakeholders. The key objective for Focal Points is to support their Advisory Forum members. This includes ensuring the exchange of scientific information between the EFSA and the EU Member States, building networks, and raising the EFSA's visibility. Moreover, Focal Points assist in populating a common database of national scientific experts. The Focal Points are an established network, useful in data collection and exchange between the EFSA and the EU Member States.

- Animal health

The World Organization for Animal Health (Office International des Epizooties, **OIE**) has a leading role in preventing and controlling animal diseases world wide. A main task of OIE is to control emerging and re-emerging zoonotic diseases (e.g. avian influenza) and to ensure the transparency of the world animal health situation. The OIE has established an "early warning system" for events of epidemiological significance that members should immediately notify to the OIE central bureau. In addition to the diseases included in the OIE ad hoc list, emerging diseases with significant morbidity/mortality or zoonotic potential also need to be notified. Once notifications have been received and are verified and validated by OIE, they are published under the heading "alerts" in the OIE website and sent to all agencies listed on the OIE-info distribution list, an electronic distribution list set up to facilitate and widen the dissemination of animal health information. This list is open not only to the delegates of the EU Member States, the OIE reference laboratories and collaborating centres and international and regional organisations, but also, by subscription, to any institution or individual interested in receiving such information directly. An OIE electronic platform with information of the animal health status of the members is operational (WAHID interface). Future collaboration with OIE regarding emerging animal diseases is considered to be of a high value.

- Plant health

The Standing Committee on Plant Health at the EU Commission has the leading role in monitoring and controlling diseases and pests in the EU with the participation of all the EU Member States (EC, 2000). Main objectives of this committee are to prevent the introduction into the Community of pests and diseases harmful to plants and plant products and to prevent their spread within the Community. Rights and obligations are placed upon the EU Member States to regulate the movement of plants and plant products within their territory and to regulate the introduction of plants and plant products into the Community from third countries.

Regarding emerging risks, the European and Mediterranean Plant Protection Organization (EPPO) is a highly relevant intergovernmental organization working for European cooperation on plant health. Fifty members covering almost all countries in the European and Mediterranean region are represented in EPPO whose website includes an “EPPO alert list” of plant pests which are considered emerging risks for agriculture, horticulture, forestry and amenity plants in Europe.

The Food and Agricultural Organization of the United Nations (FAO) hosts the International Plant Protection Convention (IPPC) which is the only global phytosanitary agreement. The activities under IPPC include setting of International Standards for Phytosanitary Measures (ISPM).

- Scientific data from research

Scientific research is one of the most reliable sources of information for the identification of risks as yet unknown. There are well established methods for the retrieval of such findings once they have been published in journals or proceedings (e.g. pubmed), but the time delay to publication is generally considerable. It would be worthwhile to develop a procedure to make such findings available to emerging risks evaluators as soon as possible. The present reluctance of experts/scientists to reveal preliminary findings and forward them as signals in an early warning system, is expected to be overcome by establishing an environment in which confidentiality is guaranteed by the EFSA.

Moreover, via DG-Research, the European Commission has the capacity to initiate, consolidate and sustain further research needed on emerging risks. In fact, in addition to providing means to develop, establish and maintain a system whereby current findings emanating from current research can be rapidly drawn to the attention of appropriate interested parties, research at several JRC and Community Reference Laboratories (CRLs) generates a considerable amount of information of relevance to the early detection of emerging risks.

- Expert judgement and the role of stakeholders

Experts/scientists and stakeholders should be engaged at different levels in the system. Their knowledge and expertise of the food and feed supply chain is needed to evaluate the host environment of the supply chain, and to generate key indicators in areas not yet covered and to create or identify further examples of signals. A network of experts/scientists representative of the expertise residing in the influential sectors of the host environment and the food and

feed supply chain could strongly support the process of early warning. Meanwhile, the involvement of stakeholders in identifying emerging issues can be facilitated by organisation of conferences, which address the issue. These conferences could be regarded as the start of stakeholder networking on behalf of the EFSA. It is important that, as in the case of the scientist's reluctance to disclose early results of research, the reluctance of industry to present confidential company information that could be regarded as a signal is satisfactorily addressed. That is, a trustworthy environment that guarantees confidentiality needs to be created.

