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A working procedure for identifying emerging food safety issues at an early stage: Implications for European and international risk management practices

H.J.P. Marvin[1,*], G.A. Kleter[1], L.J. Frewer[2], S. Cope[2], M.T.A. Wentholt[2] and G. Rowe[3]

[1] RIKILT – Institute of Food Safety, Wageningen University and Research Centre, Building 123, Bornsesteeg 45, 6708 PD Wageningen, the Netherlands

[2] Marketing and Consumer Behaviour Group, Department of Social Sciences, Wageningen University, Wageningen University and Research Centre, Hollandseweg 1, 6706 KN Wageningen, The Netherlands

[3] Institute of Food Research, Colney Lane, Norwich, NR4 7UA, United Kingdom

* Author to whom correspondence shall be sent: Fax +31-317-417 717, E-mail hans.marvin@wur.nl.

Abstract

There is a need for early identification of emerging food safety issues in order to prevent them from developing into health risks. In this paper, various existing methods and procedures which can be used for early identification of safety issues are reviewed, including the monitoring of the occurrence of specific hazards within the food supply, or the incidences of food-borne diseases, as well as the combination of these data with other data or with expert opinions. Some methods, including Hazard Analysis Critical Control Points (HACCP), operate pro-actively by pre-defining indicators for hazards and follow-up measures. Vulnerability assessment focuses on potential weak spots within the food supply, whilst futures research employs foresight to enhance preparedness for future hazards and risks. A Delphi survey on food safety risk analysis conducted among professionals revealed concerns with various aspects of current procedures for dealing with emerging issues, and these are discussed. The Delphi respondents also attached great value to the involvement of stakeholders and the inclusion of a broader range of data into risk analysis. Indeed, holistic systems employing indicators from outside the food production chain are now being developed. In conclusion, a four-step procedure for the early identification of emerging issues is proposed.

Key words

Food safety, emerging risks, early warning, risk analysis, holistic, indicator

Running title

Emerging food safety issue identification

Abbreviations

AFFA, Australian Authorities for Veterinary Health; BSE, bovine spongiform encephalopathy; CARVER, Criticality, Accessibility, Recuperability, Vulnerability, Effect, and Recognisability; CDC, Centres for Disease Control and Prevention; CDTR, Communicable Disease Threat Reports; DAFF, Australian Department of Agriculture, Fisheries and Forestry; DEFRA, UK Department of Environment, Food, and Rural Affairs; EC, European Community; ECDC, European Centres for Disease Control and Prevention; EFSA, European Food Safety Authority; ER, emerging risk; ERDSS, Emerging Risk Detection Support System; EU, European Union; Eurostat, Statistical Office of the EU; EW, early warning; FAO, Food and Agriculture Organisation; FVO, Food and Veterinary Office of the European Commission; GF-TAD, Global Framework for the Progressive Control of Transboundary Animal Diseases; GOARN, Global Outbreak Alert and Response Network; HACCP, Hazard Analysis Critical Control Points; INFOSAN, International Food Safety Authorities Network; OIE, World Organisation for Animal Health; RASFF, Rapid Alert System for Food and Feed; SINAPSE, EU network for Scientific Information and Expertise for Policy Support in Europe; UK, United Kingdom; US, United States;

USDA APHIS CEI, US Department of Agriculture, Animal and Plant Health Inspection Service, Centre for Emerging Issues; WHO, World Health Organisation

Contents

1. Introduction

The occurrence of various national, European, and international food safety issues over the last few decades has arguably resulted in a decline in public trust in food safety regulation and management inside and outside Europe (*e.g.* Houghton et al., 2008). Prominent examples of issues that have emerged over the last decade include bovine spongiform encephalopathy (BSE; Reilly, 1999; Smith, Young, & Gibson, 1999), genetically modified foods (Frewer, Lassen, Kettlitz, Scholderer, Beekman & Berdal, 2004), dioxins (Verbeke, 2001) and acrylamide (Claus, Carle & Schieber, 2008), whilst the actual risk that these issues are known to pose to consumer health varies widely.

The process of decision-making applied to risk has been termed "risk analysis." This process entails three interrelated steps, namely *risk assessment, risk management*, and *risk communication*. According to internationally accepted principles and definitions, *risk assessment* is the "scientific evaluation of known or potential adverse health effects resulting from human exposure to food-borne hazards" (FAO / WHO, 1995). It includes "the identification of the attendant uncertainties of the likelihood and severity of an adverse effect(s) and /or event(s) occurring that may have an impact on humans, food producing animals, or the environment, following exposure" (EU, 2000). Risk assessment entails the following steps: 1) hazard identification; 2) hazard characterisation; 3) exposure assessment; and 4) risk characterisation. "Hazard" is thus defined as "a biological, chemical, or physical agent in – or property of – food that may have an adverse health effect," and "risk" as "a function of the probability of an adverse effect and the magnitude of that effect, consequential to a hazard in food" (FAO / WHO, 1995). *Risk management* is defined as "the process of weighing policy alternatives in the light of the result of risk assessment(s), together with other relevant evaluations, and (if required), of selecting and implementing appropriate control options" (EU, 2000). This includes, where appropriate, monitoring and / or surveillance activities. *Risk communication* is defined as "the interactive exchange of information and opinions concerning risk and risk management activities" among risk assessors, risk managers, consumers, and other interested parties (EU, 2000). Interaction should occur between all three components of the model (FAO / WHO, 1995; FAO / WHO, 1997; EU, 2000).

To date, the analysis of food safety issues has been confined to scientific experts in risk assessment and professional risk managers, with very limited formal input from other interested parties, such as consumer organisations, non-governmental organisations, industry, or indeed, consumers themselves (Wentholt, Rowe, Konig & Frewer, 2008). Furthermore, risk analysis has tended to focus on the assessment of health risk, but has taken only limited account of the potentially relevant social, economic, and ethical aspects that may, nonetheless, have direct implications for optimising risk-management practices.

To improve some of the shortcomings of the present risk analysis process, the EU 6th Framework project SAFE FOODS was initiated in 2004. The overall objective of SAFE FOODS is to change the scope of decision-making on food safety from single risks to consider foods as the sources of risks, benefits, and costs that are associated with their production and consumption. In addition, optimisation of risk governance practices should arguably take into account the social context in which decisions are made[1]. Another significant food risk issue that potentially could be improved in the traditional risk analysis approach (identified during the development of the SAFE FOODS framework) concerns the identification of emerging risks. As a consequence of failures in preventing various food safety incidents in the recent past, it is currently recognised that there is a need for rapid identification of food safety risks at an early stage. This paper aims to describe some innovations relevant to the development of a working procedure for identifying emerging food safety risks[2], thereby extending a previously published report on indicators for such risks (Kleter and Marvin, 2008).

