TECHNICAL REPORT OF EFSA

Development and implementation of a system for the early identification of emerging risks in food and feed[1]

European Food Safety Authority[2, 3]

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ABSTRACT

According to EFSA's Founding Regulation[4], the Authority is required to *"undertake action to identify and characterise emerging risks"* in the field of food and feed safety. EFSA provides scientific advice to the risk manager, at both European and Member State level, for the identification of risks present in the food chain. In the area of currently unrecognised but potentially significant risks for public health, EFSA has set up a dedicated unit on emerging risks (EMRISK). Through the identification of drivers of emerging risks, EFSA also intends to anticipate future risks derived from changes in current food/feed production practices or factors impinging on food/feed production or changes in human exposure through food consumption. EFSA aims to establish a data monitoring capacity, data filtering methodology and networking structures to identify emerging risks and drivers of emerging risks in a timely fashion and to communicate these to the risk manager. To date, the first step of this process (data monitoring) is in place. The following steps, that is, filtering and communication, are being rapidly established. Whilst the current data sources monitored are limited, they have been sufficient to enable the elaboration of the procedures for the next steps in the emerging risks identification process. As more data sources become accessible, the process will become more effective. All processes should be in place by mid - 2010 and reported on in EFSA's first annual report on emerging risks in 2011. By the end of the second year of operation (2012), the soundness and utility of this approach will be given an initial review.

KEY WORDS

Emerging Risks, RASFF, trade, media monitoring, crisis preparedness

1 On request of EFSA, Question No EFSA-Q-2009-01075, issued on 27 October 2010.

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3 Acknowledgement: EFSA wishes to thank for the preparation of this EFSA scientific output: EFSA's staff member(s) Tobin Robinson, Andrea Altieri, Andrea Gervelmeyer, Agnés Rortais, Tilemachos Goumperis, Aglika Hristova, Laura Ciccolallo. This document was reviewed by Vittorio Silano.

4 Article 23(f) Reg. 178/2002/EC

Suggested citation: European Food Safety Authority; Development and implementation of a system for the early identification of emerging risks in food and feed. EFSA Journal 2010; 8(10):1888. [62 pp.]. doi:10.2903/j.efsa.2010.1888. Available online: www.efsa.europa.eu

SUMMARY

According to EFSA's Founding Regulation[5], the Authority is required to *"undertake action to identify and characterise emerging risks"* in the field of food and feed safety. EFSA provides scientific advice to the risk manager, at both European and Member State level for the identification of risks present in the food chain. In the area of currently unrecognised but potentially significant risks for public health, EFSA has set up a dedicated unit on emerging risks (EMRISK). Through the identification of drivers of emerging risks, EFSA also intends to anticipate future risks derived from changes in current food/feed production practices or factors impinging on food/feed production or changes in human exposure through food consumption.

EFSA aims to establish a data monitoring capacity, data filtering methodology and networking structures to identify emerging risks and drivers of emerging risks in a timely fashion and to communicate these to the risk manager.

To date, the first step of this process (data monitoring) is in place. Three principle sources of information, which is the RASFF, the media and trade data have been identified and assessed. In addition, the scientific literature is monitored. Further data sources will be assessed added to the regular monitoring.

The subsequent steps identified in the emerging risks identification process, that is, filtering and communication, should be established rapidly. Whilst the current data sources monitored are limited, they have been sufficient to enable the elaboration of the procedures for the next steps in the emerging risks identification process. As more data sources become accessible, the process will become more effective. In particular, networking with stakeholders, MS, EU and international agencies is seen as a key step in developing the effectiveness of this process, and the structures for carrying this out effectively are being developed.

All processes should be in place by mid- 2010 and will be reported in EFSA's second annual report on emerging risks in 2011. By the end of the second year of operation (2012), the soundness and utility of this approach will be given an initial review.

[5] Article 23(f) Reg. 178/2002/EC

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BACKGROUND AS PROVIDED BY EFSA

The successful identification of risks at their early inception (emerging risks) is at the heart of public health and environmental protection. Improved identification of emerging risks may become a major preventive instrument at the disposal of the Member States and the Community[6].

According to EFSA's Founding Regulation[7], the Authority is required to *"undertake action to identify and characterise emerging risks"* in the field of food and feed safety. In 2007 EFSA established, for this purpose, a dedicated unit on emerging risks. The Emerging Risks Unit (EMRISK) contributes to this mission by supporting the development, establishment and operation of structures for the screening and analysis of information sources with a view to identifying emerging risks.

EFSA has started to implement its programme to develop an effective and transparent approach to identify emerging risks. This consists of an operational definition of emerging risks and an overall strategy for the collection, analysis and evaluation of the relevant data and information (EFSA, 2006; EFSA, 2007c; EFSA, 2009b; EFSA/SC/Tender/01/2004).

Whilst EFSA has a unit dedicated to the early identification of emerging risks, the task is a horizontal one, implicating not only EMRISK, but also all of EFSA's scientific units and their associated panels.

TERMS OF REFERENCE AS PROVIDED BY EFSA

The EMRISK unit, will draft a report on emerging risks in food and feed. The report will address:

Strategy:

- EFSA's strategic plan on the identification of emerging risks in food and feed.

Medium and long term emerging risk identification and anticipation:

- A short literature review of developments in the area of emerging risks in food and feed.
- Reporting on methods assessed and developed by EFSA.
- An inventory of "hazard" databases to which EFSA has access.
- Reporting on emerging risks or drivers that have been identified (if any).

Work Plan:

- Next steps in the continued development of EFSA's capacity in the area of emerging risks.

Timeline

The technical report on emerging risks in food and feed will be approved by the end of October 2010.

Expected deliverables

The technical report on emerging risks in food and feed.

[6] Recital 50, Reg. 178/2002/EC
[7] Article 23(f) Reg. 178/2002/EC

1. Introduction

The successful identification of risks at their early inception (emerging risks) is at the heart of public health and environmental protection. Improved identification of emerging risks may become a major preventive instrument at the disposal of the Member States and the Community[8].

According to EFSA's Founding Regulation[9], the Authority is required to *"undertake action to identify and characterise emerging risks"* in the field of food and feed safety. In 2007, the EFSA established, for this purpose, a dedicated unit on emerging risks. The Emerging Risks Unit (EMRISK) contributes to this mission by supporting the development, establishment and operation of structures for the screening and analysis of information sources with a view to identifying emerging risks.

EFSA has started to implement its programme to develop an effective and transparent approach to identify emerging risks. This consists of an operational definition of emerging risks and an overall strategy for the collection, analysis and evaluation of the relevant data and information (EFSA, 2006; EFSA, 2007c; EFSA, 2009b; EFSA/SC/Tender/01/2004).

Following the formation of EMRISK and the instigation of a work plan, the first results are starting to be delivered. It is thus an opportune moment to summarise the initial achievements and also to formulate a long-term plan on how to address the goals of EFSA in the field of Emerging Risks.

Whilst EFSA has a unit dedicated to the early identification of emerging risks, the task is a horizontal one, implicating not only EMRISK, but also all of EFSA's scientific units and their associated panels.

Scope of the paper

As a first step in EFSA's strategy to address emerging risks (ERs), EMRISK is, in the first instance, focussing on food and feed ERs. Monitoring for ERs in the areas of plant and animal health will commence in 2011 and 2012 respectively, and are considered by the PLH and AHAW panels with the support of the Assessment Methodology Unit (AMU). No unit is currently specifically mandated to survey emerging animal welfare risks, though it is noted that the AHAW panel is putting a significant effort in the development of animal welfare assessment methods.

The aim of this document is to review the current situation and outline the objectives, timelines and resources needed by EFSA in order to build a capacity for emerging risks identification. In addition to the points described in the Terms of Reference, this document specifically addresses the following:

- A review of the definition of emerging risk, as used by EFSA, and the implications of this definition.
- Identification of the key players for assisting EFSA in achieving its aims in the area of emerging risks.
- Review of the work already carried out and refining of the strategy proposed for identifying emerging risks.
- Definition of the outputs to be produced for the identification of emerging risks and the mechanisms through which they can be achieved.

The issue of the early identification of emerging risks will be set out in the context of a continuum of responses undertaken by EFSA, from the anticipation of urgent issues to the prediction of emerging risks, demonstrating overlap in the use of data sources and their analysis.

[8] Recital 50, Reg. 178/2002/EC
[9] Article 23(f) Reg. 178/2002/EC

Definition of emerging risks

The definition currently in use in EFSA is developed by the Scientific Committee (EFSA, 2007c): "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".

Throughout this document, reference is made to the use of "indicators" and "signals" for identifying ERs. The use of these two terms in this document is as defined in the opinion on emerging risks of the Scientific Committee (EFSA, 2006):

"An indicator is a component of risk assessment and is (ideally) 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". Examples include the emergence of new zoonotic pathogens, increased virulence of known pathogens, unexpected increase in exposure to particular hazardous chemical, biological and/or radioactive contaminants through food.

"A signal is identified as a temporal or spatial trend in an indicator value".

2. Building a capacity for the identification of emerging risks in food and feed

2.1. Mission and strategy of EFSA with regards to emerging risks

EFSA is charged with two principal missions in this area. Firstly, emerging risk (ER) identification, which requires the development of methods, data collection, data analysis and interpretation, in order to identify ERs. The tools and databases developed for the task of ER identification may also be of use in answering both urgent and non-urgent questions.

The second mission, providing support on urgent issues, involves emergency preparation, including maintenance of the Emergency Manual, organisation of emergency or "crisis" training, and providing technical and administrative support for answering urgent issues. These issues are not reported on in this document.

A formal mandate for EMRISK outlining its areas of responsibility is proposed in this paper (see appendix C). The mandates and contracts related to specific work items of EMRISK are listed in appendix A.

2.2. Time as a factor and its impact on prioritisation of activities: crises, early warning, identification and anticipation of emerging risks

The activities currently being carried out in the area of risk anticipation and preparation may be formalised as four separate issues, according to the degree of anticipation, and so of the window of opportunity for action involved (see also Table 1). Each of the four activities has a different resource demand, due to the different timescales involved. For example, effective monitoring for early crisis warning could take place on a daily level, whereas reviewing drivers of ERs (for *anticipating* ERs) could take place as little as once every three years.

Preparation for responding to urgent issues, in particular scientific assistance.

Crisis preparation is clearly a different activity from the identification of emerging risks, and those activities of EFSA linked to crisis preparation are not discussed in this document.

Early warning (anticipation of "crises") may be the easiest task to plan and implement, in that the hazard is often (though not always) well identified, the risk relatively easy to characterise, and the need for action clear. However it requires regular (daily) monitoring and a fast response (the data becomes out of date very quickly) to be of use, and is thus relatively resource demanding. This is not currently seen as a high priority action for EFSA, as the risk manager may be better placed to have access to the relevant information and alerts. However, where such information is seen through regular monitoring for other purposes (e.g. for the identification of emerging risks) they are to be shared, even though no systematic monitoring for short-term alert data is foreseen.

Mid-term warning (identification of emerging risks) is proposed as the core of EFSA's activities in the area of emerging risks. Monitoring is on a weekly or monthly basis and therefore less resource intensive, but at the same time more resource demanding for the subsequent data analysis. Its successful implementation is more challenging than the establishment of an early warning system in that it is likely that there will be insufficient information available to carry out a full risk assessment or even hazard characterisation. There is less certainty over whether and what action needs to be taken. Dealing with such large uncertainties will be a difficult task for the risk manager and indeed for any risk communication.

Long-range anticipation of emerging risks. The current definition of ERs is hazard based. As such it is limited in scope to the medium and to the short term identification of ERs. Long term anticipation (that is, the prediction of ERs as opposed to their identification) should be based on the identification of drivers (e.g. climate change, new food production or processing technologies, etc.) for the emergence of new risks. This is an important differentiation due to the fact that one does not have to be able to identify a specific hazard in order to be able to anticipate that a certain action or change in conditions may well give rise to the emergence of a risk. It is therefore proposed that some long range forecasting activities do take place. This activity is intrinsic in the identification of "indicators", and thus is already being carried out, although not under this name.

Whereas it may not be possible to identify specific hazards, certain sectors or practices within the food chain that may warrant closer surveillance may be identified i.e. those with a "high" likelihood of producing new risks. The uncertainties are high, the need for action unclear and as a consequence it may be judged as being low priority, even though the long timescale would allow for the possibility of prevention rather than reaction to an emerging/emerged risk. An example would be the identification of changes in the processes for recycling animal by-products into animal feed as a potential generator of emerging risks, as was probably the case for BSE. It may have been possible to identify the risky practice and to have implemented control measures without any knowledge of the eventual novel hazard that emerged. Such long-range forecasting could take place over a relatively long time period, for example being formally reported once every three years.

3. Outputs

Four documents summarising the state of the art and outlining a strategy for identifying emerging risks have been published by EFSA (see appendix B). These consist of a report from an outsourced project (EFSA/SC/Tender/01/2004)[10], two documents from the Scientific Committee (EFSA 2006, 2007c) and one from an EFSA Scientific Cooperation working group (EFSA, 2009b).

In order to achieve the goals identified in chapter 2, the following outputs have been identified (see Table 1):

[10] EFSA/SC/Tender/01/2004. Food and Consumer Product Safety Authority (VWA) with BfR, BVL, FAO, FAVV-AFSCA, FSA, CSL, OIE, RIKILT and RIVM (2006) Forming a Global System for Identifying Food-related Emerging Risks (EMRISK) Final Report, 8.04.2006

EFSA's activities on emerging risks

These will be reported in EFSA's annual reports on ERs. While the present document, which is the first such annual report, focuses on the strategy and methods being put in place, future annual reports will focus more on identified signals of emerging risks, as well as reporting on methods and process development. The annual report will compile the results of monthly monitoring reports, as well as case studies addressing in more depth specific issues identified through the monitoring or identified by EFSA's Panels, MS or the Commission. It is anticipated that 4 to 6 of these short case studies will be produced per year, addressing both emerging risks and potential drivers of emerging risks. Input from stakeholders and the ER Network will be annexed to this report.

Long-term issues (ER prediction)

It is proposed that long-term issues are reviewed on a three year cycle. Furthermore, it is suggested that the EFSA panels are actively involved in this process. An example of their involvement could be that once during panel's 3-year mandate they produce a brief document on future issues (see, for example, that produced by the Biological Hazards Panel in 2008[11]). Contributions from stakeholders, MS, EC, European and international agencies will be sought through the networks currently being established. The report would contribute to EFSA's strategic plan. A proposed timeline could be that the first report on drivers of emerging risks is published in 2012, with subsequent reports published at an interval of three years.

Working groups will also produce scientific reports separate from the annual report dealing with specific technical aspects of emerging risk methodology and data.

Communication issues

Any communication, including publication, on results of ER identification needs to be handled with proper caution. Due to their nature, identified ERs come with a certain degree of uncertainty – those identified at short term will have less uncertainty (in general) than those identified over medium to long term. However, the longer in advance a potential risk may be identified, the greater the opportunity for the risk manager to successfully intervene (or the risk assessor to carry out a risk assessment) before a food crisis develops. How to handle this dichotomy of uncertainty versus advanced warning should be further explored. The Emerging Risks Network (see below) would be well placed to do this.

