

## Early Identification systems for Emerging Foodborne Hazards

H.J.P. Marvin<sup>a</sup>, G. Kleter<sup>a</sup>, A. Prandini<sup>b</sup>, S. Dekkers<sup>c</sup>, D. J. Bolton<sup>d</sup>

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<sup>a</sup>RIKILT- Institute of Food Safety, Bornsesteeg 45, PO Box 230, NL-6700 AE Wageningen, the Netherlands

<sup>b</sup>Catholic University of Piacenza (UNICATT), Via Emilia Parmense 84, 29100, Piacenza, Italy

10 <sup>c</sup>National Institute for Public Health and the Environment (RIVM), P.O. Box 1, A. van Leeuwenhoeklaan 9, 3720 BA Bilthoven, the Netherlands

<sup>d</sup>Teagasc, Ashtown Food Research Centre, Ashtown, Dublin 15, Ireland

*Corresponding author:*

H.J.P. Marvin

15 RIKILT-Institute of Food Safety

PO Box 230

Bornsesteeg 45

NL-6700 AE Wageningen,

The Netherlands

20 Telephone: + 31 317 475543

Fax: + 31 317 417717

Email: [hans.marvin@wur.nl](mailto:hans.marvin@wur.nl)

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*Abbreviations:*

30 AIDS, Acquired Immune Deficiency Syndrome; BSE, Bovine Spongiform Encephalopathy; CDC, US Center for Disease Control and Prevention; CDN, Communicable Disease Network; DEFRA, The UK Department for Environment Food and Rural Affairs; DG SANCO, The European Commission's Directorate on Public Health and Consumer Affairs; DON, Deoxynivalenol; ECDC, European Centre for Disease Prevention and Control; EFSA, European Food Safety Authority; EIP, Emerging Infections Program; EFORS, Electronic Foodborne Outbreak Reporting System; EU, European Union; FAO, Food and Agriculture Organization; FDA, Food and Drug Administration; Foodnet, Foodborne Diseases Active Surveillance Network; FVO, Food and Veterinary Office; GIEWS, FAO Global Information and Early Warning System; GLEWS: FAO/WHO/OIE Global Early Warning System; GPHIN, 40 The Global Public Health Intelligence Network; HIV, Human Immunodeficiency Virus; INFOSAN: International Food Safety Authorities Network; ISIS: National (Dutch) Infectious Diseases Information System; ITX, 2-isopropyl-thioxanthone; LCI, the National (Dutch) Coordination Structure for Infectious Disease Control; NGO, Non governmental organization; OECD, Organisation for Economic Co-operation and 45 Development; OIE, Office International des Epizooties; PHS, Public Health Service; SARS, Severe Acute Respiratory Syndrome; SCENIHR, Scientific Committee on Emerging and Newly Identified Health Risks; RASFF, Rapid Alert System on Food and Feed; USDA, United States Department of Agriculture; vCJD, variant Creutzfeldt Jakob's Disease; WHO, World Health Organisation; ZEA, Zearalenone

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## Abstract

This paper provides a non exhaustive overview of early warning systems for emerging foodborne hazards that are operating in the various places in the world. Special attention is given to endpoint-focussed early warning systems (i.e. ECDC, 5 ISIS and GPHIN) and hazard-focussed early warning system (i.e. FVO, RASFF, OIE) and their merit to successfully identify a food safety problem in an early stage is discussed..

Besides these early warning systems which are based on monitoring of either disease 10 symptoms or hazards, also early warning systems and/or activities that intend to predict the occurrence of a food safety hazard in its very beginning of development or before that are described. Examples are trend analysis, horizon scanning, early warning systems for mycotoxins in maize an/ or wheat and information exchange networks (e.g. OIE, GIEWS).

Furthermore, recent initiatives that aim to develop predictive early warning systems 15 based on the holistic principle are discussed. The assumption of the researchers applying this principle is that developments outside the food production chain that are either directly or indirectly to the development of a particular food safety hazard may also provide valuable information to predict the development of this hazard.

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## 1. Introduction

The large number of food safety problems experienced in the last decade in Europe 25 and elsewhere has brought to light the vulnerability of modern food production systems. Public trust in regulatory institutions responsible for the governance of food safety has declined due to public distrust in how such risks have been handled and managed (Siegrist and Cvetkovich, 2000), in part attributed to the high levels of media exposure directed towards these problems (Frewer, 2003).

In Europe, the European Commission responded to this development by issuing the 30 General Food Law (EU, 2002) which clearly describes the food safety framework in the Europe Union including the role and responsibilities of the different parties involved. It is anticipated that this new law will ensure improvement in the safety of the food supply and will contribute to the restoration of public trust.