In the subsequent sections, different approaches for identifying emerging risks are categorised and critiqued, and recommendations are provided for improving activities in this important area. Table 1 compares and contrasts these different types of systems and their main characteristics.

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[1] The SAFE FOODS project (www.safefoods.nl) aims to develop improved inputs into food risk analysis across five aspects of food safety risk assessment, including: i) the development of new analytical tools by adapting modern profiling technologies for use on food; ii) the improvement of models for understanding population level health impacts of combined exposures to beneficial nutrients and natural and chemical toxicants; iii) the design of a new working procedure for early identification of emerging microbial and chemical risks; iv) an investigation of the role of the different EU institutions involved in the governance of food safety; and v) the development of more effective communication strategies for the exchange of information between experts, regulators and relevant stakeholders, including the public.

[2] Reflecting research within work package 2 of SAFE FOODS

Insert Table 1 about here

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2. Present early warning (EW) systems and their applicability as emerging risk (ER) systems

2.1. Hazard-identification-based systems

2.1.1. Hazard- and disease-recording systems

The safety of the European food and feed supply is aided by various early warning systems that monitor the occurrence of hazards within the food production chain, as well as the outbreak of animal and human diseases after consumption of problematic foods. Examples of monitoring systems for hazards within the food production chain include national and regional programs for the control and detection of the presence of illegal substances or unacceptable concentrations of chemicals or pathogenic micro-organisms in food and feed. A notable example of this is the EU Rapid Alert System for Food and Feed (RASFF), which lists the food safety hazards identified by its members, including EU member state authorities (EU, 2008a). RASFF provides for the establishment and maintenance of a communication platform through which members can alert each other about relevant food hazards. This procedure of notification *via* a centralised database enables "early warning" systems to be made operational by allowing other members to instigate protection systems against certain hazards that may be disseminated from one member state. In addition, RASFF overviews are published weekly on a publicly accessible website, which also features annual reports that highlight conspicuous trends in the pertinent year. Another way of using RASFF data for identification of emerging hazards has been employed by Kleter, Prandini, Filippi & Marvin (2008b), who analysed four years of RASFF data retrospectively in order to identify the occurrence of specific, longer-term trends, such as increasing numbers of notifications involving food contact substances. They also noted that national and EU authorities had already been aware of these trends and taken measures to optimise protection of the relevant food chains.

Systems that focus on outbreaks of food-borne disease after consumption include epidemiological and surveillance systems for human and animal disease and for the prevalence of microbiological pathogens associated with disease incidences. It is noteworthy that various national and regional centres for disease registration and surveillance, such as the American (CDC) and European (ECDC) Centres for Disease Control and Prevention, as well as the World Health Organisation (WHO), have in place systems that are wholly or partially devoted to food-borne diseases. An example of this is the Global Outbreak Alert and Response Network (GOARN), which forms part of the International Food Safety Authorities Network (INFOSAN) hosted by WHO, through which member state authorities can report food-borne disease outbreaks in real time using a computerised network (WHO, 2006). The same applies to animal health reporting supervised by the World Organisation for Animal Health (OIE), which is currently setting up the Global Framework for the Progressive Control of Transboundary Animal Diseases (GF-TAD) in order to facilitate early warnings and mitigating measures [in cooperation with the Food and Agriculture Organisation (FAO) and WHO; Lubroth, 2006]. This extends the existing framework inside OIE to report animal diseases that are emerging and / or relevant to other member states. Besides early detection through improved awareness of food-borne diseases among health professionals, analytical identification methodologies, and reporting systems, these surveillance systems also allow for retrospective analysis for the detection of more gradual, long-term trends. A detailed overview of these and other monitoring and surveillance systems has been presented by Marvin, Kleter, Prandini, Dekkers & Bolton (2008).

2.1.2. Systems combining food safety with other data

Besides monitoring food hazards *per se* within the food production chain, various early warning methodologies that extend beyond monitoring activities have incorporated monitoring data into their systems. For example, data obtained from monitoring for contaminations of cereals with mycotoxins (toxic compounds formed by moulds) have provided the basis for the development of predictive systems for contamination with either mycotoxins or moulds.

One example of this is the Wheat Fusarium Head Blight Prediction Centre in the United States (US; PSU, 2008). Fusarium Head Blight is the plant disease caused by infection of wheat kernels by the mould *Fusarium graminareum*, which under certain conditions can also produce the mycotoxin deoxynivalenol (DON). Visitors of the centre's website can check the predicted risk of Fusarium Head Blight using interactive maps of a number of wheat-growing states in the US, with map colours indicating the risk within a region, *i.e.* from green indicating a low risk to red indicating a high risk. In this way, growers can estimate if fungicide treatment is warranted. In addition, wheat growers, handlers, and traders of the harvested wheat can better prepare themselves for the occurrence of contaminations in the harvest. The model used to predict the risk relies on data on temperature and humidity in the week before flowering of the wheat crop, provided by the National Weather Service, and extends upon previous experience gained with similar models (*e.g.* De Wolf, Madden, & Lipps, 2003). Other factors considered include the type of wheat (spring *versus* winter wheat) and the resistance of the wheat variety grown. Based on these inputs, the model predicts if there is a risk of reproduction of the mould prior to flowering. After flowering and during kernel development, further growth of the mould will be favoured by several days of rainfall at moderate temperature, but this stage is not considered by the model (PSU, 2008). Various other models predicting mould formation based on meteorological data have also been developed, adapted to the local circumstances elsewhere (*e.g.* in Europe or Argentina; Prandini, Sigolo, Filippi, Battilani & Piva, 2008).

Nonetheless, infection with mould may not always correlate with mycotoxin formation. Currently, there is one known commercially applied model for prediction of mycotoxin (DON) contamination of wheat, *i.e.* DONcast® (Schaafsma and Hooker, 2007). This model has been applied in Canada and Uruguay for a number of years and its applicability for other regions is also being tested. The underlying model considers the climatic and agronomic variables that occur within so-called critical time windows several days before and after flowering of the cereal (Schaafsma and Hooker, 2007).

Another interesting initiative from the perspective of combining monitoring data with outcomes from other surveys is that of Eurostat (the statistical office of the EU). Eurostat is currently compiling a database with data “from farm to fork” that may be used to show trends and developments associated with various steps in the production-consumption chain in Europe. Besides the outcomes of food safety monitoring programs within the EU, these data also include, among others, the numbers of food inspections carried out, trade statistics, and health records. Statistical analysis of this database may not only provide risk assessors and managers with a comprehensive set of data to inform management decisions, but also provide indicators for the early identification of emerging hazards (DISA, 2008).