[11] http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902588836.htm

Table 1. The four principle areas of activity, as defined by responsiveness

	Definition	*Outputs*	*Key players*	*Planning*
Crisis preparation	Not addressed in this document			
Early warning/crisis anticipation	A significant risk (emerging or otherwise) is present in the food chain and an urgent question to EFSA and/or communications activity is anticipated in the immediate future	Alerts	Risk Manager, with technical support from EMRISK when appropriate	Ad hoc
Identification of emerging risks	Early identification of an ER that is already in the food chain, but not yet recognised as a significant risk to human health	Monthly internal ER signal monitoring reports	ERIC[12]	In place by February 2010. EMRISK to lead, all science units to contribute. Monthly meetings.
		Recommendations for further action, if any	Panels and SC	Addressing the output of ERIC, from April 2010 onwards.
		Case studies	EMRISK	Trialled since July 2009, fully active from March 2010. Specific issues identified through the monitoring are treated in more detail. 4-6 reports per year, to contribute to the annual report.
		Annual reports	EMRISK, Panels, SC, StaCG-ER[13], ER Network	EMRISK to coordinate. Stakeholder group and Network to be initiated by April 2010. First annual report for February 2010.

[12] Emerging Risks Internal Collaboration group, consisting of EFSA staff drawn from the science units.
[13] Stakeholders Consultative Group on Emerging Risks

		Method development (Technical reports)		EMRISK to coordinate. WGs on data collection and data analysis methodology to be established in 2010.
Prediction of emerging risks	Identification of drivers of ERs	Tri-annual report	EFSA's Panels, StaCG-ER[11], ER Network	EMRISK to lead. Proposed that Panels provide forward looking review once per 3-year mandate

4. System for the early identification of emerging risks

The overall strategy for identifying ERs, as outlined in the documents produced by the Scientific Committee (EFSA, 2006) and the ESCO working group (EFSA, 2009b), is ambitious and long term. It relies on three fundamental steps, namely 1) data collection, 2) data analysis, signal detection and filtering, and 3) exchange of information (Figure 1). In the food/feed context the approach is largely experimental and certainly nothing on the scale proposed by EFSA has been previously attempted for active identification of ERs.

Building on the previous work mentioned above, the following strategy is proposed (Figure 1):
The first step is *data collection*, and includes the development of tools for data capture and processing. Data will be drawn from a wide variety of sources including;

- "soft" e.g. media, blogs, "grey" literature;
- " regulatory" e.g. data from the RASFF, trade data, compulsory reporting/monitoring;
- "scientific literature" i.e. published papers, proceedings, research findings, scientific reports;
- "expert judgment" i.e. EFSA's Panels and units, committees of the European Commission's DG Health and Consumers, conferences, stakeholders, Member State networks.

The types of data to be monitored will be prioritised following the 11 priority indicators defined in the ESCO report (EFSA, 2009b). Sources of data will be identified, and then assessed according to their accessibility, reliability, usefulness in the identification of emerging risks and their regularity of updating. Where appropriate, tools will be developed to aid in the extraction, exploitation and analysis of the data. Regular monitoring of the data sources will then be carried out in order to identify signals of potential emerging risks.

The second step is *data analysis and signal detection*. This is carried out by the primary filter (ERIC - Emerging Risks Internal Collaboration group), and it is here that data trends and other information are initially processed and identified as indicating potential emerging risks. The Primary Filter is managed by EMRISK.

The Secondary Filter reviews the signals identified by the primary filter. The secondary filter will be EFSA's 10 Scientific Panels and the Scientific Committee, which will have the subject of emerging risks as a standing item on their agenda. The Panels will recommend what action (if any) should be taken. Such action could include further monitoring and data gathering, research proposals, or self-tasking risk assessment.

The EMRISK will be supported by two other groups who will also facilitate the third step, that of *information exchange*;

- The Stakeholders Consultative Group (StaCG-ER), drawn from experts proposed by the Stakeholders Consultative Platform, will share information concerning identified potential emerging risks and/or signals, the methods used to detect them and the analysis of the collected data.

- The Emerging Risks Network, which will act as a forum for commenting on reports drafted by EFSA and other organisations and to enable exchanges with MS, EC and international organisations on data and methods.

In addition, two working groups will be formed in 2010, one to address data sources for ER identification, and a second one to assist in the development of methodology for the identification of signals of ERs.

In the first instance, the overall approach will reply on structured expert opinion, gradually drawing on the objective approach supplied by indicator/signal identification, as this becomes increasingly operational.

Systematic approaches to identifying ERs in the food and feed area are only now being developed and put in place, and are largely unproven. This is very much an experimental area where few if any practical examples of its successful deployment exist. At best, a number of the proposed approaches have been applied retrospectively in an attempt to gauge their predictive capacity. Hence, to date there is no confirmation of the efficacy of such approaches, their efficiency or indeed their success. By the very nature of trying to predict "surprises" it is highly unlikely that any system put in place will approach 100 % predictiveness. Furthermore, extreme care must be taken to ensure minimising false predictions, due to the potential for unnecessary disruption of the food sector and parallel loss of confidence in EFSA.

The next steps for each of the three parts of the strategy are discussed in detail below.

4.1. Data collection

EMRISK was set up at the end of 2007, and has been significantly staffed from the start of 2009, to support the development of structures and the implementation of the process leading to the identification of ERs. During its first months of operation the Unit initiated the establishment of several signal identification systems relating to hazard databases, web monitoring and trade data, started the evaluation process of these systems by looking at their value for emerging risk identification, identified more components for further development, and established contacts with external information sources.

4.1.1. Hazard databases

RASFF

The Rapid Alert System for Food and Feed (RASFF) is maintained by the European Commission, and includes daily updates of food safety events notified within the European Union. For each event, detailed information is available on the identified hazard(s), the product(s) involved, the country of notification and origin, and the contamination levels detected. The system generates in the order of 7000-8000 notifications per year, which may also be searched through their website (https://webgate.ec.europa.eu/rasff-window/portal/).

Bioactive compounds of plant origin

Following the need identified by the Scientific Committee for a database on bioactive compounds to facilitate the scientific activities of several of EFSA's Units, EMRISK has coordinated an outsourced project for the delivery of a database on bioactive constituents of food plants consumed in Europe.

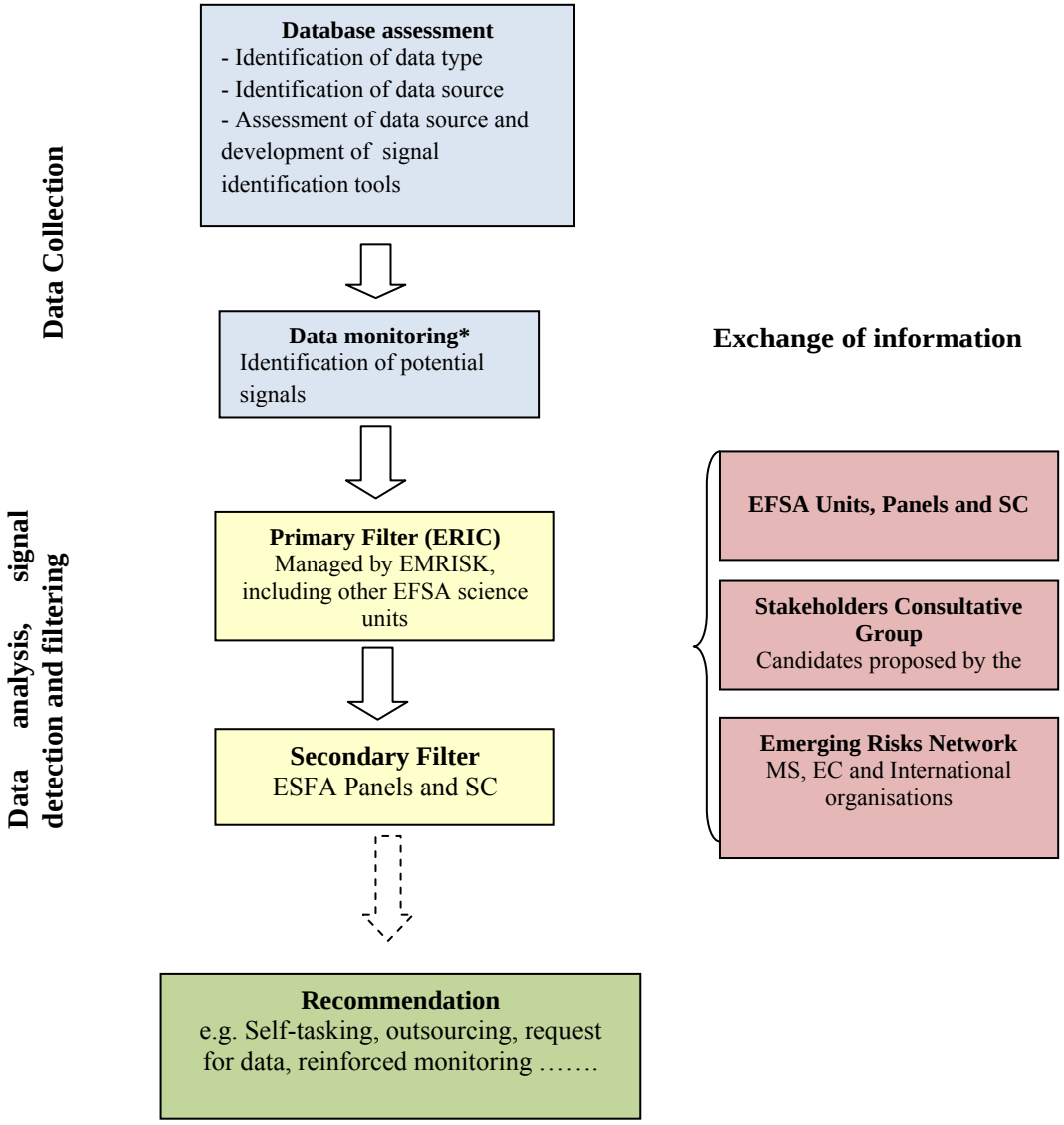

Figure 1: General procedure for the identification of emerging risks

* Data monitoring covers many sources: « soft » = e.g. media, grey literature; « regulatory » = e.g. data from the RASFF, trade data, compulsory reporting/monitoring; « scientific literature » = e.g. published papers, proceedings, research findings, documented reports; « expert judgment » = the EFSA's Panels, committees of DG Health and Consumers, conferences, stakeholder platforms.

Inventory of "hazard" databases used by ESFA

The objective of the inventory is to collect information on the current set of data sources available in EFSA. The establishment of this inventory is intended to help identify readily available data sources that may be relevant for the identification of ERs.

The main focus of interest is on "hazard" databases, that is, structured collections of data related to food/feed hazards. However, there is no exclusion of other data types (and sometimes multiple data types are present in a given database) that could provide additional information to data found in the hazard databases. In a second step, a more detailed description of chemical hazard databases will follow.

4.1.2. Web monitoring systems

MedISys and ProMED-mail

The Medical Information System (MedISys, http://medusa.jrc.it) is an application of the Europe Media Monitor (EMM) developed by the Joint Research Centre (JRC). Another web monitoring system is the Program for Monitoring Emerging Diseases (ProMED-mail) which was developed by the International Society for Infectious Diseases. MedISys was assessed for its efficiency in detecting signals of (re-)emerging risks in the food and feed sectors (EFSA-Q-2009-00490). Its efficiency was determined by assessing its rapidity to report food and feed hazards in comparison to ProMED.

Since the start of the mandate on media monitoring activities, several EU research projects related to the development of techniques and methods to monitor the media have been initiated (e.g. M-Eco: the Medical Ecosystem – personalized event-based surveillance[14]), or are in the process of being reviewed for approval. The developments made by these projects as well as the new web technologies (tools, methods, approaches) described in the scientific literature will be carefully followed by EMRISK.

4.1.3. Trade data

Eurostat and UN Comtrade

International trade and especially EU imports have been identified as potential indicators for the detection of emerging risks within EFSA's mandate. Comext is the Eurostat reference database for external trade. It contains both recent and historical data from the EU Member States and also statistics for a number of third countries. It allows the identification of volumes of imports into the EU of specified food categories, identifying both the country of origin and the destination country. The database is accessible to the public through Eurostat's web page[15].

The United Nations Commodity Trade Statistics Database (UN Comtrade) contains import and export statistics reported by close to 200 countries or areas. It concerns annual trade data from 1962 to the most recent year. UN Comtrade is available to the general public via the internet[16].

[14] http://www.meco-project.eu/
[15] http://epp.eurostat.ec.europa.eu/portal/page/portal/eurostat/home/
[16] http://comtrade.un.org/db/

Exploitation of trade data: current work in other EU institutions and future development

Automatic Monitoring Tool

The Joint Research Centre (JRC) has designed and is maintaining the Automated Monitoring Tool (AMT) on external trade and in particular on Comext database. This tool is in use by OLAF (the European Anti-Fraud Office) and by partners of OLAF in the Member States for the protection of the Community's budget, agriculture and customs.

The AMT is comprised of two parts:

- ARIADNE, a set of SAS macros, driven by graphical user-interfaces to produce the signals of interest (spikes of trade quantities and price outliers of traded goods);

The data for the AMT are from Comext and are fed to ARIADNE. The latter is an application running in client-server architecture. Its development into a web application is being explored by the JRC.

- THESEUS, a website where results (tables and graphs) are published. The website has various features to facilitate user navigation and data export.

The JRC has developed a set of alarm definitions and the application shows products which at least have one active alarm.

At the current stage, THESEUS has some limitations for helping EMRISK to identify trade trends of interest, which are:

- It is using only the CN trade classification;
- The tool is not an interactive one, so the user cannot make aggregates of code commodities, countries or time periods;
- THESEUS applies fixed thresholds.

The Food and Veterinary Office system

The Food and Veterinary Office (FVO) of DG-SANCO is in the process of developing a system called Food Safety Data Management System (FSDMS). The system is a data warehouse solution using Business Objects. The original idea was to combine 11 different existing data sources, but at the present stage the work is concentrated on a set of three databases i.e. Comext, RASFF and TRACES. The main task is to create a platform with a single access interface. The different sources should be combined using certain common fields, e.g. ISO country code, product etc. Country code based on ISO classification is possible, but commodity names, products or animals are defined in different ways in all three databases, and thus is difficult to compare data directly.

Requirements for a system for automatic scanning of Eurostat Comext

In order to monitor trade data for the identification of signals of potential ERs, an automated or semi-automated system is required. Such a system covering EFSA's mandate for automatic scanning of Eurostat Comext database should provide "alerts" (or signals) to the user, indicating for example, i) significant increase of the volume of a given product over time to a specific MS or EU in total, ii) new trade partners, iii) new food or feed commodities entering the EU.

This system should give to the user the possibility of selecting commodity classification, countries, time period, and aggregates of them. To develop such a system, firstly full access to the Comext database is needed, for example by down loading a copy in EFSA. Updating this data every three or four months would probably be sufficient, and should include data of the last six to ten years for annual analysis and three to five years for monthly analysis. Secondly, the algorithms for identification of trends should be developed. This procedure will be a continuous process, based on the experience and the needs over time.

4.1.4. Utility of current data sources for early warning or for the identification of emerging risks

The evaluation of defined "indicators" as being useful inputs for identifying ERs is complicated. An indicator, it should be remembered, consists of a number of parameters, and thus a number of data sources may be required for an individual indicator. Inversely, a data source may contribute to more than one indicator. At a primary level, rather than "indicators" one therefore deals with databases or data sources. The data sources so far assessed do not yet constitute even one of the eleven priority indicators, as identified in the ESCO report.