The process of decision-making on food safety risks has been termed **risk analysis** 35 and consists of the major components: **risk management**, **risk assessment** and **risk communication**. Risk is defined as the likelihood that, under particular conditions of exposure, an intrinsic hazard will represent a threat to human health. Hence, risk is a function of hazard and exposure where hazard is defined as the potential of an agent or situation to cause an adverse health effect(s)/event(s). **Risk assessment** is a process 40 of evaluation, including the identification of the attendant uncertainties, of the likelihood and severity of an adverse effect(s) /event(s) occurring to man or the environment following exposure under defined conditions to a risk source(s). A risk assessment comprises: hazard identification, hazard characterization, exposure assessment and risk characterisation. **Risk management** is the process of weighing 45 policy alternatives in the light of the result of a risk assessment(s) and of other relevant evaluations, and, if required, of selecting and implementing appropriate control options (including, where appropriate, monitoring /surveillance activities).

**Risk communication** is the interactive exchange of information and opinions throughout the risk analysis process concerning risk.

The above presented definitions are in line with the international accepted principles and definitions (FAO/WHO, 1995, FAO/WHO, 1997, EU, 2000).

It is apparent that food safety risks can be reduced if food safety hazards are recognised in an early stage and if necessary information is exchanged between parties engaged in maintaining food safety.

5 Many information and monitoring systems on food safety have been put in place on international level (such as Rapid Alert System on Food and Feed (RASFF) in Europe; WHO-INFOSAN, etc.) and on national levels (national monitoring and survey programmes) which have demonstrated their usefulness in the control of food safety risks. These systems have in common that they generally detect problems (i.e. the presence of a (food safety) hazard) **after** they have occurred. Therefore any intervention will be reactive. It is apparent that (monitoring) systems that do not require an outbreak to stimulate control activities but instead rely on signals /information directly and /or indirectly associated with the development of a hazard are preferable.

10 Recently EFSA has defined the term “emerging risk”(to human, animal and/or plant health) 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 (EFSA 2007). Hence systems capable of identifying or predicting the development of such risks are called “emerging risk identification systems,” which are synonymous to “predictive early warning systems”. These predictive systems should not be confused with reactive early warning systems which are based on monitoring known hazards.

15 The enforcement of food safety measures such as establishment of early warning systems is executed to ensure safer food aiming to reduce the number of foodborne illnesses. By systematically collecting such information, it is expected that the outbreak of foodborne illness can be prevented in an early stage, hence providing the opportunity to minimising the societal losses often observed with such incidents. (Buzby and Roberts 1997)

20 In this report we present an overview with examples of the various types of reactive early warning systems that are in operation in various places in the world. In addition, their possible use to predict the development of the hazard will be discussed, using RASFF as an example. Furthermore, we will present evident examples of predictive early warning systems (hence emerging risk identification systems) for the early identification of food safety risks. Also new developments in this field will be discussed.

## 2. Overview of *reactive* early warning systems

### 2.1 Introduction

40 Effective surveillance systems are critical for the detection of accidental or intentional contamination of the food supply chain. There are currently several types of surveillance systems in operation in the developed nations of the world. The various surveillance systems in place track and forecast emerging foodborne safety risks through the collection, integration, analysis and interpretation of data followed by dissemination of the information through reports, advisories and warnings. Some examples are discussed in this paper. The focus of these surveillance systems may pertain to different aspects of food safety. For example, systems may record the occurrence of diseases or intoxication as caused by pathogens and toxicants present in

foods. These are cases where the actual risk, *i.e.* the end-point, has already occurred before a report is filed. Other systems are hazard-oriented, measuring the presence of the pathogen, toxicant, or other hazardous agents present in food and feed. This also includes the occurrence of diseases in livestock that may be potentially transmitted to humans through consumption of derived edible products or through animal-human contacts.

## **2.2 Endpoint-focused systems**

While in many nations, disease monitoring systems are in place, the examples mentioned below are particularly interesting because they employ a combination of expert opinion with surveillance data (ECDC epidemic intelligence and Dutch ISIS systems), because they are specifically focused on food-related diseases (CDC- USA, WHO), or because they employ various tools including Internet for intelligence (GPHIN).

### **2.2.1 The Dutch strategy for early warning against infectious diseases**

The control of infectious disease in the Netherlands is undertaken by regional public health services, in collaboration with the regional laboratories. The National Coordination Structure for Infectious Disease Control (LCI) coordinates the 40 public health services and national institutions and is responsible for the development of guidelines, protocols and the coordination of outbreak management. The National Institute of Public Health (RIVM) undertakes or supports surveillance and outbreak investigations at the national level.