The basic principle for sharing information is that all signals are welcomed even though in some if not many cases they eventually lead to the conclusion that they did not predict an emerging risk. In conclusion, false positive signals are to be welcomed so as to ensure that the possibility that experts/scientists or stakeholders withhold any information that, in fact, could lead to an early warning (i.e. false negative signal) should be minimised.

- Other data and information sources

Other organizations at a Community level judged as potentially relevant include the European anti-fraud office (**OLAF**), JRC, EURATOM, CRLs, and the Food and Veterinary Office.

2.2.2. Mechanisms and tools for data and information gathering

Mechanisms for gathering data and information from different sources includes the use of IT tools for media monitoring, complemented by manual monitoring of relevant internet sites. The main systems consist of mandatory notifications of food incidents, rare serious diseases, sentinel networks of professionals, detection of syndromes' clusters, mortality data, and animal and human health services activities. In addition to classical surveillance systems, several other tools could be useful. These include, for example, information technology tools for media screening and experts alerting on recent scientific findings. Day-to-day communications with partner organizations and expert networks in the EU Member States are another important source of information.

2.3. Methodology for data filtering to identify emerging risks

In order to select the cases that deserve further assessment, either because there is a clear indication of an emerging risk or because available data are suggestive of such a possibility, a filtering methodology of "emerging risk indicator data", based on an "intelligence" approach and making use of available IT tools, is needed. The WG has developed initial approaches to evaluate available data and information in a systematic way.

Such a methodology for the areas included in the EFSA's mission should be developed in the follow up to this undertaking by careful consideration and analysis of filtering methodologies currently used by organizations working on emerging risk identification in all sectors as well as by making use of ad hoc documents already made available to the WG from some participants. This process will result in an interpretation which will identify whether or not it

is likely or possible that an emerging risk has been detected. A series of iterations then follows, including a sophisticated filtering process based on predetermined criteria, and, most importantly, expert evaluation. If at this stage the conclusion reached is that there is no foreseen emerging risk the data collected to-date will be retained in a data bank for future reference. If the conclusion reached is that an emerging risk is foreseen or possible, these data will be shared with sister agencies, on a collaborative basis, as well as with risk managers. It is important that the methodology should be constantly updated based on lessons learned.

2.4. Competent structure to identify emerging risks

A structure competent to identify emerging risks is necessary for effective data and information gathering and filtering. In view of the complexity and novelty of such a systematic undertaking, it is very important to consider the broad range of expertise needed in relation to the different sector(s) of competence. Within the EFSA the unit tasked with identifying emerging risks is the Emerging Risks Unit. This unit will be responsible for data gathering and filtering. Given the complexity and novelty of such a systematic undertaking, it is very desirable to support the work of this unit, at least initially, with the appointment of an ad hoc group of experts.

2.5. Assessment of emerging risks

If the conclusion reached is that an emerging risk is foreseen or possible, the data available will be further assessed by experts specialised in the particular field of concern. The conclusions of this expert assessment will be communicated to the responsible authorities.

2.6. Expert group(s) to assess the identified emerging risks

The data which have triggered a response to the evidence during the filtering phase resulting in the identification of a (possible) emerging risk as well as any subsequent relevant data, need to be assessed by highly qualified expert group(s) to provide conclusions and recommendations. In the case of the EFSA, this is a task for the relevant scientific Panel(s) or, in the case of truly multidisciplinary issues, for the Scientific Committee.

3. COMPETENT INSTITUTIONS/ORGANIZATIONS FOR EMERGING RISKS IDENTIFICATION

There are a number of different institutions/organizations currently engaged in identifying emerging risks in different sectors. Although extensive information has been gathered and reported in the present section, the work carried out so far has shown that it is quite difficult to clarify the specific methodologies used by each different body to identify emerging risks in the sector of their specific competence. This is due to several features including the lack of ad hoc guidelines and the adoption of “very flexible” or even “case by case” approaches which may be difficult to generalise and codify. The current diffuse nature, or lack, of knowledge or transparency on how the emerging risk identification is carried out by different institutions/organizations, and the absence of collaboration and harmonization among the many competent organizations, makes it difficult for them to share experience and/or to work together. Apart from some exceptions, even the exchange of information on identified emerging risks suffers from considerable limitations mainly caused by the many uncertainties underlying such evaluations and the lack of definitive and harmonised communication tools.