Each database or data source must be assessed for the quality of its data, as well as the accessibility and facility to further treat the data for signal identification. To put the volume of work required into context, in the first year of operation, EMRISK will have assessed four different types of data sources:

- Rapid Alerts (RASFF)
- Web monitoring (MedISys, ProMED-mail – the latter only for timeliness of reporting)
- Trade data (Comext, UN Comtrade)
- Bioactive constituents from plants (development of a database through Article 36)

The utility of these data sources are summarised as "no", "possible", "limited" or "yes" (Table 2), under EFSA's definition of emerging risks (new hazard, new matrix or changed susceptibility to a known hazard) and under the fields of food or feed.

The results indicate (Table 2) that the current data sources give almost no coverage concerning changed susceptibility and limited coverage of new hazards. Concerning changed susceptibility links with ECDC and ECHA should be explored as a means for covering this aspect. For the identification of new hazards, other data sources need to be assessed and integrated into the monitoring system.

The utility of the current data sources for addressing the different time-frames of risk monitoring and for supporting risk assessment activities in general are considered in Table 3. Whilst all the current data sources have potential utility for helping answer urgent issues, their use for assisting with more long term identification or prediction of ERs is probably limited.

Thus, the current palette of data sources for the identification of ERs is a starting point that needs to be expanded. The ESCO report on ERs (EFSA, 2009b) indicated 11 priority indicators for ERs, with multiple suggestions of signals (49) and data sources for each. This should provide a useful starting point, but requires further prioritisation. Investigation into the proposed data sources is necessary as they are often only indicated as institutions rather than databases. A method for prioritisation should be proposed by the working groups to be formed to identify data sources and develop methodology for the identification of signals. The additional databases should preferably complement those already in use.

It is noted that the routine use of the currently assessed data sources for ER surveillance is still in its infancy and is relatively labour intensive. There is thus limited capacity to directly monitor additional data sources. Therefore, in the long term, alternatives will have to be sought. This could include a mix of outsourcing, particularly towards the development of automated systems, and networking with MS (possibly supported during the start-up phase by article 36 funding), EU agencies and international organisations.

Table 2. Areas covered by current data sources

Data category	Database	New Hazard	New matrix	Changed susceptibility	Food	Feed
Hazard	RASFF	Limited	Limited	No	Yes	Yes
Risk	MedISys	Possible	Yes	Possible ?	Yes	Yes
Trade	Comext	No	Yes	No	Yes	Possible
Trade	UN Comtrade	No	Yes	No	Yes	Possible
Hazard	Bioactive	Limited	Limited	No	Yes	Yes

Table 3. Potential use of current data sources

Database	Crisis assistance	Early warning	ER identification	ER prediction	RA support†	Updating frequency
RASFF	Yes	Yes	Limited	Indirectly	Yes	Daily
MedISys	Yes	Yes	Yes	Possibly	Possibly	10 Minutes
Comext	Yes	No	Limited	Possibly	Yes	Monthly
UN Comtrade	Yes	No	Limited	Possible	Yes	Annual
Bioactive	Yes	No	Limited	Limited	Possibly	None/annual*

†Support for non-urgent data requests from the RA Units.
* Dependent upon securing further funding

4.2. Data analysis, signal identification and filtering

As a next step in the development phase, the intention is to develop a filtering process for emerging risks identification (see Figure 1). The foreseen procedure includes a primary filter at the internal level, including EFSA staff from various units under coordination of the Emerging Risks Unit (ERIC – Emerging Risks Internal Collaboration group) and a secondary filter consisting of EFSA's Panels and Scientific Committee.

A large amount of the initial filtering can be carried out by the EMRISK unit. Indeed, this already takes place through weekly and monthly monitoring meetings. From these meetings, urgent information derived from alerts is dispatched to the units most likely to be implicated, through email. Information pertaining to medium to long term ER issues is recorded.

A structured approach to filtering is being instigated through ERIC, with formalised criteria for the identification of signals, and a template for their reporting on a monthly basis (see chapter 6). The criteria used are drawn largely from a proposition of the DG SANCO discussion group on emerging risks (in preparation). The monthly reporting of ERIC will provide the principal route for the communication of potential ERs from the primary to the secondary filter.

The secondary filter will be the Panels and Scientific Committee. Their role is to assess the signals identified by ERIC and to recommend further actions if any. Such recommendations could include further monitoring, specific research, or self-tasking on hazard characterisation or risk assessment.

5. Key players

For both the data access aspects and also in order to have a wide base for expert opinions, formal structured networking is essential to EFSA's successful activity on emerging risks. This must include EFSA's units, their Panels, networks with other EU agencies, MS and stakeholders, particularly industry, but should also include contact with agencies outside of the EU and with non-food areas for exchanges on methodology and practical solutions to shared problems. Regular contact should be maintained with the risk manager, both at European level with the Commission, and also with Member States.

Whilst much networking has taken place and contacts have been established, no formal networks are yet in place, with the exception of the Commission-coordinated discussion group on Emerging Risks, involving European Agencies (EFSA, EEA, ECDC, ECHA, EMA) as well as SCENIHR.

Significant scientific resources already exist in EFSA covering all areas under EFSA's remit, in particular the panels and their supporting units. It is clear that the role of the EMRISK unit is not to replicate this expertise, but to coordinate its use for the identification of ERs. EFSA's Advisory Forum is already an active partner in the identification of ERs having the subject as a standing item on their agenda.

The establishment of formal networks will be a priority action in 2010 in order to add to the sources of data for identifying ERs and also to share experience on this subject in other MS, institutions and stakeholders. To this extent, it is proposed to establish:

Emerging Risks Internal Collaboration group (ERIC, the "primary filter") drawn from staff from all of EFSA's scientific units, to act as a primary filter of information concerning the identification of emerging risks. Monitoring and initial assessment of data from the currently assessed data sources is carried out by EMRISK. This will be captured through monthly summaries of this monitoring activity. These monthly summaries will be forwarded to ERIC for their consideration and further filtering before passing the information onto ESFA's scientific Panels and SC. The Task Force will meet, initially, every six weeks from February 2010 onwards.

Technical working groups, will be convened in 2010, drawn from external experts to advise EFSA on two issues; the development of methodology for the identification of emerging risks and the identification of appropriate data sources.

Emerging risks as a standing item at all Panel and Scientific Committee plenary meetings (the "secondary filter"). The monthly report issued by ERIC will be presented for discussion at the Scientific Panels plenary meetings. A recommendation will then be made on what action (if any) should be taken to follow up the issues specific for each Panel. Proposals will be communicated through the Mandates Review Committee.

Stakeholders Consultative Group on emerging risks (StaCG-ER). This group will consist of approximately 10-15 experts from stakeholders, nominated by the Stakeholders Consultative Platform, and selected by EFSA for their expertise in ER and in order to give wide representation of the whole food chain. The group will meet approximately four times in 2010, after which its role will be reviewed. The purpose of this group will be to provide support to EFSA on emerging risks data and methodology.

Establishment of a European network on emerging risks. The legal terms "emerging risks" and "emerging threats" have found their way into the European law a few years ago as tasks assigned to the EFSA, ECDC, EMEA, and non-food Scientific Committees, which advise the European Commission. These European regulations have imposed specific duties concerning emerging risks

identification in different sectors including; EFSA, (Commission Regulation 178/2002[17]); ECDC, (Commission Regulation 851/2004[18], art. 10); EMEA, (Commission Regulation 726/2004[19], chapter 3 pharmacovigilance); SCHENIR, (Commission Decision 2008/721/EC[20]). Moreover, 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. International organizations, such as the WHO (INFOSAN), FAO (EMPRES) and OIE are also active in this area. In addition, most of the bodies that are involved in risk assessment 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.

On the basis of this and as a follow up of the 1st International Conference on Risk Assessment (http://ec.europa.eu/health/ph_risk/ev_20081113_en.htm) and of the 4th meeting (http://www.efsa.europa.eu/cs/BlobServer/Event_Meeting/MeetReport4thChairsMeet_Parma_4_5nov08_FINAL23Jan09.pdf?ssbinary=true) of the Chairs and Secretariats of Commission and agency scientific committee and panels involved in risk assessment, held in Parma in 2008, it was agreed that the EFSA will take the lead on a project establishing a European network on emerging risks. This decision was further confirmed at the 5th meeting of the same body, held in Brussels in 2009.

As a first step, EFSA is currently participating in a cross-agency discussion group coordinated by the European Commission on "Identification and characterisation of emerging risks to human health and/or the environment – a framework for the EU scientific committees".

In 2010, EFSA will initiate its Emerging Risks Network, which will be based around a Member States network, with participation of the European Commission, European agencies (e.g. ECDC, EMEA, EEA, JRC) and international institutions (e.g. FAO, WHO). This group will meet at least twice per year from 2010 onwards. The role of this group will be to provide support to EFSA on emerging risk methodology and data, and to explore the most efficient way of establishing a European, even international, network for the identification of emerging risks. In the first instance, it will be the principal conduit for exchanges with these partners on emerging risks issues. This group will have the opportunity to comment on the emerging risks annual report before publication.

The interaction between these different groups is described in Figure 1. In further support of this networking activity, an EFSA colloquium on emerging risks will be organised in October 2010, in Parma

[17] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31 1.2.2002 p1-24)
[18] Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004 establishing a European centre for disease prevention and control (OJ L 142 30.4.2004 p1-11)
[19] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136 30.4.2004 p1-33).
[20] Commission Decision of 5 August 2008 setting up an advisory structure of Scientific Committees and experts in the field of consumer safety, public health and the environment and repealing Decision 2004/210/EC (OJ L 241 10.9.2008 p.21-30).

6. Initial results

6.1. Activities on emerging risks

A number of technical reports have now been produced concerning the first set of databases that have been investigated (see appendix B). From surveillance of these databases and identification of possible emerging risks, a number of trial case studies have been prepared, with a view to gaining experience with manipulating the data (summarised in appendix E).

6.1.1. Data collection

Database inventory

The inventory comprises of internal databases (those maintained by EFSA or produced through outsourcing), external databases for which EFSA has been granted access, public databases in use by EFSA, and other data sources in use such as scientific compendiums, sets of legislative data concerning EFSA remits etc.

The collection of relevant information has been performed through interviews with staff members representing all of the science units. The database features that form the inventory are:

- Location(external/internal)
- Database Name
- Database content
- Size (number of observations/rows, if available)
- Period covered (of the data)
- Frequency of updating
- Starting period of use in EFSA
- Expire period (if any)
- Software
- Data Ownership
- Access rights (if external)
- Database provider (if external)
- Unit
- Reference person
- Data category
- Other information

An electronic inventory has been set up. The inventory contains approximately 100 entries (annex D), with about half of the data sources being internal. For the most part, the use of these data sources in EFSA started from 2008 onwards. More than 80% of the data sources have been reported by the Scientific Cooperation and Assistance Units. Pesticides, microbiological hazards and chemical hazards are the most widely represented hazard categories. Around 30% of the data sources are updated regularly.

Further harmonization and classification of the inventory may be useful. However, it requires regular maintenance and updating. The inventory will assist in sharing information among all EFSA Units and particularly in ensuring wide use of data collected by EFSA and MS. A summary of the inventory is included in appendix D.

RASFF

To aid in the analysis of data from RASFF, EMRISK has developed a tool for providing statistics on the RASFF, particularly concerning the identification of trends of increased reporting and of first-time notifications (EFSA, 2010b). This tool is currently used for the regular monitoring of the RASFF database.

Bioactive compounds

The production of a database on the presence (concentrations) and specific biological activity of bioactive compounds with potential beneficial or toxic effects found in plants used in food and feed has been completed. The contractor, the Institute of Food Research (responding to the call "Delivery of a database on bioactive compounds in food and feed plants" CFT/EMRISK/EFSA/01), has delivered a searchable database accessible to EFSA's scientific Units and experts until the end of 2010. The database contains information on the occurrence, consumption and toxicology of selected bioactive compounds (e.g. capsaicinoids, carotenoids, cinnamic acid derivitives, coumestans, cysteine sulphoxides, flavonoids, glucosinolates, lignans, phytosterols, polyacetylenic compounds), and is potentially useful for the work of several scientific Units in EFSA. The database is now under evaluation by several EFSA's Units, and a re-appraisal of its usefulness by EMRISK in consultation with all the interested Unit is expected by the end of 2010.

Media Monitoring

MedISys was assessed for its efficiency in detecting signals of (re-)emerging risks in the food and feed sectors (EFSA-Q-2009-00490). Its efficiency was determined by assessing its rapidity to report food and feed hazards in comparison to ProMED.

From the RASFF database, nine case studies of food- and feed-borne hazards having various levels of notifications between January 2007 and March 2009 were selected (i.e. *Salmonella*, mycotoxins, heavy metals, melamine, dioxins, aluminium, *Vibrio cholera*, DDT, radioactivity). Subsequently, these hazards were traced back in MedISys and Pro-MED-mail to determine their reporting time delays. Searches were conducted, in the first instance, with the hazard name in English over a two-month period, i.e. the calendar month "n" having the highest number of RASFF notifications and the month "n-1" to increase search success. If this search was unsuccessful, it was expanded to include other languages and to cover a three-month period.

The results of the evaluation showed that MedISys is an efficient monitoring tool and early warning system, but it needs further development to increase its sensitivity in detecting food and feed hazards. MedISys reported RASFF hazards in four out of nine of the cases whereas ProMED-mail reported the RASFF hazards in only one of the cases. In two cases, MedISys reported hazards between 1 and 2.5 months before RASFF. In two other cases, it reported hazards between 3 and 55 days after RASFF. In the remaining five cases, it did not report RASFF hazards, possibly because they were not of public interest or because the press never got the information (e.g. border rejections). However, for *Salmonella* and Mycotoxins, MedISys and ProMED-mail reported contamination events that originated from outside the EU and that were not reported by RASFF. In the context of global trade, this information may be valuable because it may allow anticipation of crises within the EU.

The time delay between MedISys and ProMED-mail reporting was small - a couple of days for the reporting of melamine, mycotoxins and *Salmonella* events - and probably related to the time required in ProMED-mail for experts to assess the value of the information. The time delay with RASFF was usually longer (from a couple of days to a couple of weeks) and possibly linked to the time for hazards which emerged outside EU to reach EU borders and markets and/or for laboratories to confirm their presence in food and feed. However, the monitoring of ProMED-mail and RASFF proved to be complementary, due to their drawing on different data sources.

MedISys sensitivity to food and feed hazards needs to be improved through further customisation of the system. Preliminary analyses indicate that new media sources should be added (e.g. sources from countries in the Southern Hemisphere and blogs, which is a new feature of MedISys) and that multi-lingual categories related to food and feed need to be developed with proper definitions. Therefore, to further customize MedISys on categories' definition and translation, linguistic support is essential in particular in some Asian languages which are currently under-represented in MedISys.

Since early 2009, MedISys and ProMED-mail have been monitored on a daily basis to search for information on potential emerging risks in food and feed. It is proposed that for routine monitoring, this information is set up on RNS (Rapid News System), a system that is linked to MedISys and which allows users to filter the information. In this way, the signals detected in the media at any moment can be followed to determine their evolution in time (i.e. whether the signals increase, decrease or re-appear in an unexpected way after a long delay). It is also proposed that external requests, on specific alerts, addressed to EMRISK, are also followed in RNS.