Surveillance is undertaken on a continuous basis. Disease data is collected from the individual connected laboratories, analysed and interpreted and the outcomes disseminated to those responsible for taking actions to protect public health. Traditionally, analysis of surveillance data took the form of basic descriptive epidemiology (time, place and person). Electronic data collection can improve the data analysis and timeliness of outbreak detection. The electronic reporting system ISIS, which is the acronym for the Dutch national Infectious Diseases Information System, monitors and describes the day-to-day changes in frequency of all communicable diseases in The Netherlands. Descriptive epidemiological reports are disseminated in a timely manner and early warning signals sent to professionals in public health to facilitate rapid control. ISIS activities may be divided into notification of clinical cases and laboratory surveillance. The former involves practitioners in public health, the public health services (PHS), the Inspectorate of Health and RIVM, reporting clinical cases as required by infectious disease legislation. This is done using a web-based application to ensure the rapid receipt of information. The latter consists of laboratory reports on pathogens from microbiology laboratories, sentinel studies and regular laboratory surveillance. All laboratories connected to ISIS report to a central database every night and standard reports for the clinical and laboratory data are updated automatically at that time. These are available through the internet.

Parts of the site are password-protected and can only be seen by experts. Besides descriptive reports (time, place, person), early warning signals are generated. To this end, algorithms are used that recognize either incidence frequencies exceeding the historical background, such as for *Salmonella*, or a pre-determined threshold, such as zero-tolerance for Hantavirus. For comparisons with the historical background, the number of incidences reported within a given timeframe, e.g. 7 days or 4 weeks, are

5 compared with the incidences in the same period within the five previous years. In this way, seasonal fluctuations in the incidences of pathogens are also taken into account. The relevance of these signals has to be interpreted by experts, and those that are found relevant are subsequently transmitted to the professionals within the electronic network, so that measures can be taken (Widdowson, 2003).

10 RIVM are charged with the task of listing, evaluating and informing the government about all possible threats to public health. To achieve this, the “early warning committee” hosted by RIVM checks data from relevant data sources (ISIS, reference laboratories, Pro-med, WHO outbreak verification list, EU early warning and response system, etc.). The committee discusses these data on a weekly basis in order to signal infectious disease events that are threats to national public health. This committee includes various microbiological and epidemiological experts from RIVM, including LCI, and the national Food and Commodity Safety Authority (VWA). A report is made and disseminated the same day to health professionals and government officials.

20 Ramahat Langendoen and co-workers (2006) have evaluated the performance of the early warning committee. These authors have performed a retrospective study by comparing literature reports of outbreaks in The Netherlands and various other European countries with the outbreaks that have been discussed by the early warning committee during the period 2002-2003. This comparison shows that the early warning committee has discussed all relevant national outbreaks. Of 51 international outbreaks that the authors consider relevant for public health in The Netherlands, the early warning committee has not discussed three international events (*i.e.* 6%), including avian influenza, antibiotic resistance, and measles. For avian influenza, the particular virus strain at that time (2002) had not previously caused human disease. It has been discussed later in 2003, though, as reports on infections of humans became available. For measles, the reports have pertained to limited incidents on a regional scale. In addition, an additional *post-hoc* consideration is that these reports on measles have appeared at a stage that would have been too late for measures. With regard to antibiotic resistance, this pertains to extended-spectrum- $\beta$ -lactamase producing micro-organisms in Scotland, including *Escherichia coli*, *Enterobacter* spp, and *Klebsiella* spp. This signifies that little attention has been paid by the committee to emerging antibiotic resistance and infections acquired in hospitals. The authors nonetheless conclude that the early warning committee has recognized nearly all threats linked with infectious diseases (Ramahat Langendoen et al., 2006). Interestingly, this study by Ramahat Langendoen and co-workers (2006) has also identified two international issues that could have been recognized more timely as threats based on the information available, including avian influenza and antibiotic resistance. These issues also signify the utility of considering the role of reservoirs, *i.e.* animals and hospitals, in the emergence of infectious diseases.