3.1. European Commission - DG-Health and Consumers

The Rapid Alert System for Food and Feed (**RASFF**). Although the identification of emerging risks is completely different from risk assessment under emergency conditions, with a long-lasting experience in the establishment and maintenance of an efficient network system of rapid alert, the RASFF team represents one of the most competent partners to consider. The RASFF database provides useful information for the early identification and characterisation of (re-)emerging risks. The EU Member States are obliged to notify to the RASFF any measure taken regarding consignment of food and feed in case where a risk to human health has been identified and measures have been taken such as withholding, recalling, seizure or rejections of imported consignments not complying with food legislation. The RASFF team at the Commission maintains daily updates of the database containing all notifications received from the Members of the network. The network involves the 27 EU Member States, as well as Norway, Liechtenstein, Iceland and the EFSA. The RASFF database includes detailed information on the number, origin and reason of notifications, the countries and the products involved, and the identified hazards. A systematic monitoring of notifications with up-to-date statistics from the RASFF system, over time and geographical areas, could be a good source of information for monitoring the emerging risks, or known risks potentially spreading into Europe. The Emerging Risks Unit is now the designated EFSA’s contact point for the RASFF, and provides scientific and technical support to the RASFF Team.

The risk assessment Unit (C7), which coordinates the Scientific Committee on Emerging and Newly Identified Health Risks (**SCENIHR**), provides scientific assistance to the Emerging Risks Unit regarding the methodologies and criteria used by SCENIHR for emerging risks identification. C7 and the Emerging Risks Unit are now planning to collaborate in the organization of the Chairs’ WG on emerging risks (i.e. WG composed of Chairs of Scientific Committees/Panels of Community bodies involved in risk assessment, with the aim of developing and improve cooperation at the European level on emerging risks identification). Co-operation with other non-food committees at the Commission, like the Scientific Committee on Consumer Products, and the Scientific Committee on Health and

Environmental Risks, could provide additional assistance regarding the early identification of emerging risks which may impact on food safety aspects of the food/feed production chains.

3.2. European Commission - DG-Research

The European Commission has, via DG-Research, the capacity to initiate, consolidate and sustain further research on a number of issues which might be very relevant to emerging risks. In addition, it may provide opportunities to develop, establish and maintain a system whereby current findings emanating from such research can be rapidly drawn to the attention of interested parties. Thus, DG-Research is likely to be one of the most important partners as well as a valuable source of information for the identification of hazards and emerging risks at an early stage.

3.3. European Commission – European Technology Platforms

The European Commission is facilitating the development of European Technology Platforms (ETPs) to promote innovation in Europe. ETPs will bring together stakeholders in key economic sectors so as to develop a long term vision of the sector, create a strategy for delivery, and establish a management structure to ensure maximum impact. Two ETPs acting at the EFSA's remit are the ETP for Global Animal Health (focused on animal infectious diseases and how to fight against the spread of diseases), and the ETP Food for Life (focused on innovations for the agro-food industry).

3.4. European Food Safety Authority

The roles of the EFSA's internal experts have been previously described by the EFSA Scientific Committee [EFSA, 2006]. These include the Scientific Committee and Panels, the Advisory Forum, the Stakeholder Consultative Platform, and the EFSA scientific secretariat. A structured approach to involve all interested partners within the EFSA in the risk assessment of emerging risks is considered of great value. The EFSA's scientific Panel members are characterised by specialised knowledge of food and feed safety and animal or plant health. In many cases the members have also knowledge of scientific research on subjects that can be considered as emerging risks in their specialised domains. As such these experts could contribute, on the one hand, to the filtering of the relevance of certain "risks" identified as "emerging" and, on the other hand, to setting certain subjects as potential emerging risks on the agenda of the meetings of the Panels (or a specialised WG on emerging risks). The EFSA has recently launched "The Information Exchange Platform (IEP)", which has been developed to facilitate the exchange of scientific information between national food authorities in the EU Member States. This could offer an important opportunity for working together on emerging risks.