As part of anti-bioterrorism measures, the US authorities have developed strategies focusing on "situational awareness." This entails the real-time measurement of food safety hazards throughout the production chain. In addition, other measurements are included in the assessment, such as the extent to which food products and ingredients can be traced, environmental waste streams within the food production chain, public health reports, and accounts of "food tampering" or malicious interference with the safety of food. Real-time measurements of food hazards will be facilitated by advanced technologies for identification of products and for the analysis of food hazards contained within these products. To automate the accommodation and interpretation of the data flow from these measurements, computer algorithms similar to Internet search engines can be applied (Lindberg, Grimes & Giles, 2005).

The combination of monitoring data with other data pertaining either to the relevant hazard or to the product affected by the risk allows risk professionals to place the detected hazards into broader perspective, allowing for further distinction between true increases in the frequency of a given hazard and "false positives."

2.1.3. Systems involving data recording and expert opinion

In addition to actually collecting data (*e.g.* collating reports from laboratories performing routine analyses, or publications including those found on the Internet), filtering and interpreting the huge amount of available information associated with emerging food risks represents one of the main challenges to the success or otherwise of any system designed to warn authorities of an emerging food hazard. Human judgement plays an important role both in identifying and collecting data, as well as in filtering and interpreting it. Retrospective studies of recent food safety incidents have clearly shown that lack of compliance to syndrome-reporting procedures, together with lack of knowledge and ignorance of signals, has compromised existing food safety warning systems, leading to the development of food safety issues (VWA, 2006; Hagenaars et al., 2006).

The sharing of information and knowledge is a significant driver in proposals to overcome the problem of misinterpretation and ignorance of emerging risk signals. Thus the European Commission has established an open electronic network, the EU network for Scientific Information and Expertise for Policy Support in Europe (SINAPSE), which enables persons and organisations to post warnings and discuss pertinent scientific issues in a protected area (EU, 2008b). The European Commission, in its publication "First report on the Harmonisation of Risk Assessment Procedures" (EU, 2000), emphasised that new food safety problems may be identified by non-governmental organisations (including consumer groups and the mass media), though transparency regarding *how* and *when* such identified concerns should trigger the formulation of a pertinent risk management question and subsequent risk assessment requires improvement.

An example of a working procedure involving expert opinions on reported hazards that has already been made operational is the Communicable Disease Threat Reports (CDTRs) of the ECDC. CDTRs feature threats identified by public health authorities within and outside the EU, including those mentioned in information provided on the Internet, which may also include unconfirmed reports of emerging food risks. Importantly, the public health surveillance and epidemiological activities of the ECDC do not act as a substitute for national programmes, but aim to complement them. If diseases are observed in one EU member state, which may have implications for other member states, this will be reported through ECDC, which also maintains an Early Warning and Response System, and keeps contacts with other alert systems like RASFF.

An example of how ECDC identifies emerging issues has been described in a recently published report on the increased incidence of norovirus, which resulted in the ECDC convening a meeting with experts on this issue (ECDC, 2006). The meeting focused particularly on the occurrence of norovirus outbreaks on cruise ships, as this is considered an important route for the global dissemination and emergence of new norovirus strains. The conclusions of this meeting included recommendations to develop a common approach towards coordinated responses to outbreaks in cruise ships and to develop guidelines for the prevention of infection with noroviruses. The experience gained by the American authorities with monitoring of- and control measures against noroviruses in cruise ships can be shared for this purpose. Similar principles apply to other settings where norovirus infections also frequently occur, such as hospitals. With regard to the first recommendation for developing a common approach towards control on cruise ships, ECDC also participates in the EU-sponsored SHIPSAN project, aiming at developing a common approach for ship sanitation in Europe. It is also worth noting that ECDC leads the DIVINE-NET project, which monitors for food-borne viral diseases, including noroviruses, in Europe (ECDC, 2006).

2.1.4. One-off stakeholder and expert events

Besides the inclusion of experts' opinions and observations in databases, as discussed in the previous sections, experts may sometimes be called upon to contribute their knowledge on, for example, hazard identification, during the course of one-off stakeholder events. An example of how experts may help identify and prioritise hazards is provided in the report of the "expert choice session" on food safety hazards associated with farmed salmon (VWA, 2005). In this exercise, the experts who participated in a meeting convened by the Dutch National Food and Consumer Product Authority were able to name hazards associated with salmon farming and assign priorities regarding resource allocation directed towards risk mitigation to them. For example, the highest priority in farmed salmon was assigned to residues of environmental organochlorine contaminants, followed by the bacterial pathogen *Listeria monocytogenes*, noxious metals (*e.g.* organic mercury, inorganic arsenic, lead, cadmium), antibiotic residues, and various other hazards, respectively (VWA, 2005).

Another, prominent example is that of the European Food Safety Authority's (EFSA) activities involving stakeholders in the identification or prioritisation of food safety issues. EFSA's Stakeholder Consultative Platform, which was established in 2005, consists of representatives of various EU-wide organisations that are active within EFSA's remit and that have no legal obligations to EFSA. This platform is to provide a forum for dialogue and exchange. It advises EFSA's management on a number of general issues, including emerging and key issues on food safety, as well as the organisation of stakeholder events. These events include the consultations of larger groups of stakeholders, either through meetings or through the web-based posting of documents developed by EFSA for feedback. Examples of topics of recently held consultations include meetings on animal welfare aspects of aquaculture systems, and risk assessments of feed additives, nutritional and health claims. In addition, draft documents, such as guidance on the safety assessment of genetically modified foods and feeds, have been put onto the website for consultation prior to finalisation. These activities fit into EFSA's strategy towards transparency, openness, and dialogue (EFSA, 2008).

2.1.5. Proactive methods

Most early warning systems currently in place are based on the detection / identification of a hazard that is already known about. Hence, measures to circumvent the identified hazards will by definition be reactive. Developments in analytical methodologies, as well as in reporting systems, including real time reporting, may accelerate the time elapsed between the first detection of a hazard and the decision to take measures to mitigate that hazard. In addition, systems that could predict the development of a hazard would be beneficial for protection of human health since they would allow proactive interventions in the food production system.