Trade data

EMRISK screened the Eurostat Comext database (EFSA-M-2009-0079) for trade volumes of selected food and feed commodities. A technical report on the "Collection and routine analysis of import surveillance data with a view to identification of emerging risks"[21] has been published. The report includes examples of trade data for selected food commodities that are examined to assess the potential of trade data for identifying emerging risks.

As part of the regular reporting on specific emerging risk subjects, three case studies have been prepared based on surveillance of these trade databases (see Appendix E for a short summary), and are currently under review.

The Eurostat Comext database has been found to be a useful tool that could assist the identification of emerging risks in combination with data coming from other sources, including the Comtrade database, as it provides trade data reported by countries all around the world and not only from EU MSs. However, statistics from these two databases are not directly comparable as methodological inconsistencies may exist among different countries during collection, analysis and reporting of information.

Searches in Comext and Comtrade databases revealed many discrepancies in the volume of trade reported. These are probably due to the following reasons: different data collection methodology among countries, false declaration of product or country of origin, confidentiality, time delay, threshold and adjustment applications, revisions of reported data, valuation and reporting in different commodity classifications.

Scientific expert judgment is pivotal for selecting the most appropriate food commodities during a search, interpretation of trade data and evaluation of their weaknesses as well as their relevance to data from other sources. Trade data should also be considered when carrying out exposure assessments and can be complementary to consumption data.

6.1.2. Data analysis signal identification and filtering

During the period of September 2009 to January 2010, a trial signal surveillance system was experimented with, drawing solely on staff from EMRISK, with a view to gaining experience in how such a system could be applied. A variety of sources have been suggested to support the identification of a potential emerging risk (EFSA, 2009b). The monitoring activities of EMRISK include the screening and collection of data and information from different types of sources, followed by a critical evaluation of the relevant issues identified in Unit round table discussions.

A monthly report summarizing most relevant issues identified by the Unit is then compiled and, since February 2010, discussed with the Emerging Risks Internal Collaboration group (ERIC), with a view to bringing signals of potential emerging risks to the attention of the Panels for further evaluation (the secondary filter). Below is a description of the rationale used in the identification of relevant issues.

[21] European Food Safety Authority; Collection and routine analysis of import surveillance data with a view to identification of emerging risks. EFSA Journal 2010; 8 (3): . [35 pp.]. doi:10.2903/j.efsa.2010.1531. Available online: www.efsa.europa.eu

Data collection

A wide range of sources of information are screened and reviewed, including reports from rapid alert systems, outputs from media monitoring systems, official reports and bulletins, and the scientific literature, including data from RASFF Comtrade and Comex databases. Annex F includes the list of sources of information that are systematically screened by the Unit. It is anticipated that the utility of these data sources will be evaluated after some experience with them has been gathered, and sources of limited utility discarded, and a new set of sources examined.

Data evaluation

A large amount of information becomes available from the data collection performed by the Unit. All relevant data selected are discussed in unit briefings, and decisions are made about follow-up actions to be taken by the Unit (e.g. inform the relevant EFSA Unit, collect additional information and continue monitoring the issue, submit the issue to the primary filter). The relevant information identified and decisions made are then filed and stored in a database to facilitate follow-up, reporting and further trend analysis.

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 qualitative assessment of the potential risk is performed based on the Unit's scientific knowledge, and considering a pre-determined set of evaluation criteria. This assessment is validated by the primary filter.

However, a rigid framework is not appropriate because, by definition, information about emerging issues is inevitably limited and scattered and hazards may be of a not previously encountered nature. Nevertheless, a structured framework is needed in order to rank them to inform priorities for detailed follow up. The criteria used for this purpose have been identified as:

i) ***Novelty***. The evaluation considers whether the potential hazard is known, reported for the first time, or re-emerging, either in the same or in another matrix. Past events regarding hazards potentially similar are also considered.

ii) ***Soundness***. Criteria such as reliability of sources (*e.g.* peer-reviewed, authoritative media headings, blogs), and consistency of the information are evaluated (e.g. several independent sources reporting the same issue, anecdotic observations from the consumers, or reports from health officials or clinicians).

iii) ***Imminence***. The delay before a significant exposure may occur (e.g. alert, emerging risk, or an indicator of a driver of emerging risks).

iv) ***Scale***. An indication of the number of people that may potentially be exposed to this hazard, taking into account trade and consumption patterns.

v) ***Severity***. The severity (e.g. morbidity and mortality) of the possible consequences of exposure to the potential hazard under evaluation are considered, with particular emphasis on the identification of specific vulnerable sub-groups.

Each criterion is evaluated and scored as high, medium, low, none or noted as having insufficient information on which to make a judgment. The aim is to describe the characteristics of the signal. An overall score is, however, derived through a general consideration of the signal, and not calculated through the scores for the individual criteria. Each judgment is made on a case by case basis. Numerical scoring systems or matrices have felt to be inappropriate for comparing and ranking such a potentially broad range of hazards and risks described by sparse data.

With reference to the RASFF, relevant issues are identified by a first exploratory analysis of the overall monthly distribution of notifications according to most relevant variables (i.e. hazard, product, country of origin), followed by the identification of new hazards or combinations of Hazards(s) and Product(s), or Hazard(s) and Country(ies) by means of an specifically developed software program (EFSA, 2010b). Statistically significant trends over time (monthly, annual and multi-annual, with the possibility for correcting for seasonal trends) are detected by Poisson regression analysis using the Farrington method (Farrington et al, 1996).

The recommendations of the ESCO WG on Emerging Risks (EFSA, 2009b) on relevant search terms and on the 11 indicators were used to design a preliminary search strategy to retrieve articles from the scientific literature. Pubmed is the main search engine used to collect the scientific literature.

Output

A monthly report summarizing the most relevant issues identified and follow-up actions taken by the Unit is then compiled (template, Table 4). This report is intended as a basis for discussion by the primary filter (ERIC). As such, it must be emphasised that it contains a significant number of signals that will eventually be discarded as being not relevant in the context of emerging risks identification. The fields given in the table include:

- Description of the **source** of information (e.g. RASFF, Medisys, journal reference);
- The **hazard** category, using the RASFF categorization, unless the hazard identified does not fall in any of the available RASFF categories. The specific hazard is mentioned in the subject field;
- A short description of the **subject** of the event is given. If applicable the food matrix is mentioned in this field;
- Any information relevant for the evaluation is recorded in the **evaluation notes** column, including the evaluation criteria;
- On the basis of the evaluation, the **level of relevance** (i.e. low, medium, high). The level of relevance is based on a critical interpretation of the overall scores of the evaluation profile;

The last column gives the **follow-up action** decided by the Unit on the event evaluated (e.g. inform relevant EFSA Units, collect additional information, and submit the issue to the secondary filter).

Table 4. Template for reporting to the primary filter, the list of signals of potential emerging risks.

Hazard category[1]	Subject[2]	Evaluation notes[3]	Level of relevance[4]	Source[5]	Date[6]	Country	Other details[7]	Follow-up[8]

[1] Where applicable the RASFF categorization is used.
[2] Description of the event
[3] Any information relevant for the evaluation (i.e. novelty, soundness, imminence, scale, severity)
[4] Level of relevance (i.e. none, low, medium, high) as a potential emerging risk.
[5] Reference to the source of information (e.g. RASFF, MediSys, reference from a scientific journal)
[6] Date of publication/emission of the original report
[7] Other details of potential interest (e.g. country of origin, food product involved)
[8] Follow-up action.

6.1.3. Networking

During 2008 the unit organized 12 meetings of the ESCO Working Group on Emerging Risks, bringing together experts from EFSA scientific panels and representatives from more that 15 Member States. This resulted in a technical report on emerging risks (EFSA, 2009b).

Eight meetings with potential network partners and stakeholders within Europe and beyond (incl. EC, MS, FAO, ECDC, SAFE-FOODS, SAFEFOODERA, and TNO) have also been held. The Emerging Risks unit was established as EFSA contact point for the EC Rapid Alert System for Food and Feed (RASFF). Close collaboration with the JRC over use and adaptation of their MedISys media monitoring tool has proven productive. Presentations at conferences, workshops and meetings of experts and decision makers have also been given (e.g. Public Health Agency Canada, FAO conference on Climate Change, Rome 2008).

6.2. Long term issues

A variety of data sources have been suggested to support the identification of potential emerging risks (EFSA, 2009b). The monitoring activities of the Emerging Risks Unit include the screening and collection of data and information from different types of sources, followed by a critical evaluation of the relevant issues identified in round table discussions. Information about current foodborne outbreaks or incidents, new and emerging food-related hazards, animal and human infectious diseases potentially related to food occurring worldwide are considered in the evaluation and complemented with a routine screening of the most recent publications in the scientific literature.

The objective of the review found in appendix G was to conduct a preliminary review of the scientific literature, to report on potential emerging risks in areas related to food safety being identified by the scientific community. These include areas with direct impact on food safety such as microbiological hazards and chemical contaminants, but also those forces that might have an impact on the onset of new or re-emerging risks, such as socio-economic, political or environmental factors, i.e. the so called drivers of change. This type of information could be useful as a potential signal of an emerging risk to be further evaluated in the framework of the EFSA emerging risk identification system, even if the definition of emerging risks used in the scientific literature varies considerably.

7. Work plan

In order to implement EFSA's strategy on emerging risks, as detailed in this document, the following actions are planned;

- Establishment of the primary filter (ERIC) – first quarter 2010.
- Establishment of the secondary filter. Introduction of emerging risks as a standing item on Panel and Scientific Committee plenary agendas, and analysis of signals identified by the primary filter – second quarter 2010.
- Establishment of the Stakeholders Collaborative Group (StaCG-ER) – second quarter 2010.
- Establishment of the Emerging Risks Network - second quarter 2010.
- Establishment of a Working Group on the identification of data sources for emerging risks identification – second quarter 2010.
- Establishment of a Working Group on developing methods for emerging risks identification – third quarter 2010.
- EFSA Colloquium on Emerging Risks – October 2010.
- Review of the functioning of ERIC – first quarter 2011.
- Review of the functioning of StaCG-ER – second quarter 2011
- 1st annual report on emerging risks – June 2011.

All processes should be in place by mid- 2010 and reported on in EFSA's second annual report on emerging risks in 2011. By the end of the second year of operation (2012), the soundness and utility of this approach will be given an initial review. The methodology and criteria for validating the approach being put into place need to be defined. This task will be conferred to the Working Group on methodology.

CONCLUSIONS AND RECOMMENDATIONS

According to EFSA's Founding Regulation[1], the Authority is required to *"undertake action to identify and characterise emerging risks"* in the field of food and feed safety. In order to address this, EFSA has set up a dedicated unit (EMRISK). Through the activities of this unit, EFSA aims to establish a data monitoring capacity, data filtering methodology and networking structures to identify emerging risks and drivers of emerging risks in a timely fashion and to communicate these to the risk manager.

Whilst concentrating on food and feed risks during the start up phase, monitoring of emerging risks in plant health and animal health will commence in 2011 and 2012, respectively.

Taking account of the broad scope of the task, it is evident that networking will be key element in gathering and analysing data. To this extent, formal networks with MS, EU and international agencies and stakeholders are being established.

To date, only the first step of this process (data monitoring) is partially in place. The following steps, that is, filtering and communication, are being established. Whilst the current data sources are limited, they have been sufficient to enable the elaboration of the procedures for the next steps in the ER identification process. As more data sources become accessible, the process will become more effective. Tools will need to be developed to assist in handling increasing amounts of data, particularly for their analysis. From issues identified during this monitoring, detailed case studies on specific issues are being prepared.

Whilst systematic data monitoring is a central part of the emerging risks identification process, expert opinion will remain a key input. EFSA is organising a colloquium on emerging risks in October 2010 as part of its strategy for accessing expert opinion, along with the networks mentioned above. The colloquium will aim to gather information from experts, risk assessors, risk managers and other stakeholders on their views on emerging risks.

All processes should be in place by mid- 2010 and the results coming from these processes will be delivered in the next annual report. By the end of the second year of operation (2012), the soundness and utility of this approach will be given an initial review.

[1] Article 23(f) Reg. 178/2002/EC

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APPENDICES

A. EMRISK MANDATES AND CONTRACTS IN THE AREA OF EMERGING RISKS IDENTIFICATION

EMRISK Mandates

Mandate number	*Start*	*End*	*Abbreviated Title*
EFSA-Q-2009-00490	27/03/2009	31/12/2009	Development of web monitoring systems for the detection of emerging risks
EFSA-Q-2009-00494	27/03/2009	31/12/2009	Collection and routine analysis of import surveillance data
EFSA-Q-2009-00495	27/03/2009	31/12/2009	Establishment and maintenance of routine analysis of data from the RASFF
EFSA-Q-2009-00812	09/06/2009	30/09/2011	Modelling, predicting and mapping the (re)emergence of aflatoxin B1 in cereeals in the EU due to climate change
EFSA-Q-2009-00813	22/12/2008	24/11/2009	Delivery of a database on bioactive constituents of food plants
EFSA-Q-2009-00854	01/04/2009	25/02/2010	Collection and routine analysis of import surveillance data
EFSA-Q-2009-00982	18/12/2009	17/12/2010	Internal collaboration working group on emerging risks in food and feed
EFSQ-Q-2009-01075	18/12/2009	28/02/2010	Technical report on emerging risks in food and feed
EFSA-Q-2010-00077	28/01/2010	27/01/2011	Stakeholder Consultative Group on emerging risks
EFSA-Q-2010-00168	09/03/2010	31/12/2010	WG on data collection for the identification of emerging risks
ESFA-Q-2010-00792	19/04/2010	-	Establishment of an Emerging Risks Exchange Network

EMRISK Contracts

Contract number	*Start*	*End*	*Abbreviated Title*
NP/EFSA/EMRISK/2008/02	02/12/08	02/06/09	Development of a SAS macro to import, analyze and visualize data from RASFF
CFT/EFSA/EMRISK/2008/01	22/12/08	22/09/09	Delivery of a database on bioactive constituents of food plants
CFP/ESFA/EMRISK/2009/01	16/12/2009	30/09/2011	Modelling, predicting and mapping the emergence of aflatoxin B1 in cereals in the EU due to climate change

B. OUTPUTS

A number of documents have been produced by EFSA, defining ERs and proposing a strategy for their identification:

VWA, 2006. Forming a global system for identifying food-related emerging risks. Report of the EFSA Service contract EFSA/SC/Tender/01/2004.

EFSA 2006. Opinion of the Scientific Committee on a request from EFSA related to the early identification of emerging risks. Adopted 4 July 2006.

ESFA 2007. Definition and description of "Emerging Risks" within the EFSA's mandate. Statement from the Scientific Committee. Adopted 10 July 2007.

EFSA 2009. Report of the EFSA Scientific Cooperation (ESCO) working group on emerging risks. Issued on 24 March 2009.

Internal reports on evaluation of databases, and tailoring search tools and data analysis tools to the task of identifying ERs have been produced:

ESFA 2009. Development of web monitoring systems for the detection of emerging risks. EFSA Journal 2009; 7(10): 1355.

EFSA 2010. Establishment and maintenance of routine analysis of data from the Rapid Alert System on Food and Feed. EFSA Journal 2010; 8(1): 1449.

ESFA 2010. Collection and routine analysis of import surveillance data with a view to identification of emerging risks. In press.