3.5. European Centre for Disease Prevention and Control

Among different EU agencies as possible relevant partners of the Emerging Risks Unit, the European Centre for Disease Prevention and Control (**ECDC**) has been identified as a key partner. In particular, the “Preparedness and Response Unit” at ECDC has recently set up structures and procedures of epidemic intelligence and response that could be of interest, such as risk assessment procedures for the identification and evaluation of (re-)emerging threats, information technology tools for media monitoring and data tracking, a new emergency operation centre, simulation exercises for emerging threats identification and crisis management, procedures for the active involvement of the EU Member States in the risk assessment process, platforms for the rapid exchange of information. In addition, the sections of food- and waterborne diseases, and the one on emerging threats at ECDC have potentially important areas of activity that could complement activities of the Emerging Risks Unit. The food- and waterborne disease section runs several initiatives on human foodborne diseases surveillance, including standardization of data collection in the EU Member States, analysis and data sharing, rapid information exchange, and early outbreak detection. The section for emerging threats carries out two relevant initiatives: one on the effect of climate change on the (re-)emerging threats for human health, and a Delphi study for the identification of the top emerging human threats related to infectious diseases in Europe. The Emerging Risks Unit has started active collaboration with ECDC in order to adopt, where suitable, common tools and procedures for emerging risks/threats identification.

3.6. European Environment Agency

In 2001, an expert Panel commissioned by the European Environment Agency (**EEA**) published a report [Harremoës et al, 2001] on “Late Lessons from Early Warnings: The Precautionary Principle 1896–2000”, which explored 14 case studies. This report's stated goal was to gather "information on the hazards raised by human economic activities and its use in taking action to protect better the environment and the health of the species and ecosystems that are dependent on it". It looked at controversial topics such as asbestos, BSE, growth hormones, PCBs and radiation – all of which demonstrated how not heeding early warnings had led to a failure to protect human health and the environment. The EEA report identified 12 “late lessons” on how to avoid past mistakes as new technologies are developed.

3.7. Other European agencies

Other EU agencies including the European Medicines Agency (**EMA**), the European Chemical Agency (**ECHA**), and the European Agency for Safety and Health at Work are potential relevant partners for the EFSA in the identification of procedures and methodologies for the identification of emerging risks, and possible common sources of information.

3.8. The Joint Research Centre

The JRC has different activities in the field of horizon scanning for emerging risks. Collaboration between the Emerging Risks Unit and the Support to External Security Unit at JRC at ISPRA has been started in 2008. JRC has developed the EMM. The core system monitors in real time selected websites of major news headings in more than 40 languages to extract articles according to user-specified criteria and terminologies. Currently, 50,000 news articles are monitored every day in more than 30 languages. The aim of this collaboration is to customise the JRC web mining tool in order to scan efficiently news and media from the web on (re-)emerging issues in the food area. The WG has already supervised and contributed in setting the objectives and strategies of the initiating steps of this project. The WG has developed with the Emerging Risks Unit search strategies related to the food and feed area, which have been embedded in the JRC system specialised in public health (i.e. Medisys). The aim is to implement a tool to retrieve as early as possible articles selectively covering areas of food safety. The current system presents, however, considerable noise, thus, the strategy needs to be refined by the Emerging Risks Unit in order to restrict the results of the system into an amount of information manageable by this Unit with the available resources.

Collaboration between JRC and the EFSA has been strengthened and several bilateral meetings are foreseen in 2009/2010 to agree on a common roadmap. The JRC hold a yearly meeting with all interested DGs and other JRC customers to look at possible forthcoming challenges in the following year.

3.9. Competent organizations in the EU Member States

The EFSA intends to 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, and exchange of expertise. Setting up an emerging risks system has little probability of success without a strong commitment from the EU Member States. As a starting point, the WG has developed a questionnaire for dissemination by focal points to identify existing systems for identifying emerging risks within the EU Member States. The questionnaire was distributed to relevant government departments and agencies dealing with food/feed safety, animal/plant health, and for the research community.