Kleter, Groot, Poelman, Kok & Marvin (2008a) considered various case studies of emerging chemical and biochemical issues, including toxic botanical preparations, unauthorised genetically modified organisms, antibiotics in farmed shrimp, contaminants in farmed salmon, and pesticides of natural origin. These authors inferred general recommendations from these cases, including: i) the need to list contaminants that may occur in particular food and feed product categories and for which different requirements exist in importing and exporting countries; ii) the requirement for pro-active search for the presence of the contaminants identified under i); and iii) imposition by exporting countries of quality and safety control measures [*e.g.* Hazard Analysis Critical Control Points (HACCP)], regulatory requirements, and checks of consignments to be exported (Kleter et al., 2008a).

Another example of the proactive use of hazard identification within the food production chain is seen in the HACCP approach. Hazard identification is a mandatory part of risk assessment in HACCP. Within this approach, a food manufacturer, handler, or processor has to develop a diagram of the production process and compile a risk assessment for the various microbiological, chemical, and other hazards that may occur during food processing and handling. Based on this risk assessment, hazards are identified that can be measured on a routine basis through critical control points within the production process. In addition, threshold levels are set for quantitative outcomes of hazard measurement, based upon which decisions have to be taken, such as whether to apply corrective measures to reduce the occurrence of a certain hazard or to block a production batch from entering the market. Such risk assessments should also take into account certain changes that may occur within the production process and that could constitute emerging hazards. It appears likely that in these cases, the risk assessments will primarily focus on known hazards.

2.2. Vulnerability assessment

The examples provided above mainly focus on the identification of specific hazards and the subsequent actions to be taken. It can be envisaged, however, that the focus of identification is not necessarily on a specific hazard *per se*, which has to be known or at least identifiable, but on the points within the food supply chain where the introduction of hazards is most likely to occur. Thus the HACCP has also to take hazard introduction into account when defining the control points in the food manufacture process where already identified hazards can be measured. An example of an approach focusing on vulnerable segments of the food production chain is the "CARVER-Shock" approach, a US initiative developed to shield the food supply against threat of terrorist attacks and new dangers (CARVER stands for Criticality, Accessibility, Recuperability, Vulnerability, Effect, and Recognisability). The approach also has features that could be relevant for the identification of "classical" food safety issues. No specific hazards are identified within this approach, but rather the parts called "critical nodes" of the food production chain are identified that would be vulnerable to attack and potentially lead to contamination with agents adversely affecting the health of consumers. In addition to the identification of indicators, the analytical capabilities for detection and control of the hazards, as well as countermeasures, including awareness raising, technology changes, and regulations, can be formulated.

Application of the *vulnerability* approach requires the involvement of a team of experts across a wide array of issues, including food microbiology, food technology, food chemistry, epidemiology, fraud, threat intelligence, economics, risk assessment, medical science, entomology, veterinary health, plant pathology, botany, and psychology (among others). These experts would focus on the production chain for a specific product, mapping the "farm to fork" pathway in a flow diagram and compiling a profile of the hypothetical attacker on the food chain. For each segment of the pathway in the flow diagram, values ranging from 1 to 10 (with 10 being the highest impact) would be assigned to each of various parameters of the CARVER-Shock model. The "Shock" component brings together the CARVER components and considers the national non-technical impacts of the threat, including the *psychological* and *economic* impacts.

The outcomes of a vulnerability assessment do not apply to a single company, but are of a more general nature, pertaining to a particular sector of the food production chain (FDA, 2006).

2.3. Futures research

In *futures research,* various techniques are used in order to increase preparedness for future developments. For example, the Australian Authorities for Veterinary Health (AFFA) and the Australian Department of Agriculture, Fisheries and Forestry (DAFF) recently launched a "strategic foresight initiative," in which multiple plausible scenarios of the future were explored by groups of experts so that timely response could be given to problems, including food safety issues, before they become critical (DAFF, 2007). Similar initiatives on animal health have been undertaken in other countries, including a quadrilateral initiative between the central veterinary offices of Canada, US, Australia, and New Zealand. This initiative held a meeting in 2005 with stakeholders from various backgrounds on alternatives for animal waste disposal. Four different scenarios for the year 2020 with varying degrees of utilisation of animal materials and public concern were considered as "drivers" of change. These scenarios took into account the predicted economic, political, technological, scientific, and educational developments and aspects associated with each of these scenarios. The position of the current and desirable future scenarios were considered, and how to reach the latter from the former in the form of required policy change. The outcomes can aid the development of policies that take into account various scenarios (Willis, 2006). It can be foreseen that as time progresses, evaluation of the developments and possible re-adjustments of the selected strategy have to be applied. These foresight activities are therefore more broadly orientated than the one-off stakeholder events described above, which focus more on specific safety issues.

Another example of a futures research activity is "horizon scanning" by the United Kingdom (UK) Department of Environment, Food, and Rural Affairs' (DEFRA) Scientific Advisory Group. This activity addresses future risks for which ideas are obtained both from scanning information sources and from inputs after a public consultation. After the first round of a recent consultation, in which more than 500 suggestions had been submitted, five priority areas were identified, including food safety. Short-term projects on future risks and opportunities were then initiated, one of which pertained to the key drivers of the food economy of the UK in 2024, involving both desk studies and an expert workshop. Currently, strategies for the continuation of horizon scanning are being reconsidered and essays have been published on the methodology followed. Amongst others, it is noted that this type of futures research entails the involvement of multidisciplinary teams, shared language for internal communications, and clear guidance from a steering group (DEFRA, 2008).

3. Problems with existing systems: Stakeholder views on emerging risk identification, prevention and mitigation

Although the contents of this review are largely based on the existing scientific literature, the views of various international food safety experts regarding early risk identification were also elicited as part of the SAFE FOODS project. These views were collected using the Delphi method (see Wentholt et al., 2008). This method essentially involves the repeated polling of a variety of experts through a questionnaire (in this case, Internet-based), in which experts' anonymous views are fed back in successive "rounds" to help inform decision making across the whole group. The Delphi methodology has the advantage of enabling the polling of multiple experts who might not otherwise be able to meet in a formal group (because of time and place constraints), and improves upon the standard survey in allowing a degree of interactivity through the provision of feedback and iterative use of a questionnaire. Furthermore, by structuring the information exchange (*e.g.* using feedback anonymously, and giving equal weight to all inputs) the method aims to pre-empt certain social and political problems associated with group meetings (*e.g.* following the lead of the most powerful individual; agreeing with the group to avoid sanction). Further discussion of the Delphi methodology is provided by Rowe and Wright (1999).