C. SCOPE AND RESPONSIBILITIES OF THE EMERGING RISKS UNIT

The Emerging Risks Unit is responsible for the implementation and maintenance of 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 EFSA's mission, and in particular as related to food and feed.

The Unit works closely with other Units in the Scientific Cooperation and Assistance Directorate, the Risk Assessment Directorate and the Communications Directorate and with the Unit supporting the Scientific Committee and the Advisory Forum. The Unit collects information from many different sources; these sources include EFSA staff and members of the Scientific Committee and Panels, who can bring in new knowledge from a wide environment, the Advisory Forum and the Stakeholder Consultative Platform for a broad information exchange regarding emerging risks. It maintains direct links with external sources of information such as relevant research projects, EU and international bodies, and is the contact point within EFSA for the European Commission's Rapid Alert System for Food and Feed (RASFF).

Aside from collection of data relevant to the identification of emerging risks, the Unit is also responsible for developing and implementing procedures and instruments to collate and analyse the incoming information and data.

In addition, the Unit plays a key role in assisting with EFSA's preparation to respond to urgent issues. The Unit is responsible for maintaining and updating the Emergency Manual and the crisis contact cards. The Unit also organises training for EFSA staff as preparation for responding to urgent issues and crises.

D. INVENTORY OF DATABASES USED BY EFSA

Database Name	Database content (general description)	Size (number of observations/rows)	Period covered (of the data)	Data Category
MOPER (MRL)	Aggregated results of the national monitoring programs on pesticide residues from all Member States (incl. EEA countries).	ca 144.000 samples ca 24.000 kB/year	2007-2008	pesticides
DCF Pesticide Monitoring (MRL)	Detailed results of the national monitoring programs on pesticide residues from all Member States (incl. EEA countries).	ca 6.000.000 observations	2008	pesticides
PRAPeR Tox Database (MRL)	Compilation of ADIs (approximately 1150) and ARfDs (approximately 950) established at national, European or international level for approximately 650 pesticides. General information on the general properties of pesticides (approximately 1200) is also available.	ca 4200 entries	from 1965 onwards	pesticides
Food Consumption Database for Assessment of Pesticide Residues (MRL)	Compilation of European diets used by national authorities for pesticide residues risk assessment. The compilation contains 19 acute diets and 27 chronic diets covering 13 EU Member States.	ca 16.700 entries	from 1999 onwards	pesticides
PRAPeR CXL Database (MRL)	Compilation of codex MRLs for approximately 80 active substances. Database also includes information which is considered essential for inclusion of these CXLs in a European consumer riks assessment (HR values, STMR values, variability factors,…).	ca 2.000 entries	from 2008 onwards	pesticides
Database on pesticide MRLs	All legal MRL values established in Regulation (EC) No 396/2005, including information on the history of MRL regulations.	ca 200.000 entries	from 2008 onwards	pesticides

Data Pool of the Community Reference Laboratories for Residues of Pesticides (MRL)	Validation experiments of analytical methods for enforcement of pesticide residues in food and feed, including information on the types of method, fortification levels,... Data are available from official control laboratories or other laboratories willing to share their validation data with CRLs.	ca 160.000 experiments	from 2000 onwards	pesticides
BfR Compilation of Processing Factors for Pesticide Residues (MRL)	Compilation of processing factors established at German, European or international level for approximately 150 pesticides.	ca 1500 entries	from 1991 onwards	pesticides
BfR Compilation of Residue Definitions for Pesticides (MRL)	Compilation of the residue definitions for enforcement and risk assessment of approximately 300 pesticides.	ca 300 entries	from 2000 onwards	pesticides
EU Pesticides database	Inforamtion on active substances with regard to: - status of risk assessment under Dir 91/414, ref. to EU legislation, incl. review reports - toxicological information - MRLs in fodd/feed	above 1000 entries	(cover all existing and new active substances)	pesticides
OECD database on Pesticide/Biocide reviews	A tool to check when and where an active substance (pesticide/biocide) has already been evaluated in the world. Search by a.s. name, CAS number, country, status of review, status of registration etc.)	not known	from 1990 onwards	pesticides
Compendium of common names (Physical-Chemical properties)	Information on structure of active substances, their chemical names and relationship to other active substances.	More than 1100	1969-onwards	pesticides
Pesticide manual (Physical-Chemical properties)	General information and history of active substances	More than 1000	not known	pesticides
FAO/WHO specifications (Physical-Chemical properties)	International specifications for the quality control of active substances and formulations.	Circa 200	1960-onwards	pesticides

CIPAC methods (Physical-Chemical properties)	Methods of analysis for active substances and active substance content of formulations. Methods for physical and chemical properties of active substances and formulations.	More than 400		pesticides
JRC - Annex I of Directive 67/548/EEC (Mammalian Toxicology)	Information related to classification and labelling of chemical substances for their toxicological properties	ca 4133 chemicals	from 1967 onwards	pesticides
Annex VI of Regulation 1272/2008 on classification, labelling and packaging of chemical substances and mixtures (Mammalian Toxicology)	Information related to classification and labelling of chemical substances and mixtures for their toxicological properties.	more than 4133 chemicals	from 2008 onwards	pesticides
INCHEM Chemical Safety Information from Intergovernmental Organizations (Mammalian Toxicology)	Internationally peer reviewed information on chemicals commonly used throughout the world			pesticides
Reports/Monographs of JMPR (Mammalian Toxicology)	Annual Joint FAO/WHO Meeting on Pesticide Residues, setting up reference values (ADI, ARfD) for active substances	ca 280 active substances	from 1963 onwards	pesticides
US - EPA - Specific Chemical Fact Sheets (Mammalian Toxicology)	Toxicological information about pesticide chemicals (new active ingredients, biopesticides and those undergoing reevaluation)			pesticides
US - ATSDR - Toxicological Profiles (Mammalian Toxicology)	Toxicological information on hazardous substances from a priority list in the US (National Priorities List)	308 tox profiles published or under development		pesticides
Toxicology Data Review Summaries - California (Mammalian Toxicology)	Brief technical summaries of the Department of Pesticide Regulation reviews of toxicology data on chronic health effects, listed by pesticide active ingredient	465 Tox Summaries		pesticides
Toxicology Data Network (TOXNET) (Mammalian Toxicology)	Collection of databases on toxicology, hazardous chemicals, environmental health and toxic releases		from 1965 to present	pesticides

EFSA Compendium on Botanicals (Mammalian Toxicology)	General information on chemical of concern/toxic effect of plant (extracts).		not indicated	pesticides
EXTOXNET (Mammalian Toxicology)	Pesticide Information Profiles (PIPs), specific pesticide information relating to health and environmental effects		not indicated	pesticides
Comparative Toxicogenomics Database (Residues)	Provides information about molecular mechanisms by which environmental chemicals affect human disease			pesticides
Pesticide Compendium (Residues)	Classification, information, on pesticide active substances (chemical structure, ISO name, CAS, IUPAC number…)	about 1200 a.s. referenced		pesticides
Zoonoses DB	The Zoonoses database is composed of the following parts: A) Animal Populations Tables B) Zooonoses and Zoonoses Indicators data (Prevalence tables, Serovars and Phagetypes tables, Disease Status tables C) Foodborne Outbreaks D) Antimicrobial Resistance Data (Breakpoints, Quantitative and Qualitative Tables)	Every year the amount of data changes	From 2004 to 2008	microbiological vet
Baseline survey Campylobacter and Salmonella in Broiler flocks and broiler carcasses	European Commission DG Health and Consumer Protection Baseline study Campylobacter broilers and Campylobacter/Salmonella broiler carcasses	29968 observations.	15 December 2007 to 15 January 2009	microbiological
Baseline survey Salmonella Slaughter pigs	European Commission DG Health and Consumer Protection Baseline study slaughter pigs	34029 observations.	15 September 2006 to 15 October 2007	microbiological
Baseline survey Salmonella - broiler flocks	European Commission DG Health and Consumer Protection Baseline study Broilers	37141 observations.	15 September 2005 to 15 October 2006	microbiological
Baseline survey MRSA Breeding pigs	European Commission DG Health and Consumer Protection Baseline study MRSA breeding pigs	5071 observations.	15 December 2007 to 15 January 2009	microbiological

Baseline survey Salmonella Breeding pigs	European Commission DG Health and Consumer Protection Baseline study Salmonella breeding pigs	56791 observations.	16 December 2007 to 15 January 2009	microbiological
Baseline survey Salmonella - breeding and fattening turkeys	European Commission DG Health and Consumer Protection Baseline study on Breeding and Fattening Turkeys	21541 observations.	15 September 2006 to 15 October 2007	microbiological
Baseline survey Salmonella - laying hen holdings	European Commission DG Health and Consumer Protection Baseline study on Breeding and Fattening Turkeys	39663 observations	1 October 2004 - 30 September 2005	microbiological
EFSA GIS Geodatabase	Geographica data such as EU administrative boundaries at various levels + special subsets of zoonoses data on which we base the maps	Several tables and records	n/a	maps
Furan Database	Data collection on Furan in food	2000	2004-2009	chemicals
Cadmium Database	Cadmium in food	130000	2003-2008	chemicals
Lead Databse	Lead in food- Data collection	90000	2003-2008	chemicals
Selenium and Chromium Database	Selenium and chromium in food	70000	2003-2008	chemicals
Arsenic Database	Arsenic in food	77000	2003-2008	chemicals
Dioxin Database	Dioxin in food -data collection until 2008	21000	1995-2008	chemicals
Melamine Database	Melamine in food and feed-data collection	2000	2008	chemicals
Acrylamide Database	Data collection on Acrylamide	13000	2001-2007	chemicals
Palytoxin database	Occurrence data on palytoxins	102	2004-2008	chemicals
Ocadaic acid Database	Occurrence data on Ocadaic acid group toxins	6072	1999-2006	chemicals
Azaspiracids Database	Occurrence data on Azaspiracids	12275	2003-2007	chemicals
Yessotoxin Database	Occurrence data on Yessotoxin group toxins	2881	2000-2007	chemicals
Saxitoxin database	Occurrence data on Saxitoxin group toxins	20248	2000-2008	chemicals
Pectenotoxin Database	Occurrence data on Pectenotoxin group toxins	1220	2005-2008	chemicals
Domoic Acid Database	Occurrence data on Domoic Acid group toxins	42962	1999-2008	chemicals
Melamine	Occurrence data on Melamine and cyanuric acid in food and feed	29654	2008-2009	chemicals
Residue application	Data from the monitoring of veterinary medicinal product residues and other substances in the member states	NA	from 2005 onwards	vet

Comprehensive food consumption Database	Competent organisations in EU Member States were requested to provide EFSA with data from the most recent national dietary survey in their country, including the adult population, at the level of consumption by the individual consumer. The consumption data were requested to be expressed at the most disaggregated level recorded at national level. Twenty Member States accepted to participate in this project and signed a collaboration agreement with EFSA for the provision and processing of such food consumption data.	5 500 000	1997 - 2008	Food consumption
Concise food consumption Database	The Concise European Food Consumption Database is called "concise" since it is intended to provide a limited number of data that will allow easy performance of a conservative exposure assessment. Nineteen Member States provided food consumption and related data to EFSA.	971 137	1997 - 2006	Food consumption
Aflatoxins Database	Occurence data on Aflatoxins in nuts and cereals	ca 40 000	2000-2006	chemicals
Ethylcarbamate and hydrocyanic acids	Occurence data on Ethilcarbamate and hydrocyanic acids in food and drink	ca 29 000	1998-2006	chemicals
Nitrate Database	Occurence data on Nitrate in food and drink	ca 42 000	2000-2007	chemicals
PAH Database	Polycyclic Aromatic Hydrocarbons in food	ca 10 000 for 16 compounds	2005-2007	chemicals
Aspartame	Case reports associated with exposure to aspartame	1 135		chemicals
Colony loss Bees	Information related to colony losses in bees	318	2000	bees
Index of Common Names	Compendium of pesticide common names			pesticides
EUROSTAT	Statistical Office of the European Communities			statistics
FAO	Food production statistics			statistics
Organism names	Index to organism names			statistics
GIS data	Downloadable maps			maps
European Space Agency	Satelite data			statistics

WAHID	OIE notifiable diseases			vet
ICD 10	International Statistical Classification of Disease and Related Health Problems			statistics
ExpoFacts	Data on exposure factors			statistics
Leaf wetness	Data on leaf wetness measurements in citrus orchards			plants
CLIMPEST	Specific models in plant health for fungi infection			plants
Protected Crop Area	Area and characteristics of protection structures			plants
Climatic data of Europe	CLIMEX climatic data			statistics
EcoRegion	Data on soil communities			statistics
cfp-ahaw-2007-02.mdb	disease status of countries, SU, EQ density and SU, EQ trade in EU	36 MB		vet
EHD-CCHF.mdb	disease/vector presence	2.7 MB	1944-2009	vet
Hunting practices and CSF vaccination of wild boar	Hunting practices and CSF vaccination of wild boar	2 MB	2000-08	vet
CSF Vaccines	Classic swine fever Vaccines (inactivated, live)	ca. 500 KB (several files)	2008	vet
AI vaccines	Avian Influenza vaccines	ca. 400 KB (several files)	2007-08	vet
Compendium of botanicals reported to contain toxic, addictive, psychotropic or other substances of concern	botanicals scientific names and synonyms, parts of plants containing compounds of possible concerns, chemical of concerns, specific remarks and references	900 entries	up to March 2008	botanicals
Europhyt	Interceptions of harmful organisms in EU			pests
EPPO	Plant quarantine data retrieval system			pests
Prassis	Pest Risk Assessment in the European Community: Inventory of data sources	580 data sources analysed		pests
MoPest	Models for pest's epidemiology: Review, documentation and evaluation for Pest Risk Analysis			pests
Eurostat	Statistical Office of the European Communities			statistics
FaoSTAT	Trade data			statistics
Crop Protection Compendium	Database of information on plant pests (taxonomy, distribution, biology, control etc)			pests
Forestry Compendium	Knowledge on tree species and their pests			pests

ISTAT	Italian Institute of Statistics			statistics
Entrez cross-database search page	scientific publications, nucleotide sequences, amino acid sequences, others	not known	not known	GMO
FCM DB (Food Contact materials Database)	Applications for FCM and Recycling processes in order to have an history of the substances and the recycling processed evaluated by the CEF (former AFC) Unit and Panel. This database was developed on the basis of a previous database. The applications present in the previous database were imported in the new one.	5.62 MB	2003-onwards (the applications 2003-2006 imported from the old database still need to be updated according to the new fields)	Food Contact Materials
RASFF	detailed information on food safety events reported through the RASFF network of official contact points	ca 25.000 notifications	1979- ongoing	microbiological, GMO, chemicals, vet, food contact materials, pesticides, etc
EUROSTAT-Comext	trade data between MSs and also trade statistics for a number of third countries	na	1995- ongoing	statistics
UN Comtrade	import and export statistics reported by ca 200 countries	na	1962-ongoing	statistics
Bioactive compounds in plants	database on the presence(concentrations) and specific biological activity of bioactive compounds with potential public health or toxic effects found in plants used in food and feed.	ca 140 compounds in 70 plants	1979-2009 (non continuous)	bioactive compounds

E. SELECTED CASE STUDIES ON EMERGING RISKS

Trade data surveillance

As part of the regular reporting on specific emerging risk subjects, three technical reports have been prepared based on surveillance of these trade databases. These technical reports compile information retrieved from the Eurostat Comext, UN Comtrade, RASFF, media monitoring and scientific literature. The starting point for each report is a change in a recent trend in trade into the EU, analysed against information from the other sources mentioned, as a means of identifying a potential emerging risk, i.e. signal generation. A summary of each technical report is given in the following section.