According to this limited survey that included information from 18 respondent countries, all countries reported to have a system in place for the monitoring of emerging risks in the form for example of a dedicated team, or an automated IT system, including a system to monitor selected relevant websites. Most used sources of information on emerging risks included the EFSA, and international alerts systems such as RASFF or the International Food and Safety Authorities Network (**INFOSAN**), as well as governmental bodies, the media, scientific databases, and congresses proceedings. Among the one proposed in the questionnaire, the most requested ways to exchange information on emerging risks would include e-mail alerts, online alerts, bulletins, or a new dedicated electronic platform. The totality of the responding countries reported that they would be willing to be part of a European network on emerging risks involving the EFSA and the other EU Member States.

3.10. Global Public Health Intelligence Network

GPHIN of 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, and is then analyzed and presented by Public Health Agency Canada officials. The Emerging Risks Unit has established a first contact with GPHIN in order to explore the possibility to test the system, focusing on the food and feed safety area.

3.11. Food and Agriculture Organization

FAO has recently started a process of streamlining an early warning system in the food and feed chain. During the first two bilateral meetings between the Emerging Risks Unit and the FAO (i.e. Food Quality Liaison Group), it emerged clearly that the two projects started by the EFSA and FAO have large areas of common interest: identification of key sources of information, identification of relevant indicators to be monitored by means of trend analysis, web news and information monitoring, structure and unstructured data mining. Areas of future collaboration such as, media monitoring systems, platform for exchanging information, implications for food safety of climate change, effects of international food trade and fraud on food safety have been discussed.

3.12. World Health Organization

The Global Outbreak and Alert and Response Network (**GOARN**) from the World Health Organization (**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.

3.13. FAO and WHO

INFOSAN was established by WHO in collaboration with FAO in 2004. INFOSAN is an information network for disseminating important information on food safety issues between participating countries. There are currently 167 countries participating. INFOSAN emergency is part of the INFOSAN system, which is broadly equivalent to the EU RASFF system. INFOSAN can alert member countries to emerging issues very rapidly. In addition to ensuring appropriate measures are in place to manage such issues, the network provides a means of sharing advice and expertise to help the notifying country deal with the problem.

3.14. FAO, OIE and WHO

The Global Early Warning and Response System (**GLEWS**) for major animal diseases is an instrument to be developed by FAO/OIE/WHO, aiming to assist in predicting and preventing livestock animal diseases. GLEWS is a joint system that builds on the added value of combining and coordinating the alert mechanisms of FAO, OIE and WHO for the international community and stakeholders. The aim of GLEWS is to assist in prediction, prevention and control of animal disease threats, including zoonoses, through sharing of information, epidemiological analysis. GLEWS also aims at contributing to joint field missions to assess and control relevant epidemiological outbreaks.

3.15. Other organizations and sources

The WG has initiated an endnote database including an inventory of selected relevant scientific articles and reports from initiatives on emerging risks at European and international level. The database contains some 100 references on emerging risks in different areas including ongoing and recently completed ongoing projects, but also specific areas such as nanotechnology, climate change and media monitoring. Such a database, once completed and regularly updated could be of considerable value when forming an emerging risks database to share information with interested partners.

4. ESTABLISHMENT OF A COMPREHENSIVE NETWORK ON EMERGING RISKS

When gathering large amounts of data from heterogeneous sources, the control of an overflow of information and the complexity and heterogeneity of the data sources involved in the system, should be carefully taken into account. In this context an effective collaboration between different institutions/organizations dealing with emerging risk assessment in various sectors and countries would be very helpful to better manage different data sources and to share in a structured manner available data and analyses. Therefore, the institutions/organizations mentioned in Section 6 are seen as key partners of the EFSA in the implementation of a sustainable network to exchange data and outcomes in their processes related to emerging risks identification. This could be even more the case particularly if a common approach could be developed and some harmonization achieved in the respective methodologies used by the different agencies and other bodies. In fact, the identification of emerging risks in one sector may be highly relevant to those working on the same objectives in other sectors. For all the parties concerned such links and the potential for collaboration with the Emerging Risks Unit should be fully explored. Furthermore, such an approach could help overcome current resources limitations for the different institutions/organizations and greatly increase the scientific value of analyses.