In the present case, the Delphi method was applied to *two* different and distinct sets of stakeholders: the first set comprised relevant stakeholders from within the EU; the second comprised relevant stakeholders from outside the EU (non-EU). Two lists were developed, identifying potential participants from four key constituencies: *food risk managers*, *risk assessors*, *members of Non-Governmental Organisations* (NGOs) and *risk communicators*. Potential "panellists" received an E-mail invitation to take part in the Delphi, informing them of the purpose of the study and what it would involve, and emphasising that their opinions would be treated anonymously. The expert panellists were first sent a questionnaire about the SAFE FOODS framework, and then were presented with a second survey with similar questions, which they were asked to complete, reconsidering their views in the light of the opinions expressed by the other panellists in the first round. The SAFE FOODS framework amongst others consists of a revised risk analysis cycle consisting of various stages from identification of an issue towards implementation of measures and their monitoring and reviews (SAFE FOODS, 2008). The first-round Delphi questionnaires were very similar for both sets of stakeholders (EU and non-EU), with only a few differences, mainly in phrasing. The second-round questionnaires diverged across the two stakeholder groups as different key issues emerged (the questionnaires being informed by the responses to the first rounds). A detailed analysis of the Delphi study, in particular related to the SAFE FOODS framework, is provided elsewhere (Wentholt et al., 2008). However, a number of questions within our survey allowed participants to comment upon issues salient to the identification of emerging risks, as well as pertinent issues such as how to select and integrate experts into the process of emerging risk identification, and these are discussed here.

The results from the Delphi survey elaborate a number of problems in dealing with ”emerging risk” and the requirements (or even feasibility) of a system to handle these. Participants were particularly unified by their concern regarding the challenge of *predicting* unintended consequences and emerging risks as opposed to picking these up through *monitoring*:

> “If it is unexpected, you will not know.” [EU participant]

> “Unintended effects, by definition, cannot be predicted. They can only be considered in retrospect after careful monitoring in cases where it is considered important. Case-by-case depends on how much information comes from previous common use of similar situations. It should only be important for radically new situations.” [International participant]

As such, some participants wondered at the feasibility of a universal proactive system:

> “It does not seem logical that better planning will provide more information about unintended consequences. The monitoring system will have to consult with stakeholders on a case-by-case basis.” [EU participant]

> "I would agree [with the identification of hazards in the Framing stage] when this is to the extent that hazards are known and a rationale with the issue at hand can be substantiated on existing knowledge. In [some] cases, this will not be possible as emerging issues are dealt with or [treated as] new, yet unknown links […] [between] hazards and issues might be in play." [EU participant]

However, other participants did emphasise some features that might aid identification of emerging risks. Responses from some highlighted the need for expert involvement, advocating the internet as a tool to improve the process:

> "I think that the identification of early warning indicators might be delegated to experts in (an) assessment round." [EU participant]

> "There needs to be clear institutional responsibility [for identifying unintended consequences], *e.g.* a national directorate for food safety. This body should build up Internet-based and publicly available sites for feedback and reports of unintended consequences." [EU participant]

Explicit support for a more holistic approach incorporating different aspects of food safety (food inspections, public health, trade) was expressed in the Delphi survey when experts were asked to suggest measures that could be taken to identify unintended consequences of emerging food risks.

> "Cooperate with *e.g.* Eurostat by incorporating *e.g.* inspection data etc." [EU participant]

> "It is indeed key that any relevant information […] also that on unintended consequences, is fed back into the risk analysis. In the first instance, monitoring of unintended consequences could be set-up on a case-by-case basis to make it somewhat more efficient to identify stakeholders and existing surveillance systems that might pick up unintended consequences. [EU participant]

More generally, it was thought important that any uncertainties within the food risk analysis process are exposed and this is as true of early risk identification as the assessment of established risks.

> "Risk assessment is a process of reasoning under uncertainty. It should define the degree of uncertainty with which the decision maker has to work and requires an understanding of probabilities. Uncertainty reduction can only be achieved by applying better forward planning and use of available information; additional scientific research; stakeholders consultation about unintended consequences and how these should be monitored; feeding back information into the risk analysis process; a case-by-case basis; [and] general surveillance to identify such consequences if they arise." [EU participant]

Within the SAFE FOODS Risk Analysis framework, the cycle incorporates the subsequent phases of framing, assessment, evaluation, decision making, implementation, monitoring, and review. The risk analysis process is considered to be cyclic (iterative) in nature, and so the outcomes of the final phase feed back into the first phase of the following repeat of the process. Participants tended to agree that the outcomes of the monitoring and review phases may lead to the identification of new issues, such as unexpected trends in monitored hazards, and that these might then be considered during a new framing phase in which policy makers, risk assessors, and stakeholders set out a strategy for further risk analysis of the hazard under consideration. For example, it was noted that previously unidentified or unexpected consequences of either food-safety-hazard- or food-safety-risk-mitigating measures may be novel, and therefore need to be categorised as an emerging issue in their own right. As a case in point, consumption of fish containing unsaturated fats may help reduce cardiovascular risks but increase exposure to contaminations that commonly occur in fish, such as heavy metals and persistent organic pollutants such as dioxins. Consideration of these unidentified or unexpected consequences may help to identify emerging issues.

The following quotes are from various participants in the Delphi survey who commented on how a cyclical process might reveal unidentified consequences leading to new issues to be considered in the risk analysis, and they were generally favourable about the ability of the model to cope with emerging issues due to this cyclical feature:

> "Indicators for monitoring the consequences should be monitored by decision makers/regulatory institutions and risk managers. These data should be provided to risk assessors and those involved in the framing stage if these data indicate an unforeseen event." [EU participant]

> "[…] as a practical matter, risk managers should be doing environmental scans so as to be able to identify new and emerging risks, and they must have some discretion as to which of them seem to be sufficiently urgent to warrant further action." [International participant]

> "The risk / benefit assessment needs to be constantly kept under review to take into account new thoughts / data." [EU participant]

> "I particularly appreciate the inclusion of the review stage - these processes are dynamic, as they are part of societal learning, in a strategic sense - including the continuing need in all societies for learning to cope with new knowledge and techniques […]." [EU participant]

> "Consultation with stakeholders should have the priority" with respect to a monitoring system to consider unintended consequences of the hazard [EU participant]

> "If you define the risk you are dealing with the sequence: 1) Identification of risks, costs, benefits, and their distribution; 2) Risk profiling; 3) Identification of decision options; 4) Developing criteria [for evaluation] is sensible but they will have to be risks, not identified hazards." [EU participant]

In summary, the participants in the study tended to agree that the issue of identifying emerging food safety issues is difficult, especially identifying these proactively as opposed to revealing them through diligent monitoring. Indeed, unidentified consequences might emerge and be identified at various stages of the risk analysis process. Existing early warning systems rely on the detection of a hazard in monitoring programs and therefore by definition are reactive. Delphi participants indicated that more proactive system would be desirable, if feasible, since the potential risk may be prevented by issuing proper counter-actions. Among the features suggested as enabling better coping with emerging issues is a more "holistic approach" that considers the wider context in which a particular hazard is being assessed, and facilitates institutional ability to react rapidly, and emphasises on the use of expert knowledge. Further, given that some respondents indicated they were unfamiliar with the terminology linked with early warning and emerging issues, better communication about these is important in order to provide all stakeholders involved with information relevant to reporting emerging issue which they have identified.