It is noted that the conclusions derived must be treated with caution as the data sources used have limitations and weaknesses. Further investigation using other potential sources of information is required to verify the pertinence of such signals.

i) EU imports of fresh or chilled mackerel and the parasite Anisakis

Parasitic infestation of *Anisakis* sp. in fresh fish and fish products, in particular in mackerel, has been reported in the literature. Data obtained from the Eurostat Comext database for fresh or chilled mackerel demonstrated a significant increase of imports into the EU from extra-EU countries from 2005 onwards, mainly due to an increase in UK imports from Norway and the Faroe Islands.

Many notifications related to *Anisakis* sp. in seafood can be found in the Rapid Alert System for Food and Feed (RASFF) database, with the main notifying country being Italy. In particular, Italy has notified *Anisakis* sp. in fresh mackerel from Norway or from Norway via Denmark 20 times since 2004, even though no imports from Norway to Italy have been reported in Eurostat. Over the same period and despite being the principal EU importer of mackerel from Norway between 2006-2008, no notifications on *Anisakis* sp. infestation in mackerel or any fish in general were made to the RASFF by the UK.

Potential underreporting of Anisakis sp. in some MS may lead to an underestimation of the health burden due to this parasite in the EU.

ii) Recent trends in trade of shrimps and prawns and nitrofuran antimicrobial residues

Production and trade of aquaculture products continue to grow, responding to the increased global demand for fish and seafood. In particular, shrimp farming has been one of the fastest growing aquaculture sectors in Asia, Latin America, and more recently in Africa. At the same time, the sustainability of shrimp aquaculture has been questioned in view of self-pollution in shrimp growing areas, combined with the introduction of pathogens, leading to major shrimp disease outbreaks, and significant economic losses in producing countries.

The use of veterinary drugs in aquaculture has contributed to the detection of chloramphenicol and nitrofuran antimicrobial residues in shrimps imported from South East Asia and China into the EU in 2001 and 2002. These findings have previously led the EU to impose temporary controls for the presence of antimicrobial residues on all shrimps imported from those countries.

During the routine monitoring of the RASFF database, the EMRISK unit has noted several notifications on frozen shrimps and prawns originating from Bangladesh, India and Sri Lanka, contaminated with nitrofuran metabolite residues. This information has prompted the EMRISK unit to investigate further the import patterns of these products originating from South East Asia and China into the EU.

Trade data retrieved from Eurostat Comext and UN Comtrade databases as well as notifications from the RASFF database were compiled in this report. The Emerging Risks unit is using this information as indicators of the possible (re)emergence of chemical contamination (antimicrobial residues) in shrimps and prawns.

Eurostat's trade data indicate that in 2008, the EU's imports of frozen shrimps and prawns accounted for 466 thousand tonnes, 39% of these originating from South East Asia and China. Moreover, EU's imports of frozen shrimps and prawns from South East Asia and China have increased from 2003 to 2008 by 71%, when during the same period the total EU imports from all over the world have increased by only 14%. For the same period, United Nations' trade data show an increase of exports of frozen shrimps or prawns from some South East Asian countries to world trade partners.

Trade growth, and as a probable consequence growth of production of aquaculture products, could lead to increased intensity of aquaculture, constituting a potential driver of emerging risks. One example is the increased use of antimicrobial substances that can result in human exposure to chemical residues in the foodstuff and also to increased prevalence of antimicrobial resistance.

iii) Recent trends in trade of Pangasius catfish products from Vietnam and reporting of Listeria monocytogenes

During the routine monitoring of the RASFF database, several notifications on frozen fish products originating from Vietnam contaminated with pathogenic bacteria were noted, in particular frozen *Pangasius* fillets contaminated with *Listeria monocytogenes.*

According to the EFSA's definition of "emerging risks", these notifications potentially constitute "an increased significant exposure to a known hazard". This information prompted EMRISK to further investigate the import patterns of *Pangasius* products originating from Vietnam into the EU.

Rapid growth of the aquaculture sector in Vietnam has occurred during the last two decades. According to FAO statistics, the production of *Pangasius* sp. has grown by five times from 2004 to 2007 and constituted 60% of the total Vietnamese freshwater fish production in 2007.

EU imports of frozen fillets of freshwater fish (used as a proxy for frozen *Pangasius* fillets) from Vietnam have increased 25 fold from 2003 to 2008, to approximately 206,000 tonnes in 2008, and continued to show an increase for 2009. EU imports of this commodity from Vietnam were covering 85% of total imports from all world partners in 2008.

The leading cause of *L. monocytogenes* contamination may be the hygiene conditions of processing plants, storage facilities and transportation vessels. Taking into account that imports of *Pangasius* fillets are significant in volume and increasing every year, their relative importance as a route of exposure to *L. monocytogenes* and other pathogens should be considered, taking into account preparation and consumption patterns in the EU.

Whilst smoked salmon is a recognised route of exposure of EU consumers to *L. monocytogenes*, *Pangasius* products are a new or under-recognised route, the significance of which has not, to date, been assessed. The latter could pose a potential route of introduction of *L. monocytogenes* into the household kitchen or the industrial processing environment and exposure of humans through cross contamination or undercooking.

Monitoring of the media and scientific literature

Pharmaceutical products in drinking water

The media and the scientific literature report more and more frequently events of water contamination by emerging chemicals. Emerging chemicals are defined as chemicals which are not currently regulated by water quality legislation and which toxicological properties and environmental effect are very little known. Among these molecules, pharmaceutical products are becoming a global issue both for the environment and human health because of the increasing use of these products in human daily life, their bioaccumulation and persistence in the environment and the difficulty to detect and remove these substances present at low concentrations by typical water treatment.

It is estimated that approximately 3000 different substances are used worldwide today, including analgesics, antibiotics, antiepileptics, antidiabetics, β-blockers, contraceptives, blood-lipid regulators, antidepressants and impotence drugs. Most pharmaceutical products (PPs) and their by-products (BPs) are polar compounds and their molecular weights range typically from 200 to 500/1000 Da. They are small molecules and often called "micro-pollutants" because they are found in the µg/L or ng/L range in the aquatic environment. However, only a small subset of these compounds has been investigated in environmental studies, and important classes are still under-described due to a lack of instrumental technique or analytical standards for low concentrations. Only a few PPs have a maximum residue limit and in most cases there are no legal requirements to assess the long-term exposure to low concentrations.

Recent scientific reviews indicate that the daily-life intake of pharmaceuticals through drinking water may have been under-estimated because the effects of chronic exposure of low concentrations of pharmaceutical products, the variability of the responses of individuals and the effects of mixtures of pharmaceutical products are not taken into account.

Therefore, we recommend that the new data published in the recent scientific literature is re-assessed to determine human exposure and risk to pharmaceutical products through drinking water.

F. LIST OF SOURCES OF INFORMATION

SOURCE	FREQUENCY OF UPDATES
RAPID ALERT SYSTEMS AND RECALLS	
Rapid Alert System for Food and Feed	Daily
WHO INFOSAN	~ 5 / year
WHO Disease Outbreak News	~ 5 / year
FAO and emergencies	~ 5 / year
FDA recalls, alerts, and Warnings	Daily
US-CDC Foodnet	Monthly
USDA Food Safety and Inspection Service	Monthly
Food Standard Agency – Food alerts	Daily
New Zealand Food Safety Authority - Alerts	~ 5 / year
MEDIA MONITORING	
Medical Information System (MedISys)	> Daily
Food Navigator	Weekly
BULLETINS, OFFICIAL REPORTS, NEWSLETTERS	
EU-DG Health & Consumers (i.e. food safety)	Weekly
US-CDC-Food safety	~ Weekly
USDA-Food safety inspection service	~ Weekly
US Portal on food safety	Weekly
WHO food safety news	~ 5 / year
WHO Food safety gateway	~ 5 / year
Australia and New Zealand: Newsletter	Monthly
OIE food safety	~ 5 / year
EFSA newsletter, press review, register of questions	Weekly
NGO's (e.g Greenpeace international news)	~ 5-10 / year
EU-Food Law	Weekly
EFSA international exchange platform report	Monthly
SCIENTIFIC JOURNALS AND DATABASES	
Food safety	
Environmental Health Perspectives – Food Safety	Monthly
Food Additives and Contaminants	Monthly
Food Chemistry	Monthly
Food Control	Monthly
Food Microbiology	Monthly
Food & Chemical Toxicology	Monthly
Food Process Engineering and Technology	Monthly
Food Processing	Monthly
Food Research International	Monthly
Food review international	Monthly
Food Toxicants Analysis	Monthly
Global Issues in Food Science and Technology	Monthly
Innovations in Food Packaging	Monthly
Innovative Food Science & Emerging Technologies	Monthly
Journal of Agricultural & Food Chemistry	Monthly
Journal of Food Engineering	Monthly
LWT - Food Science and Technology	Monthly
Microbiological Analysis of Food and Water	Monthly
Food Chemical News (user:an08986 pass:mouse)	Daily
Journal of Food Protection	Monthly
International Journal of Food Microbiology	Monthly

Trends in Food Science and Technology	Monthly
Innovative food science and emerging technologies	Monthly
Transboundary and Emerging Diseases	Monthly
Environmental	
Environmental Science and Technology	Monthly
Environmental Monitoring Assessment	Monthly
Journal of Environmental Monitoring	Monthly
Science of the Total Environment	Monthly
Environmental Science and Pollution Research	Monthly
Chemosphere	Monthly
Environment International	Monthly
Journal of Environmental Management	Monthly
Ecological Indicator	Monthly
Environmental bioindicators	Monthly
Environmental Forensics	Monthly
Environmental Health perspectives	Monthly
Others	Monthly
Emerging infectious diseases	Monthly
Emerging Health threats journal	
The Lancet	Weekly
BMJ	Weekly
JAMA	Weekly
Eurosurveillance	Weekly
Science	Weekly
Nature	Weekly
Pubmed (alert on emerging risks in food)[1]	Monthly
ISI Web of Knowledge[2]	Daily
SELECTED INITIATIVES ON EMERGING RISKS	
Moniqa FP6	~ 5-10 / year
EnviroGenomarkers FP7	Less than 5 times / year
SELECTED NATIONAL FOOD SAFETY AUTHORITIES	
France	~Daily/Weekly
Germany	~Daily/Weekly
UK-FSA	~Daily/Weekly
VWA	~Daily/Weekly

[1] See Annex III describing the search strategy
[2] See Annex IV describing the search strategy

G. REVIEW OF RECENT SCIENTIFIC LITERATURE ON EMERGING RISKS IN FOOD

Materials and Methods

Data for this review were identified mainly through Pubmed searches, focusing on the publications of 2009 and early 2010. Articles published earlier have been included, where deemed particularly relevant. The following search strategy was used in Pubmed to identify potentially relevant articles: ("Risk"[Mesh] OR threat OR hazard OR hazardous OR safety OR toxic OR identification OR new OR novel OR emerging OR emergent OR emergence OR "new pathogen" OR unexpected OR surprisingly OR "first time" OR "increased virulence" OR "increased resistance" OR resistance OR unknown OR unexplained OR "increased exposure" OR contaminant OR contamination OR increased susceptibility Or "no legislation" or "dietary change" OR "change in diet" OR "change in nutrition patterns" OR "change in food consumption patterns") AND ("Food"[Mesh] OR "Feed" OR dietary OR diet OR "food chain"[Mesh] OR meat OR poultry OR milk OR cereal OR dairy OR vegetables OR fruit OR fish OR foodstuff). The articles obtained were then screened and selected by one scientific officer though the abstracts. The data collection was complemented with manual screening of selected journals publishing in the area of food safety, public and environmental health, and with available conference proceedings and unpublished data (e.g. data presented at the WHO Conference "Estimating the Global Burden of Foodborne Diseases" on the prevalence of peanut allergy and on the global burden of echinococcosis).

Results

Microbiological hazards

Several reviews describe the changing landscape of microbiological food safety of the last few decades (Erickson and Doyle, 2007; Havelaar et al., 2009; Newell et al., 2010; Tassios and Kerr, 2010; Tauxe et al., 2009). New pathogens have emerged; established pathogens acquired new characteristics and appeared in unexpected food vehicles. Approximately 30% of all new globally emerging infections identified in the past 60 years have been reported to include pathogens commonly transmitted through food (Jones et al., 2008). As a consistent proportion of all causes of intestinal infectious disease appears to be still unidentified, it seems likely that new foodborne pathogens will be discovered in the 21st century (Mead et al., 1999; Tompkins et al., 1999).

Table 4 summarises the data collected from the recent scientific literature on emerging risks and drivers of change. The emergence and spread in the community of new genotypically different strains of well known pathogenic species has caused mounting concern. New hypervirulent or antimicrobial resistant strains of *Salmonella, Campylobacter, Escherichia coli, Clostridium difficile, Staphylococcus aureus* and *Mycobacterium avium* have been isolated from food animals and food (Amar et al., 2007; Eltholth et al., 2009; Freeman et al., 2009; Kluytmans; Sahin et al., 2008; Switt et al., 2009; Tassios and Kerr, 2010; Tauxe et al., 2009; Weese). Post-genomic studies have been confirming how rapidly and effectively these pathogens adapt to environmental stresses such as antimicrobials and temperature changes by exploiting the remarkable plasticity of their genome, and becoming more fitted to new hosts, novel environmental niches, reservoirs and routes of exposure (Amar et al., 2007; Barak et al., 2005; Franz and van Bruggen, 2008; Freeman et al., 2009; Kluytmans; Sahin et al., 2008; Switt et al., 2009; Tassios and Kerr, 2010; Tauxe et al., 2009; Vincent et al.; Weese).

Some parasitic food-borne infections have been reported as (re-)emerging in the last two decades (Dorny et al., 2009). For *Cryptosporidium* sp. and *Giardia* sp., some evidence shows the potential of transmission not only through contaminated water, but also through food (i.e. fruit, salad vegetables and shellfish), and handling animals (Dorny et al., 2009). However, there is still uncertainty about host-specificity, zoonotic potential, and about the actual public health threat posed by these parasites

(Dorny et al., 2009). Whilst human fasciolosis, an infection mostly concentrated in low and middle income countries and acquired by the ingestion of *Fasciola hepatica* carried by various freshwater aquatic plants, and leading to liver failure, has been known about for a considerable time, only in the last two decades has its importance been recognized (Dorny et al., 2009; WHO unpublished data, 2009). Echinococcosis is an infection usually caused by the accidental ingestion of *Echinococcus* eggs shed by a carnivore host or occasionally through contaminated food (Dorny et al., 2009; Moro and Schantz, 2009). Four species have been recognized of public health concern and several studies have shown that these diseases are an increasing public health concern in several parts of Asia and in some parts of Europe (i.e. worldwide approximately 33 000 human cases of alveolar echinococcosis per year, of which more than 10 000 cases per year are from contaminated food)(Moro and Schantz, 2009; Newell et al., 2010; WHO unpublished data, 2009). *Trypanosoma cruzi*, the causative agent of Chagas disease, has been reported to be spreading from Central and South America to several European countries and North America (Rodriguez-Morales, 2008), and recent evidence suggests that this parasite may be orally transmitted via fruit juices, probably contaminated with faeces from infected bugs (Nobrega et al., 2009).