5. CONCLUSIONS

The success in identifying risks at their early inception (emerging risks) is at the heart of public health and environmental protection. In fact, it would make possible to better control and, often, to prevent and/or minimise the impact of serious hazards on health and the environment. It is, therefore, not surprising that identification of emerging risks is a priority issue in a number of different sectors.

Both old and recent European regulations have imposed duties concerning emerging risks identification in different sectors. In fact, the legal terms “emerging risks” and “emerging threats” have found only a few years ago their way into the European law as tasks assigned, respectively, to the EFSA and ECDC as well as to the SCENIHR, which is one of the non-food Scientific Committees, advising the European Commission. On the other hand, EMEA has the responsibility of pharmaco-vigilance, a very effective tool to detect emerging risks associated with new medicinal products entering the clinical practice, for many years. Moreover, several other bodies including specific units in DG-Health and Consumers, EEA, JRC and several organizations in the EU Member States and third countries are involved in the identification of emerging risks. Several international organizations, such as WHO, FAO and OIE are also actively working in this area. Lastly, most of the bodies that are involved in risk assessments in a specific sector are likely to consider as a common part of their work the detection of risks as soon as possible after inception, thus developing an investigative trend on emerging risks supported by the rapid development of scientific knowledge.

As data leading to a correct identification of risks at their early inception are likely to be, in general, characterised by considerable limitations and uncertainties, it is not surprising that the identification of emerging risks requires a “structured intelligence approach” based on a high level of organization and expertise in the relevant sector. This explains why competent bodies in emerging risk identification tend to specialise in specific sectors and, rightly so, to carry out emerging risks identification selectively in their own sectors. While less structured systems, such as those relying solely on qualified expert groups with no access to systematic tools for early retrieval and appraisal of relevant data, may also be able to identify emerging risks, experience tells us that such systems could be affected by many uncertainties and could be characterized by low analytical power.

The work carried out so far has shown that it is quite difficult to clarify specific methodologies used by different bodies to identify emerging risks in different sectors. This is due to several features including the lack of ad hoc guidelines and the adoption of “very flexible” or even “case by case” approaches which may be difficult to generalize and codify. Apart from some exceptions, even the exchange of information on identified emerging risks suffers of considerable limitations mainly caused by the many uncertainties underlying such evaluations and the lack of definitive and harmonised communication tools.

In recent years, the EFSA and competent ESCO WGs have carried out an intensive programme to develop an effective and transparent approach to identify emerging risks, consisting of an operational definition of emerging risks and a procedure, based on indicators and signals as well as relevant data sources, in principle applicable to all sectors, while work on mechanisms and methodologies for data filtering is still pending. The main results of a general nature achieved so far are as follows: (i) emerging risk definition; (ii) emerging risk indicators and signals; (iii) data and information sources and appraisal tools; (iv) establishment of a competent structure to identify emerging risks ; and (vi) establishment of

expert group(s) able to fully assess the identified emerging risks. In relation to the EFSA's specific mission, the ESCO WG has also developed, in the above-mentioned framework, a set of indicators relevant for food and safety, and has listed examples of valuable sources for data and information useful to identify emerging risks. Clearly, a specific set of indicators and sources would be helpful for each different sector in which emerging risks are considered.

The structure competent within the EFSA to identify emerging risks is the Emerging Risks Unit. In view of the complexity and novelty of such a systematic undertaking, it is very desirable to support the work of this unit, at least initially, with the appointment of an ad hoc group of experts. Data which trigger a response to the evidence during the filtering phase, resulting in the identification of a (possible) emerging risk as well as any subsequent relevant data, are then expected to be assessed, in the case of the EFSA, by the relevant scientific Panel(s) and its Scientific Committee in the case of truly multidisciplinary issues. Work on relevant methodologies for data filtering is still pending.