4. Developing emerging risk systems based on a "holistic approach"

Various initiatives have attempted to develop predictive early warning systems based on signals directly and indirectly related to a hazard, collected from both *within* and *beyond* the food production chain – the "holistic approach." It is argued that drivers of emerging food safety risks are often not directly linked to the food production chain (for example, changes in climate conditions may lead to new or re-emerging food safety issues and diseases), and that a plurality of factors should be taken into account. Within the Periapt project (EU 6th Framework Programme; PeriApt, 2008) the *holistic host environment strategy* has been proposed, advocating the need to take impacts from outside the food production chain into account when developing pro-active emerging food safety identification systems (Periapt, 2005). This initiative has built on innovations regarding proactive risk identification identified in the OECD report "Emerging risks in the 21st Century" (OECD, 2003), a strategy which has been further elaborated by research teams in the EU projects EMRISK and SAFE FOODS, and in a Dutch national research program entitled "Emerging Risks in the Dutch Food Chain" (Achterbosch, 2007; Van der Roest et al., 2007). Within these projects, host environment analysis has been applied to a large number of recent food safety issues (among others BSE, acrylamide, dioxin in fish and milk) resulting in the identification of a large number of indicators within and beyond the food production chain that were directly and / or indirectly related to the development of the specific issue being studied. Hence, *indicators* are defined by EFSA as a measurement and / or observation that should be reliable, sensitive, and quantifiable, and should provide the information of the nature of the hazard (agent / process involved) and the source of risk (EFSA, 2007). Changes in such indicators are defined as signals and may give rise to the development of a risk. Two groups of researchers recently applied the recommended methodology to potential contamination of foods and feeds with mycotoxins by identification of indicators within and outside the food and feed manufacture chains. This can be regarded as a first step towards the establishment of a holistic early identification system for mycotoxins (Park & Bos, 2007; Van der Fels – Klerx, Kandhai & Booij, 2008).

It has been suggested that awareness of the significance of these signals (*i.e.* changes in the indicators) most probably could have contributed to an earlier recognition of the developing hazard, which potentially could have prevented the occurrence of the food safety issue (VWA, 2006; Hagenaars et al., 2006; Kleter et al., 2008a). However, it has also been noted that it is unrealistic to monitor all potentially relevant signals. To overcome the problem of many potentially relevant signals, an expert group convened by EMRISK performed a ranking procedure using defined criteria to identify the most important indicators. Two methods were tested, namely a decision tree approach and a ranking system using weight factors. Based on the outcome of this comparison, it was concluded that ranking procedures using weighting systems were preferable. Furthermore, this study observed that, of all the indicators identified within EMRISK (*i.e.* 217), 16% were located in the sector Agriculture & Fisheries, followed by Environment & Energy (14%), Population & Social Conditions (14%), and Health (10%). The subsequent step proposed by EMRISK was to apply the so-called "traffic light" theory for interpretation of trends associated with changes in signals. In this, the direction of change of a signal is connected to a colour, *i.e.* green for a positive change / trend; red for a negative change / trend; and yellow for a neutral / intermediate one. Furthermore, different urgency-weighting factors can be assigned to signals with a different colour. EMRISK applied this principle to design an extended flow diagram for a pre-early warning system, with both technical and human factors (the utilisation of *search engines* and employment of *scientific experts*, respectively). The scientific experts had to provide a description of each of the selected indicators so that computer software could formulate an "indicative question," and derived keywords serving as input for automatic searches of the Internet for information. Subsequently, the information coming out of these searches needs to be assessed by scientific and computing experts prior to selection of those items that require further risk management measures.

Following the EMRISK report, the European Food Safety Authority (EFSA) issued an opinion, emphasising that networks of scientists are essential elements in the structure of early warning systems if a food-borne hazard is to be identified at an early stage (EFSA, 2006). To generate enough intellectual power to deal with a specific food safety case and / or to identify an emerging food safety problem, it is preferable to link and combine existing relevant expert networks rather than developing a large, new, comprehensive expert network. However, the harmonisation of existing networks must ensure inclusion of all kinds of scientific disciplines (health, environment, societal, legal, economic) that may be needed to tackle future food safety problems.

Maeda, Kurita & Ikeda (2006) developed an early warning support system for food safety risks that comprises two subsystems - a "clearing house" for food safety risks and "Risk Path Finder." The former is a comprehensive database with documents pertaining to food safety risks, which are retrieved and selected from the Internet using a dedicated search engine and applying specially designed algorithms. This information is required to determine possible paths from causes to consequences, which is achieved with the Risk Path Finder tool. The outcome of this system provides interrelationships between events and causes, which aid the risk manager to find all possible effects of a specific event.

The Emerging Risk Detection Support System (ERDSS) is being developed by a multidisciplinary research team in a Dutch project entitled "Emerging Risks in the Dutch Food Chain" (Achterbosch, 2007; Van der Roest et al., 2007). The objective of this research is to combine expert knowledge on food production and changes in indicators in a system that will give a warning when increased risk occurs for the development of a food safety problem. Due to the high complexity and novelty of this approach, it was decided to focus on the salmon production chain.

Initially an extensive analysis of the salmon production chain was conducted, including an analysis of its environment (indicator analysis) and interviews with key stakeholders (Van der Roest et al., 2007). This study was complemented with information obtained from host environment analysis of several food safety incidents in the fish production chain (Hagenaars et al. 2006; Kleter et al., 2008a; Van der Roest et al., 2007). A large number of indicators were identified, both inside and outside the salmon production chain. Data sources that can be used to generate a signal from changes in the indicator were identified and coupled to the expert knowledge system. In this way, a relation can be made between the development of a food safety problem and risks and changes in an indicator. In contrast to the approach proposed in EMRISK, all indicators and data sources identified are used. All data sources will be continuously monitored and changes are automatically fed into the system and used by the system to assess the chance for the development of a food safety issue. In addition, ERDSS will have the possibility to manipulate the input signals allowing the operators to conduct scenario studies. This is particularly important for managers to investigate the effect of potential measures. A schematic presentation of ERDSS is given in Figure 1. ERDSS is still in an experimental phase and the applicability of such an approach will have to be demonstrated in the future.