With increasing living standards and the pursuit of exotic foods, populations around the world, particularly in Asia, have seen infections with liver flukes (i.e. *Clonorchis sinensis* and *Opisthorchis viverrini*) becoming more important (Keiser and Utzinger, 2005; Lun et al., 2005; Zhang et al., 2008). Thirty-five million people are estimated to be infected globally, of whom approximately 15 million are in China, a country that registered a 3-fold increase in incidence in the last two decades (Keiser and Utzinger, 2005; Lun et al., 2005). The recent official recognition by WHO, that infections with *C. sinensis* or *O. viverrini* are carcinogenic, causing cholangiocarcinoma adds further concern about the spread of these parasitic infections (Bouvard et al., 2009).

It is known that several foodborne pathogens (e.g. *Campylobacter, E. coli, Listeria monocytogenes, Salmonella* and *Toxoplasma gondii*) can cause, in a small percentage of cases, serious acute and/or life-long complications, including kidney failure, paralysis, seizure, hearing/visual impairments and mental retardation. Inflammatory Bowel Disease may be added to this list, as reported by a large population-based cohort study on individuals affected with gastroenteritis infections caused by nontyphoid *Salmonella* or thermophilic *Campylobacter* (Gradel et al., 2009).

Emerging and re-emerging foodborne infections are not exclusively associated with bacterial or parasitic pathogens. There is now ample documentation that the burden of foodborne viral illness is significant (Future Challenges to Microbial Food Safety, 2008; Newell et al., 2010). The past decades have witnessed the emergence of new viruses able to infect humans, such as SARS coronaviruses, different strains of highly pathogenic avian influenza, Nipah virus and new genotypes of hepatitis E virus (Newell et al., 2010). More recently, evidence is accumulating to suggest that some of these virus infections are far more common than previously recognised, and that they can be acquired through consumption of contaminated food products (Dalton et al., 2008; Newell et al., 2010; Tassios and Kerr, 2010; Teo). Which foods, routes of exposure, and variant strains represent the greatest risk for consumers is still under debate. Thus, foodborne transmission of viruses has long been recognised, but as the microbiological quality control criteria for food globally rely on standards developed for bacterial infections, these criteria seem to be insufficient to protect from viral foodborne infections (Newell et al., 2010). The issue of foodborne viruses is currently being addressed by the BIOHAZ Panel through a self-tasking mandate (EFSA-Q-2009-00877).

Chemical hazards

With reference to chemical hazards, a mounting body of evidence has been has been published on the measurement of the occurrence of several chemicals in different food commodities, and on the detection of biological markers (biomarkers) of exposure to these chemicals.

Several studies have reported the presence, at different levels, of persistent organic pollutant (POP) contamination of food, by measuring perfluorinated compounds (PFCs), organochlorine pesticides, and polychlorinated biphenyls (PCBs), polybrominated diphenyl ethers (PBDEs) and hexabromocyclododecane (HBCD) brominated flame retardants, and heavy metals in composite food samples (Borchers et al., 2009; Fowler, 2009; Schecter et al., 2010).

Serum levels of these and other chemical contaminants have been associated with poor health outcomes. For example PBDEs, DEHP and MEHP have been associated with the onset of pubertal gynecomastia (Durmaz et al.); perfluorinated chemicals such as perfluorooctanoic acid (PFOA) with liver failure (Lin et al., 2009); high urinary concentration of bisphenol A has been associated with diabetes, liver toxicity, and heart disease (Lang et al., 2008; Melzer et al.); cadmium exposure with cardiovascular diseases (Peters et al., 2010); high serum concentrations of selenium with a higher prevalence of diabetes (Laclaustra et al., 2009); and blood lead level with kidney dysfunction (Fadrowski et al.).

With reference to natural toxins, biogenic amines by gram negative bacteria isolated from poultry skin have also been recently reviewed (Bunkova, 2010), and indeed are the subject of an EFSA self-tasking opinion of the Biological Hazards Panel EFSA-Q-2009-00829.

Drivers of emerging risks

Several drivers of change have been reported to have a potential impact on food safety in the mid or long term perspective (EFSA, 2009c; Havelaar et al., 2009; Kleter and Marvin, 2009; Quested et al., 2010). These include climate change, genetic evolution of pathogens, intensification of livestock husbandry including aquaculture, environmental contamination with persistent chemicals for which little toxicological information exist, recycling of food and animal processing waste into animal feed, changes and innovations in food processing, changes in consumer behaviour and preferences, lack of legislation, globalization, international trade, demographic changes, fluctuations in food prices (Havelaar et al., 2009; Kleter and Marvin, 2009). In the following paragraphs possible implications of selected drivers for which evidence in the literature was found are listed.

Climate change

Climate change has been reported as one of the greatest challenges to mankind, potentially affecting different aspects of society, including food safety, in the next decades (Costello et al., 2009; DaMatta et al., 2010; Meerburg and Kijlstra, 2009; Miraglia et al., 2009; Moretti et al., 2010).

Several aspects of climate change (e.g. changes in temperature, rainfall, carbon dioxide) have been reported to have a potential impact on the distribution of plant and animal diseases, food and water security, shifts in production areas and cultured crops, use of agrochemicals, food storage, and production of natural toxins (Costello et al., 2009; DaMatta et al., 2010; FAO, 2008; Meerburg and Kijlstra, 2009; Miraglia et al., 2009; Moretti et al., 2010). However, the mechanisms by which climate change could affect food safety are highly complex and interrelated with many societal factors (Havelaar et al., 2009).

Pathogens that cause disease at very low doses and/or have notable environmental persistence (e.g. enteric viruses and parasitic protozoa), have been suggested to be of greater concern in this context (Miraglia et al., 2009).

If the temperature increases in cool or temperate climates, the relevant countries may become more liable to aflatoxins, whereas tropical countries may become too inhospitable for conventional fungal growth and mycotoxin production (Paterson and Lima, 2010).

Drought-prone areas are likely to increase in extent, leading to loss of fertile land, southern Europe being one such example. In contrast, increased water availability and temperature in high-latitude areas could lead to an increase in cereal production (Costello et al., 2009). However, some of these benefits could be offset by crop damage from water-logged soil and storms, pests and diseases. Aside from agriculture, increased sea temperatures are likely to put further strain on aquaculture.

Alongside these direct effects, significant indirect effects in response to climate change could also occur (Costello et al., 2009). For example, the development of taxation and trading schemes related to the release of greenhouse gases have the potential to transform not only agricultural practices, but also have a strong impact on consumption of key food groups (Costello et al., 2009) and their international trade. The threat through climate change to food security may have consequences on food safety, with increased pressure on food production leading to pressure to reduce safety standards.

Changes in consumer behaviour and consumption patterns

Changes in consumers' behaviour and preferences, including food consumption patterns, have been indicated as a potential source of emerging risks (Kleter and Marvin, 2009). Recent consumer behaviour has been influenced by convenience, increased choice, and the rise of ethical and novel foods. For instance, the increasing trend registered in the last decade, towards consumption of fresh produce and fish, and other ready-to-eat produce consumed without additional heating, have been consistently reported as a matter of increasing concern, as confirmed by several surveillance studies on microbiological contamination (2009b; Ilic et al., 2008; Lahuerta et al., 2010; Little and Gillespie, 2008; Maki, 2009; Pezzoli et al., 2008).

New culinary techniques (e.g. molecular gastronomy, mild cooking conditions, and use of new ingredients) involve more and more technical creativity and exotic ingredients to improve quality and meet consumer expectations. This may result in unexpected risks (e.g. inadequate inactivation of pathogens), if information on preparation, cooking and storage is not clearly conveyed to the consumers (Future Challenges to Microbial Food Safety, 2008; Bassett and McClure, 2008; Havelaar et al., 2009). There continues to be a market for new or different food which increases novelty and diversity in the market place, with the consumer often perceiving a benefit from consuming them. Relatively recent examples include the use of different types and combinations of leaves in bagged salads, the array of flavours and combinations of fruit-based drinks (e.g. smoothies) and the availability of a diverse range of edible seeds. Similarly, exotic and ethnic foods (e.g. reptile meat) are fashionable in the market, but little is known about the underlying preservation system and zoonotic risks in the European population (EFSA, 2007a; Havelaar et al., 2009; Magnino et al., 2009). Chinese salt-preserved fish is an example of an exotic food that is consumed in several regions around the world, and that has been recently classified as carcinogenic (i.e. nasopharyngeal and possibly stomach cancer) to humans by WHO (Secretan et al., 2009).

With the rapid development of living standards in recent years, the organic food market has become a rapidly growing sector of most developed agricultural economies around the world and in fast developing countries like China where a 30% increase / year has been recently registered and further growth is expected in the near future (Shenga et al., 2009). Organic food production and other related practices, such as improving animal welfare, however, may lead to the re-introduction of pathogens with wildlife reservoirs (e.g. *Trichinella spiralis* and *Toxoplasma gondii*), and may increase the prevalence of other known hazards (ESFA, 2007b; Gebreyes et al., 2008). Other relatively recent trends include the rise of the so-called ethical foods, including elements of fair trade, assurance of farming standards and animal welfare, and a growing emphasis on local produce.

Public bodies in many countries are actively engaged in promotion of a balanced, nutritious diet, especially in light of the obesity epidemic many countries are experiencing (Berghofer et al., 2008). Such a trend has been suggested to have a potential influence on food choice relevant to microbial food safety. If protein sources high in saturated fats are discouraged in favour of alternatives, red meat consumption could decline in favour of poultry, fish and vegetarian options. Fresh produce consumption could also be encouraged as an alternative to processed foods. Specific nutrition-related activities could also affect microbiological safety in particular ways, e.g. reducing salt levels in processed foods could shorten the shelf-life of certain products unless such foods are reformulated to ensure there are adequate preservation hurdles to prevent or minimise microbial growth. In particular, habituating the consumer to potentially reduced shelf-life of products evolved from traditional ones could be a major challenge. Marketing and advertising are likely to play a continued strong role in shaping food preferences. The nature of this role will be determined by how food brands and retailers wish to be portrayed (e.g. as having our health as their concern) and how advertising regulation and implementation develops with time (Future Challenges to Microbial Food Safety, 2008).

The recent trend in the promotion of the use of dietary supplements is an issue that will continue to be of increasing concern. For instance, despite the proposed beneficial effects of folate, there are rising health concerns about an excessive intake of this vitamin, which could potentially mask vitamin B12 deficiency, especially in elderly individuals, or promoting the progression of already existing preneoplasms.

Increasing burden of susceptible groups

Food safety is particularly important for certain subgroups of the population who are more vulnerable to foodborne diseases compared to the general population. The impact of foodborne illness on these individuals is more likely to be serious and/or long-lasting. Several studies reported new figures on emerging or increasing subgroups of the population that will be at higher risk of foodborne diseases (Gillespie et al., 2009; Lahuerta et al., 2010; Neill, 2005; Sivapalasingam et al., 2004; Tauxe et al., 2009).

The global immunocompromised population continues to increase due to the HIV/AIDS epidemic, life-prolonging treatment of immunodeficiency diseases, the use of chemotherapeutics and immunosuppressive drugs in cancer and transplant patients, and the well documented increase of the elderly population. It is estimated that about 4% of the USA population is immunodeficient and when pregnant women and the elderly are included, the percentage increases to about 20% (Neill, 2005). These individuals have increased susceptibility to infections, a greater likelihood of more severe illnesses, including death, and increased potential for illness caused by an opportunistic pathogen (Neill, 2005).

Estimates indicate that in 2050, there will be three times more elderly (age≥65 years) than in 2002, comprising 17% of the global population (Bureau, 2004). Although the population of Europe is set to remain relatively constant, the age structure is estimated to alter significantly, for example, in 2020, 30% of Germany's population is predicted to be 60 years old or above, compared with 25% in 2005 (and 37% by 2050)(United Nations, 2008). For many reasons, including weakened immune systems, more underlying illnesses, decreased protection by vaccines, longer hospitalizations, permanent catheterization, decreased absorption of nutrients, renal insufficiency, and problems with drug interactions, and stomach acloridia, the elderly are at increased risk of pathogenic microbes (Gillespie et al., 2009; Ohlsen and Hacker, 2005; Tauxe et al., 2009). For example, age-related differences in uropathogenicity of *Salmonella* infections and blood invasiveness of *S. enterica* serotypes have been reported, with greatest occurrences in elderly populations (Sivapalasingam et al., 2004; Tauxe et al., 2009). Similarly, the elderly population appears to experience higher rates of listeriosis (EFSA, 2010a; Lahuerta et al., 2010).

In the last decades, obesity has reached epidemic proportions in North America, and more recently in Europe (Berghofer et al., 2008; Flegal et al.), and it is estimated that up to 50% of all adults will be obese by 2050 in certain parts of Europe (Foresight, 2007). Globally, there are more than 1 billion overweight adults, at least 300 million of them clinically obese. Being obese or overweight is a widely discussed risk factor associated with a substantial health burden with, for example, increased risks of cardiovascular disease, type 2 diabetes, stroke, some cancers, and immune system impairments (Berghofer et al., 2008; Flegal et al.; Foresight, 2007). Similarly, the population affected by diabetes is steadily increasing. The prediction is that between 2005 and 2020, new cases of type 1 diabetes in European children younger than 5 years will double and that the prevalence of cases in those younger than 15 years will increase by 70% (Patterson et al., 2009). Several national health surveys indicate that food allergy prevalence has increased in North America and Europe in recent years (Branum and Lukacs, 2009), with peanut allergy affecting up to 1% of the population in the US and 4% in Europe (WHO, 2009).

Evidence of genetic susceptibility to certain environmental exposures is emerging in the post-genomic era (Huen et al., 2009; Mead et al., 2009; Secretan et al., 2009). Carriers of specific genetic variants of certain detoxifying enzymes may be more vulnerable to organophosphate pesticides (Huen et al., 2009). Similarly, carriers of certain genetic variants of aldehyde dehydrogenases, have about 10% enzyme activity, and if they consume alcohol beverages accumulate acetaldehyde (a known carcinogen), becoming more susceptible to alcohol-related cancers (Secretan et al., 2009).

Food trade

Food trade is increasing for many countries at unprecedented rates, as the supply of fresh food becomes year round (Doyle and Erickson, 2008; Quested et al., 2010; Tauxe et al., 2009). The global trade of foods has more than tripled in the past two decades, with big differences by region, with Europe being reported as the major importer and exporter worldwide (Doyle and Erickson, 2008), making Europe an important cross-roads for food and foodborne hazards.

Microbiological food safety issues associated with imported foods include inadequate sanitary practices used for food production and preparation in many countries exporting perishable foods and the movement of pathogens from areas where they are indigenous to other areas where they are rare or do not exist (Brown; Doyle and Erickson, 2008). Foods like fresh produce, or fresh and frozen seafoods which are handled as ready-to-eat are of particular concern. Produce can become contaminated from a variety of sources, including sewage/manure used as soil fertilizers or through environmental contamination, contaminated water used to spray plants or in processing, and poor hygienic practices or infected food handlers. For example, in some parts of China and Vietnam, the centuries old tradition is still practiced of using human excreta (fresh or partially composted) to fertilize farmlands or gardens. Irrigation water in parts of countries like Mexico and India is derived from untreated wastewater sewage from large cities (Doyle and Erickson, 2008). Aquaculture practices in seafood and fish production in many exporting countries are also potentially conducive to foodborne pathogen contamination (Doyle and Erickson, 2008). Future gains in seafood production are projected to come from farmed fish.