6. RECOMMENDATIONS

To-date the work carried out by the EFSA to identify and communicate emerging risks is very promising. Although the overall approach has not yet been finalised, it is clear that many results have been achieved and that the work undertaken by the EFSA should be continued and further intensified along the following lines:

- Completion of the overall approach(es) of the EFSA to identify emerging risks for food and feed safety, particularly with respect to a detailed proposal on data sources and modalities to access them in relation to the indicators already identified as well as to the development of an effective procedure for data filtering. It would also be important to establish a mechanism to follow up the emerging risks identified at different times since the first identification. To support the work of the Emerging Risks Unit, at least for the first two years of activity, an ad hoc group of experts available to meet on a regular basis and according to needs should be established.
- Check and validation of relevance, reliability, sensitivity and specificity of the approach(es) selected by the EFSA to identify emerging risks in the food and feed chain. To this end, a group of experts from all relevant areas should be asked to choose one example of risks occurred in each one of the main sectors of food and feed chain, that have emerged during the last decades and to apply to them the above methodology developed to identify emerging risks. Such a historical analysis tool has the aim of validating whether the methodology would have been able to identify the emerging risk and could help to further optimizing possible indicators, sources of data/information as well as the "intelligence" approach used for data analysis.
- Ensuring that the work of the EFSA maintains the current broad perspective and that the approach developed will be as much as possible applicable also in sectors other than food safety. To this end, an analysis of the current world situation in search of the circumstances leading to the appearance of emerging risks according to approaches used in different sectors would be appropriate. This analysis of the current situation worldwide could be performed at a (biennial) colloquium on emerging risks, preferably held in collaboration with the European Commission, and receive feedback from EU and third countries competent scientific bodies, the EU Member States authorities, international organizations (e.g. WHO, FAO, OECD) and stakeholders fora.
- Development by the EFSA of an approach to communicate emerging risks avoiding any unnecessary alarm and facilitating full understanding of all underlying implications.
- Establishment by the EFSA of a network and its operational procedures to share data and results with other scientific international, European and national bodies specialised in identifying emerging risks in sectors belonging to the EFSA's mission and in sectors other than those covered by the EFSA's mission should be pursued by the EFSA as it could considerably reduce resources needed and facilitate the EFSA's task by effectively preventing the risk of information overflow. Possible incentives to share data and information should be also considered.
- Promotion of effective interactions between the EFSA and DG-Research aiming at initiation of research programmes devoted to the development of new indicators, data sources and filtering tools and methodologies to identify emerging risks.

- Promotion by the EFSA of activities (e.g. training courses and public general information on the EFSA's site) aimed at increasing the awareness of emerging risks and the transparency of the EFSA.

TABLE 1

List of priority indicators, examples of signals and data sources.

#	Indicator	Class	Example of signal	Examples of data sources
1	New research data indicating toxic properties of substances possibly occurring in food or feed	Chemical	<ul style="list-style-type: none"> Data on toxic activity 	ECHA, ECETOC, NTP, Pubmed, Toxline, RTECS
2	Unexpected detection in food or feed of a potentially toxic/radioactive chemical	Chemical	<ul style="list-style-type: none"> Analytical results by established and new detection methods Clusters of non-infectious human/animal diseases with possible association with food/feed (including water) 	EURATOM, EFSA occurrence database, EEA, ELCOM, OSPAR
3	Emergence of new zoonotic and other foodborne pathogens	Biological	<ul style="list-style-type: none"> Outbreak surveillance Clinical and diagnostic data Other laboratory data Mortality/morbidity data Syndromes identification Health care activity / monitoring Prescriptions data 	ECDC, CDC, INFOSAN, GOARN, PulseNet, EFSA zoonoses database
4	Emergence of a new or exotic biological agent pathogenic to animals	Biological	<ul style="list-style-type: none"> Outbreak surveillance Animal health and diagnostic data Other laboratory data 	OIE, WHO, ERANET, EUROSTAT, Defra, Glews, CRLs
5	Emergence of increased resistance to antimicrobials and plant protection	Biological	<ul style="list-style-type: none"> Surveillance (sporadic and outbreaks) Laboratory data 	EMEA, ECDC, FAO stat, EFSA zoonoses