Insert Figure 1 about here

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5. Description of identified steps in an ER system

Whilst the characteristics and the aims of the various systems to identify emerging hazards in an early stage of their development can vary, some general features that these systems share in common with each other can be defined (see Figure 2).

The first step usually comprises a delineation of either the particular food products or sectors in which the emerging hazards are to be addressed, or the particular types of hazards that are to be detected in an early stage. The information sources that are linked to these particular items should be made accessible, and a method chosen to process information. Indicators may have to be formulated if the aim of the system is to detect and process signals related to changes in the indicators, as is for the hazard identification systems already described. As before, multidisciplinary teams of experts can aid in the formulation of which food products or hazards should be considered, or (further downstream), which indicators should be selected (as has been done in the EMRISK project). The American CARVER-Shock methodology provides an example of how a wide array of experts can be used to identify the "critical nodes" of the food production chain that are sensitive to threats. The involvement of external experts in initial identification of indicators (included as part of the "framing" stage in the SAFE FOODS project) was also identified in the Delphi study.

The data from the information sources can also be used to construct plausible future scenarios, as well as the measures chosen to anticipate and prepare for these scenarios, a topic relevant to the development of futures research activities. It is important to note that the information can pertain to the food production chain itself, as well as to the influential sectors which have impact on the food production chain.

The second step comprises the generation of data from the information sources by using various processing methods. For hazard identification systems, this may entail the measurement of signals coming from indicators, retrospective analysis of trends, or the reporting of hazards through dedicated reporting systems. Another route may be the search for information in media sources by automated search algorithms, for example with the aid of indicative questions such as recommended by EMRISK. The data collected need not be only directly related to the hazard under consideration, but also include data from influential sectors that might indirectly affect the occurrence or magnitude of the hazard. The latter is particularly valid in holistic systems. For futures research, this may comprise the identification of measures that are important for preparedness for possible future events.

In the following and third step, the data resulting from the second step needs to be processed. Part of this is amenable to automation, such as in the case of signals linked to indicators below or above a pre-set threshold level. Furthermore, if multiple outcomes are considered, weighting factors may have to be attached to these outcomes in order to reflect the relative importance of each of outcome for the development of a specific hazard. In other cases, expert teams with a multidisciplinary composition may be involved with the interpretation and selection of results. This may have the advantage that all changes can be viewed in context, because not every change may signify a hazard. The process required to evaluate emerging risks and to trigger a more comprehensive risk-benefit assessment was suggested by Delphi respondents to include both risk assessors and managers.

Of course, in addition, combinations of automated selection procedures coupled to expert advice can be envisaged, as recommended by the EMRISK report. In the case of horizon scanning or futures research, a comparison can be made with the current actual status of food safety systems and what should be done to fulfil the requirements formulated in the second step for preparedness for future incidents.

In the fourth step, the outcomes can be summarised and the various options for follow-up actions highlighted. Risk managers can use these inputs for decisions on how to mitigate the issues selected after the first three steps for further risk management.

The ERDSS developed in the Netherlands aims to combine the four steps described above thereby eliminating or minimising the filtering step needed in other systems to handle the huge amount of data. Furthermore, full advantage of expertise is taken in ERDSS, which is collected from the literature and through interviews with stakeholders. The ERDSS also enables inclusion of knowledge of various aspects either directly or indirectly related to the food production chain.

Insert Figure 2 about here

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6. Conclusions

Assurance of the safety of the food supply has been a priority in many constituencies in past years. This may, in part, relate to the fact that various incidents have heightened general awareness of food safety. These incidents have also highlighted the need for early identification of food safety issues before they become real risks. In this review various methods and procedures have been discussed that can be used to identify food safety issues at an early stage, including early detection and warning systems, vulnerability assessment, and futures research. Usually, these methods and procedures consider either hazards occurring within the food production chain or risks (disease) occurring among consumers.

A Delphi survey on the new food risk analysis framework proposed by SAFE FOODS has shown that respondents consider the detection of previously unidentified or unexpected effects of known hazards or of risk-mitigating measures as a way to detect emerging issues. Whilst the respondents furthermore acknowledged the important role of experts in identification and interpretation of the signals, they also envisaged a role for information coming from stakeholders that are to be involved in risk analysis. In addition, respondents indicated that information over and above food monitoring data can be useful for this purpose.

It appears therefore that there is a need for a more holistic approach towards the early identification of emerging food safety issues, involving other stakeholders besides risk managers and risk assessors, as well as input data from sectors outside the food production chain. No holistic systems are yet in place which can fulfil this function, whilst various initiatives have provided inputs for their development. At the present time, an automated system based on the holistic approach (*i.e.* ERDSS) is currently being developed within the frame of a scientific project sponsored by the Dutch government. Further to this, a four-step approach is proposed for an early identification of food safety issues, which can be partially automated, but which in all cases will require inputs from expert panels to select indicators, hazards, weak points in the chain, and future scenarios (Figure 2). Expert advice will also be needed to interpret the outcomes of the subsequent steps in which issues will be identified and reported, in order to “filter” them and “translate” the data for risk managers, so that the latter can take appropriate mitigating measures. This approach needs to be further refined in the future as experience accumulates with various activities on emerging issues and their early identification and prevention.

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Conflict of interest statement

All authors are professionals employed by RIKILT - Institute of Food Safety, by Wageningen University, and by the Institute of Food Research, and as such do not have any interests that may conflict with the contents of the article above.