Changes to world food-trade rules could shift the balance of countries supplying food to the EU. Recent negotiations relating to global trade are, in general, reducing the level of import tariffs and liberalising global trade. One example is development of the Economic Partnership Agreements between the EU and members of the Africa, Caribbean and Pacific group. These would allow specified countries quota-free and duty-free access to the EU markets. Although this has the potential to radically increase the amount of food imported into the EU, in practice it is likely that change will be gradual as many of the relevant exporter countries do not have the capacity to fill their current quotas.

Food and energy prices

The global economic and financial crisis has played a critical role in high food and fuel prices (Brinkman et al.). Increasing food prices are likely to compromise food security on a global scale. Consumers may opt for less costly alternatives (Bloem et al.; Brownell and Frieden, 2009; Quested et al., 2010). These may lead to less consumption of animal proteins. Higher food prices may also cause consumers to use food more frequently past its shelf-live and may increase recycling of food (Havelaar et al., 2009).

Another influence on consumer choice is price. The cost of the food basket has increased in several countries, forcing households to reduce quality and quantity of food consumed (Brinkman et al.). The food consumption score, which is a measure of diet diversity, is negatively correlated with food prices.

Oil and energy prices fluctuate to a greater extent than most other influences on the food system and this makes changes in price notoriously difficult to predict (FAO/OECD, 2007). They represent a significant uncertainty in any prediction of future food prices. However, foods which will be strongly affected by oil and energy prices can be hypothesised (e.g. foods that depend on a high level of manufactured fertilisers, such as leafy green vegetables, cereals, and indirectly beef; foods that require energy-intensive processing; foods from locations that require a high level of transportation). Although robust predictions regarding oil and energy prices can not be estimated, these prices could be tracked and thus be forewarned of impacts on food prices.

Increase in biofuel feedstock production could exert considerable upward pressure on food prices and restrict supply. The increase in planned biofuel feedstock production in the EU stems from the potential for many positive outcomes, e.g. an overall reduction in greenhouse gas emissions, diversity of energy supply and generating income and employment in rural areas. However, the most favourable method of achieving these goals is still under debate. Nevertheless, the EU biofuel feedstock production is predicted to nearly triple between 2008 and 2016 and large increases are expected in other regions (FAO/OECD, 2007). Where biofuel feedstock production impinges on land used for food production, it will place an upward pressure on food prices and a downward pressure on food availability. Recent food-price increases were thought to be only slightly affected by biofuel feedstock production, but if predictions for EU and US production are realised, there would be considerable upward pressure on food prices (FAO/OECD, 2007).

Demographic changes

Demographic changes will probably increase world food demand. As argued previously, global food demand is closely linked to global population, which is predicted to rise from 6.6 thousand million people in 2008 to between 7.4 and 7.8 thousand million in 2020 (United Nations, 2008). Thus, the world food demand is likely to grow substantially over this period, not only from this rise in population, but also from an increasing urban and affluent population in countries with emerging economies. These trends will continue to exert an upward pressure on food prices and could reduce the global availability of certain foods. In contrast to the world population, Europe's population is predicted to be relatively stable, reducing from 730 million in 2008 to 720 million in 2020 (United Nations, 2008). Given that the EU is self-sufficient in many food types, this creates a degree of security of food availability in the future and a moderating influence on food prices in Europe relative to global prices. It is the food-importing developing countries that are likely to face the biggest challenges as a result of increasing world food prices.

Changes in food processing technology

During the last 25 years, consumer demands for more convenient and varied food products have grown exponentially, together with the need for faster production rates, improved quality and extension in shelf life. The food industry is constantly implementing new technologies to reduce costs, improved quality, increase availability, reduce waste, introduce product innovation, utilize new sources of raw material and improve safety. The general trend is toward minimising food processing so that, despite long distribution chains, foods can be presented as being fresh or of comparable quality (Havelaar et al., 2009; Quested et al., 2010).

These demands together with the severity of the traditional food processing technologies were driving forces for improvements in existing technologies and for the development of new food preservation technologies. Therefore, many technological developments have been directed towards unit operations such as pasteurization, sterilization, cooking and drying, and currently the new technological approaches for food preservation are serious candidates to replace the traditional well-established preservation processes. Minimally processed fruits and vegetables (MPFV) have a short shelf-life due to their metabolism and the action of spoilage microorganisms. Chlorine dioxide is a powerful oxidizing agent that can be used as decontaminant. It does not form significant amounts of chlorinated by-products, as chlorine does. Emerging technologies for food processing are generally non-thermal, such as high-pressure, pulsed electric field, osmotic dehydration, ultrasound, irradiation, radio frequency electric fields, pulsed light, and athermal membranes (Sun, 2005). Extensive investigations have revealed the potential benefits of non-thermal food processing as an alternative to heat treatments (Pereira and Vicente, 2010). These benefits are apparent in various areas of food processing, such as the inactivation of microorganisms and enzymes, denaturation and alteration of the functionality of proteins and structural changes to food materials.

Alternative thermal processing techniques include microwave heating, radio frequency processing, ohmic heating, combined microwave-vacuum drying, new hybrid drying and thermal monitoring utilizing NMR technology. In addition, technology is being applied to improving cooling and freezing of foods through such methods as vacuum cooling of foods, ultrasonic assistance of food freezing, high-pressure freezing and controlling the freezing process with antifreeze proteins.

The impact of these new technologies on microbial inactivation should be followed closely, as should their potential to introduce or provoke the formation of new chemical contaminants.

While reducing packaging is a laudable initiative, industry and consumers should be aware of those situations where packaging has a preservative function by minimizing growth and/or recontamination of micro-organisms.

Some evidence suggest that foodborne outbreaks appear to be on the rise in some industrialized countries, shifting from traditional problems with food from animal origin to fresh foods such as produce (Havelaar et al., 2009; Lynch et al., 2009), shellfish and dry products and ingredients (e.g. peanuts)(2009a) and raw milk (Oliver et al., 2009). By 2010, it is projected that 230 million people will be affected with metabolic syndrome, a diet related disease, associated with an elevated risk of developing type II diabetes mellitus, cardiovascular disease (CVD) and premature death (Isomaa et al., 2001). In an attempt to curb these diet related epidemics, governments across the globe are passing aggressive legislation to limit and in some cases ban the use of trans-fats. To achieve these new legislative requirements, the food industry must vigorously investigate alternatives to traditional triacylglyceride (TAG) structuring. TAGs provide structure in numerous food products including ice cream, cheese, butter, lard, etc. Unfortunately, it is the trans- and saturated lipids which provide the elastic structure (i.e., hardness, mouth-feel or solid-like properties) of these foods. Although the structure they confer on products is desirable, and indeed required, in many products, both types of fatty acids have been shown to deleteriously influence human health (Rogers, 2009).

Nanoscience and nanotechnology are new frontiers of this century. Their applications to the agriculture and food sector are relatively recent compared with their use in drug delivery and pharmaceuticals. Smart delivery of nutrients, bioseparation of proteins, rapid sampling of biological and chemical contaminants and nanoencapsulation of nutraceuticals are some of the emerging topics of nanotechnology for food and agriculture. Advances in technologies, such as DNA microarrays, microelectromechanical systems and microfluidics, will enable the realization of the potential of nanotechnology for food applications. The applications of nanotechnology relevant to food and nutraceuticals together with identifying the outstanding challenges have been recently reviewed (Bouwmeester et al., 2009; EFSA Scientific Committee, 2009; Sozer and Kokini, 2009).

Others

The current risk assessment paradigm is generally applied to single chemicals via a single route of exposure. It is increasingly recognized, however, that many of the numerous chemicals we are exposed to everyday are ubiquitous, resulting in exposure from food, water, air, dust, and soil. In addition, many of these chemicals act on the same target tissue by similar mechanisms. "Mixture toxicology" is a rapidly growing science that addresses the complex interactions between chemicals and investigates the effects of cumulative exposure to such "common mechanism groups" of chemicals (Borchers et al., 2009). It is to be hoped that this results in a deeper understanding of the risks we face from multiple concurrent exposures and makes our food supply safer. In order to this approach to be valid, each one of the multitude of natural and synthetic chemicals to which we are exposed would have to act independently. In recent years, there has been increasing recognition that information on the cumulative risk for multiple chemical exposure is urgently needed, and the field of "mixture toxicology" has emerged (EFSA, 2009a).

Annual global aquaculture production has more than tripled within the past 15 years, and by 2015, aquaculture is predicted to account for 39% of total global seafood production by weight. Given that lack of adequate nutrition is a leading contributor to the global burden of disease, increased food production through aquaculture is a seemingly welcome sign. However, as production surges, aquaculture facilities increasingly rely on the heavy input of formulated feeds, antimicrobials, antifungals, and agrochemicals. Current aquaculture practices can lead to elevated levels of antimicrobial residues, antimicrobial-resistant bacteria, persistent organic pollutants, metals, parasites, and viruses in aquaculture finfish and shellfish. Specific populations at risk of exposure to these contaminants include individuals working in aquaculture facilities, populations living around these facilities, and consumers of aquaculture food products. Additional research is necessary not only to fully understand the human health risks associated with aquaculture fish versus wild-caught fish but also to develop appropriate interventions that could reduce or prevent these risks (Sapkota et al., 2008).

Discussion

This preliminary review of the scientific literature to identify reported emerging risks in areas related to food safety was carried out with the aim of collecting information to be further evaluated in the framework of the EFSA emerging risk identification system.

Microbiological and chemical re-emerging risks reported were mostly related to the changing epidemiology of known pathogens, and the health effects of chronic exposure to certain chemical hazards. Drivers of change that could affect the scale or frequency of these risks and trigger new unknown hazards included potential consequences of climate change on food safety, changes in consumer behaviour and preferences, changes in food processing technology, international trade, demographical changes, food and energy prices. The increasing burden of susceptible groups of the population (e.g. immunocompromised individuals) has also been consistently reported as an issue of increasing concern for the next decades.

The broad nature of this review, spanning from microbiological risks to socio-economic factors, makes this study unique and particularly useful in the first stages of a horizon scanning process. Emerging risks found in the scientific literature are mostly related to issues raised in the last few years and decades. Drivers of change appear to be more informative for long term predictions. In order to increase the efficacy of the horizon scanning process and identify more recent and more specific issues, expert consultations are advisable.

Table 4. Potential Emerging risks and drivers of change as reported in the scientific literature recently published.

Hazard	Subject	References
Microbiological		
Changing epidemiology of known pathogens	• Isolation of new hypervirulent or antibiotic resistant strains of *Salmonella, Campylobacter, E. coli, C. difficile, S. aureus, M. avium*. • Adaptation of these pathogens to new environmental stresses, hosts, niches, reservoirs and routes of exposure.	(Amar et al., 2007; Barak et al., 2005; Eltholth et al., 2009; Franz and van Bruggen, 2008; Freeman et al., 2009; Kluytmans; Sahin et al., 2008; Switt et al., 2009; Tassios and Kerr, 2010; Tauxe et al., 2009; Vincent et al.; Weese)
Re-emerging parasites	• Evidence of the potential transmission of *Cryptosporidium* and *Giardia* through contaminated water, food, and animal handling. • Uncertainties on the public health impact of infections. • Evidence on the increasing burden of *Fasciolosis, Echinococcis*. • Spreading of Chagas disease and of oral transmission of *T. cruzi*. • Increasing burdern and cancerogenicity *of C. sinensis* or O. *viverrini* infections	(Bouvard et al., 2009; Dorny et al., 2009; Keiser and Utzinger, 2005; Lun et al., 2005; Moro and Schantz, 2009; Newell et al., 2010; Nobrega et al., 2009; Rodriguez-Morales, 2008; WHO unpublished data, 2009; Zhang et al., 2008)
Long term effects of GI	Inflammatory Bowel Disease may be added to this list of long term complications of GI infections	(Gradel et al., 2009)
Viruses	• New strains of known viruses (e.g. SARS coronaviruses, highly pathogenic influenza, Nipah viruses, Hepatitis E) • Evidence on the increase of hepatitis E infection in developed countries • Microbiological control criteria relying on standards for bacterial conta,ination may be insufficient for viral contamination	(Future Challenges to Microbial Food Safety, 2008; Dalton et al., 2008; Newell et al., 2010; Tassios and Kerr, 2010; Teo)
Chemical		
Biomarkers of chemical contamination	• Endocrine disruptors (e.g. PDBE serum levels for high meat consumption, Plasma phthalate levels and onset of gynecomastia) • High cadmium levels and increased risk of stroke and heart failure • Liver toxicity of PFOA • Association between high urinary concentrations of BPA and heart disease • Association between high selenium levels and the risk of diabete	(Bunkova, 2010; Durmaz et al.; Fraser et al., 2009; Laclaustra et al., 2009; Lang et al., 2008; Lin et al., 2009; Melzer et al.; Peters et al., 2010)
Occurrence of chemical contaminants in food commodities	• Heavy metals • PFCs • PCBs • PBDEs • HBCDs	

Drivers		
Potential impact of climate change	• Distribution of plant and animal diseases • Food and water security • Shifts in production areas and cultured crops • Use of agrochemicals • Food storage • Production of natural toxins • Production and quality of crops • Aflatoxins production • Stress on oceans and marine organisms • Increase of drought prone areas • Development of taxation and trading schemes related to release of greenhouse gasses	(Costello et al., 2009; DaMatta et al., 2010; Meerburg and Kijlstra, 2009; Miraglia et al., 2009; Moretti et al., 2010)
consumer behaviour and consumption patterns	• Increasing trend in consumption of fresh produce, fish, ready-to-eat produce • New culinary techniques (e.g. molecular gastronomy, mild cooking conditions, usage of new ingredients) • New and exotic foods (e.g. new combinations of leaves in bagged salads, flavours and combinations of fruit-based drinks, diverse range of edible seeds, bushmeat) • Increase in organic food production (e.g. reintroduction of pathogens with wildlife reservoirs) • Carcinogenicity of Chinese salted fish	(2009b; Ilic et al., 2008; Lahuerta et al., 2010; Little and Gillespie, 2008; Maki, 2009; Pezzoli et al., 2008) (Future Challenges to Microbial Food Safety, 2008; Bassett and McClure, 2008; Havelaar et al., 2009; Magnino et al., 2009; Secretan et al., 2009; Shenga et al., 2009)

H. GLOSSARY AND ABBREVIATIONS

EMRISK	EFSA's Unit on Emerging Risks
ER	Emerging risks
ERIC	Emerging risks internal collaborative group
ESCO	EFSA Scientific Cooperation
EUROSTAT	Statistical Office of the European Communities
GIS	Geographic Information System
IT	Information Technology
MedISys	Medical Information System
OLAF	European Anti-Fraud Office
ProMED-mail	Program for Monitoring Emerging Diseases
RASFF	Rapid Alert System for Food and Feed
SCENHIR	Scientific Committee on Emerging and Newly Identified Health Risks
StaCG-ER	Stakeholders Collaborative Group on Emerging Risks
TRACES	Trade Control and Expert System
WG	Working group