	products			database, EFSA pesticides review and database
6	Emergence of a new or exotic biological agent pathogenic to plants/food/feed crops	Biological	<ul style="list-style-type: none"> • Surveillance data (including quick scan from plant protection programs) • Outbreaks • New disease in crops 	EMAN, EPPO, NAPPO, WTO, DAFF, EXAMINE, APPO, IPPC, FAO, ETP
7	Increased virulence of known pathogens (including plant pathogens)	Biological (re-emerging)	<ul style="list-style-type: none"> • Outbreak surveillance • Clinical and diagnostic data • Other laboratory data • Mortality/morbidity data • Syndromes identification • Health care activity / monitoring • Prescriptions data 	ECDC, INFOSAN, EFSA zoonoses database, FAO, IPPC, EPPO, NAPPO
8	Unexpected evidence of increased exposure of specified human (sub)population to particular hazardous chemical/biological/radioactive contaminants and other agents in the food/feed chain	Chemical/Biological	<ul style="list-style-type: none"> • Analytical results from food/feed • Food/feed consumption patterns • Biomonitoring data (i.e. biomarkers) • Outbreak surveillance • Clinical and diagnostic data • Other laboratory data • Mortality/morbidity • Syndromes • Health care activity / monitoring • Prescriptions 	EFSA consumption database, EEA, poison centres
9	Unexpected evidence of increased exposure of specified animal	Chemical/Biological (re-emerging)	<ul style="list-style-type: none"> • Analytical results from food/feed 	Eurostat, ECDC, OECD

	(sub)population to particular hazardous chemical/biological/radioactive contaminants and other agents through food		<ul style="list-style-type: none"> • Food feed consumption patterns • Biomonitoring (i.e. biomarkers) • Outbreak surveillance • Clinical and diagnostic data • Other laboratory data • Mortality/morbidity • Syndromes • Health care activity / monitoring • Prescriptions 	
10	Unexpected increased susceptibility of (sub)populations to known contaminants and other hazardous substances not regulated in the food/feed chain	Chemical/Biological (re-emerging)	Trends in specific diseases (e.g. allergenic test on population; monitoring of workers exposed to pesticides; exposure to radioactivity fallouts)	Eurostat, WHO, hospitalizations services
11	Dietary changes or unbalances caused by modification of food consumption habits	Nutrition	<ul style="list-style-type: none"> • Increase in diseases related to specific food components (e.g. increase in diabetes in infants, gluten origin; diseases related to the lack of specific nutrients, such as vitamins and minerals) • Trends analysis of food consumption in specific groups of populations (e.g. elderly populations) 	EFSA food consumption Database, US national Nutrition Monitoring and Related Research Program, Dutch Food Consumption Surveillance System

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APPENDIX

Definition and Description of “Emerging Risks” within the EFSA’s Mandate (EFSA\SC\415_final)

ABBREVIATIONS

APPO	African Plant Protection Organization
CDC	Centres for Disease Control and Prevention
CRLs	Community Reference Laboratories
DAFF	Department of Agriculture, Fisheries and Forestry
ECHA	European Chemical Agency
ECETOC	European Centre for Ecotoxicology and Toxicology of Chemicals
EEA	European Environment Agency
EFSA	European Food Safety Authority
EMAN	Ecological Monitoring and Assessment Network
EMEA	European Medicines Agency
EMM	Europe Media Monitoring System
ESCO WG	EFSA Scientific Cooperation Working Group
EPPO	European and Mediterranean Plant Protection Organization
ETP	European Technology Platform
EU	European Union
EXAMINE	Exploitation of Aphid Monitoring systems in Europe
FAO	Food and Agricultural Organization of the United Nations
GOARN	Global Outbreak and Alert and Response Network
GLEWS	Global Early Warning and Response System
GPHIN	Global Public Health Intelligence Network
INFOSAN	International Food Safety Authorities Network
IPPC	International Plant Protection Convention
ISPM	International Standards for Phytosanitary Measures
NAPPO	North American Plant Protection Organization
NTP	National Toxicology Program
OECD	Organisation for Economic Co-operation and Development
OIE	Office International des Epizooties - World Organisation for Animal Health
OSPAR	Convention for the Protection of the Marine Environment of the North-East Atlantic
RASFF	Rapid Alert System for Food and Feed
RTECS	Registry of Toxic Effects of Chemical Substances
SCENIHR	Scientific Committee on Emerging and Newly Identified Health Risks
WG	Working Group
WHO	World Health Organization
WTO	World Trade Organization