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Tables and figures

Captions:

Table 1: Classification of various approaches currently in place and amenable to address early identification of food safety hazards

Figure 1: Emerging Risk Detection Support System (ERDSS)

Figure 2: Four identified steps in an ER system

Table 1 Classification of various approaches currently in place and amenable to address early identification of food safety hazards

Reactive Systems (identification of problem as occurs)					
Type	**Description**	**Domain of interest**	**Responsive?**	**Actors / experts involved**	**Examples**
Early warning systems/ networks	• Centralised hazard database or electronic network that provides a platform for communication through which member states can alert each other about relevant hazards that may be disseminated (in real time potentially) *or:*	Food safety Human / Animal disease (food-related);	Discretionary response; Reliant on actors' interpretations of posted data; No formal mechanism for action	Institutionalised forms of cooperation and hazard reporting at the national and international levels between policy makers and / or scientists	RASFF; CDC; ECDC; WHO (INFOSAN/ GOARN); OIE
	• Centralised database of health risk outcomes or electronic network of that provides a platform for communication through which experts, organisations, and public health authorities can report and discuss pertinent scientific issues in a protected area	Food-borne disease Animal disease		Experts, organisations, public health authorities (Multi-disciplinary, though often self-selecting, without proper processes or forum of influence)	SINAPSE; CDTRs (from ECDC); Various Food Safety Networks

Combinatorial data systems	• Database that combines monitoring data and hazard / product data from several sources related to outcomes "from farm to fork" to validate and contextualise increases in the identified hazards • Involves advanced technologies, such as automated Internet search algorisms, for the identification and analysis of products and related food hazards may be used • May provide indicators for the early identification of emerging hazards	Food and health generally	Discretionary response reliant on actors' interpretations of posted data; No formal mechanism for action	Multi-disciplinary, though presently rather specific (precise issues)	EUROSTAT; USDA APHIS CEI
Retrospective Applications (based on retrospective analysis of reactive systems)					
Retrospective analysis of reactive systems	• Retrospective analysis of early warning and combinatorial data systems in order to detect (long-term) trends associated with various steps in the production-consumption chain, possibly through modelling	Food and health generally	Discretionary response reliant on actors' interpretations of posted data; No formal mechanism for action	Experts	Annual reports of RASFF, FVO, and food inspection agencies
Predictive Systems					

Proactive hazard identification systems	• Involves predictive risk assessment to identify various potential hazards that may occur at critical points in the food process, which are then measured routinely. If hazards exceed quantitative threshold levels, measures to mitigate the hazard are rapidly initiated • Analytical methods and reporting systems may often involve real-time procedures to accelerate the implementation of a mitigation process	Safety of food products	Responsive only to pre-defined risks; Reliant on monitoring to identify pre-defined risks	Manufacturers / Producers – process / manufacturer specific	US- Wheat Fusarium Head Blight Prediction Centre; HACCP
Vulnerability assessment	• The process (*i.e.* food production chain) is divided into smaller segments, and the critical nodes that are sensitive towards hazards are identified. Indicators for hazards are identified and monitored, and countermeasures are formulated	Could be applied to food chains	Responsive only to threats that occur within the identified vulnerable areas; Reliant on monitoring to identify risks within defined vulnerable areas	Potentially multi-disciplinary and international approach, though not yet formalised in food domain	CARVER-Shock

Futures research	• Various techniques to increase preparedness for future developments, which involve one-off events or consultations with expert and / or stakeholder groups through meetings / web-based forums to exchange knowledge, discuss hazards and emerging risks, and in some cases prioritise identified hazards • *Strategic foresight initiatives* where expert groups explore multiple future scenarios that account for predicted developments. Policy changes are developed to reach desirable future scenarios given the predicted outcomes. • *Horizon scanning* for future risks based on information from public consultations, in order to identify priority areas and develop short-term projects (such as desk studies and expert workshops) to mitigate potential risks	Whatever issue of interest-address various problems	Discretionary response; Reliant on actors' interpretations of posted data; No formal mechanism for action	Events are various and widespread, including specific expert constituencies (likely to be multi-disciplinary and international), but lack of formal organisation	DEFRA horizon scanning; Australian/New Zealand/Canada/US veterinary health foresight; Dutch National Food and Consumer Product Authority event; EFSA's Stakeholder Consultative Platform; Delphi

Figure 1: Emerging Risk Detection Support System (ERDSS)

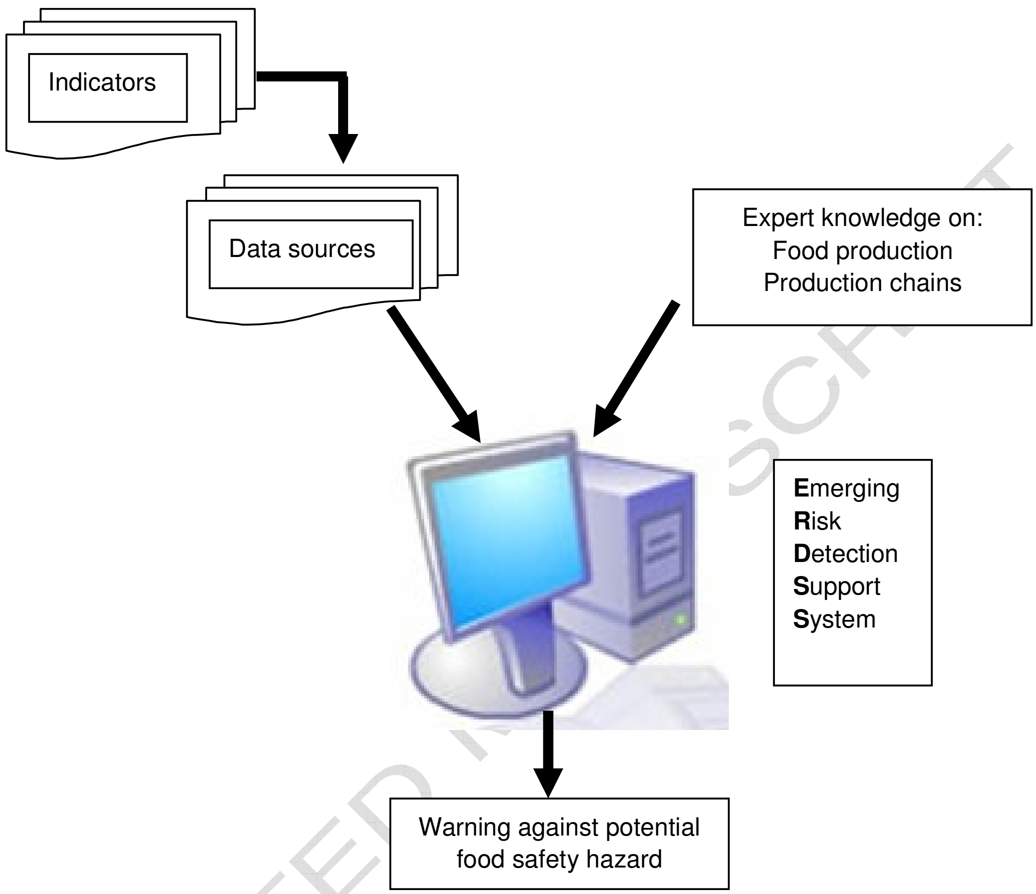

Figure 2: Four identified steps in an ER system