### 2.2.2 European Centre for Disease Prevention and Control (ECDC)

45 Millions of people travel to, from and within the European Union every day. Thus communicable diseases are a major threat to public health. In order to monitor disease and potential spread the European Commission established a Communicable Disease Network (CDN) in 1999. This is currently based on ad hoc cooperation between Member States within the legal framework of Decision 2119/98/EC. However, the effective control of communicable disease required a substantial reinforcement of this

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system, so in 2004 the European Parliament adopted enabling legislation to create a European Centre for Disease Prevention and Control (ECDC). The primary function of the ECDC is to provide a structured and systematic approach to the control of communicable diseases and other serious health threats in partnership with national health protection agencies. The well known diseases such as avian influenza, HIV/AIDS and SARS as well as the detection and warning of infectious foodborne disease are within the ECDC remit.

For example, the ECDC carries out epidemic intelligence for identification of emerging health infections based on inputs involving both indicators and events from member states' national and European-level laboratories and authorities, but also other institutions, such as international organizations. The aim is to identify emerging threats, including those that may affect multiple member states or that may be transferred through transboundary movement. These threats are discussed in daily briefings by the epidemic intelligence team. Warnings can then be issued through the Early Warning and Response System (EWRS) to EU member states. In addition, contacts are maintained with the European Commission and World Health Organization, among others (ECDC, 2006; Paquet et al., 2006).

The EWRS system has been recognized as a unique tool for the dissemination of information on unpredictable incidents, such as SARS. Furthermore, the SARS incident showed that EWRS was able to report signals at an early stage, *i.e.* in March 2003. EWRS also helped informing member states about the measures taken against SARS by other members, facilitating coordination of measures. In addition, this information also aided the assessment of the impact of the measures in retrospect. Following a review of its functioning in 2002-2003 and an exercise simulating of an incident in 2005, the system has been adjusted and is to be re-evaluated in 2007. EWRS is considered to have an important role in the implementation of the WHO International Health Regulations 2005 in Europe (Guglielmetti et al., 2006).

### 2.2.3 Early Warning Activities in the USA

Although the US Center for Disease Control and Prevention (CDC) does not have a specifically dedicated early warning system there are several 'early warning' activities performed by CDC. These include FoodNet, EFORS, CaliciNet, the Foodborne Outbreak Response Unit and PulseNet.

The Foodborne Diseases Active Surveillance Network (FoodNet) is a collaborative project of the CDC, 10 of the centres involved in the CDC's Emerging Infections Program (EIP), the U.S. Department of Agriculture (USDA), and the Food and Drug Administration (FDA). The objectives of FoodNet include:

- To determine the exact burden of foodborne diseases
- To monitor foodborne disease trends in the USA
- To relate foodborne disease to specific foods

The Electronic Foodborne Outbreak Reporting System (EFORS) is CDC's internet-based system designed for state health departments to report foodborne disease outbreaks. Besides the facilitation of quick responses to early reports of outbreaks, the reports collected through the centralized EFORS system also allow for trend analysis based on retrospective data. For example, a recently published report oversees the notified outbreaks of foodborne diseases during the five-year period of 1998-2002 (Lynch et al., 2006). Bacterial pathogens were the cause of most of the outbreaks

with known etiology, *i.e.* for which the details of their development were known, which comprised approximately one-third of the reported outbreaks. During the five-year period, the share of noroviruses among the known causes increased from 3.6 till 15.0%, which likely correlates with improved local analytical capacities for foodborne viruses as previously described (Widdowson et al., 2005). *Salmonella enteritidis* as an implicated agent decrease during this period, probably caused by implementation of quality assurance in egg production. It was actually at the end of this period, in 2001, that EFORS was implemented, which was anticipated to lead to increased timeliness of reporting, while other new supporting tools included an algorithm for detecting increased in the outbreaks of food infections with *Salmonella*, *Shigella*, and *Escherichia coli* (Lynch et al., 2006).

CDC estimates that 50% of all reports on acute gastroenteritis can be attributed to norovirus infection. Sequences of norovirus strains obtained from clinical and environmental samples are entered into the Calicinet database. This database has been developed on the basis of PulseNet and facilitates epidemiologic studies by linking cases and sources. Furthermore, it helps public health officials to identify more quickly contaminated food products associated with norovirus outbreaks.

CDC's Foodborne Outbreak Response and Surveillance Unit provides outbreak reports and publications, an investigation toolkit, and reporting forms for use in the investigation and reporting of foodborne associated illness.

PulseNet is a national network of public health laboratories that performs DNA "fingerprinting" (pulsed field gel electrophoresis), on bacteria that may be foodborne. The network permits rapid comparison of these "fingerprint" patterns through an electronic database at CDC. PulseNet Europe is establishing a similar approach within Europe with a close collaboration to the above mentioned system.

#### **2.2.4 WHO Early Warning Activities**

The WHO has a global alert system that systematically gathers official reports and rumours of suspected outbreaks from a wide range of different sources including formal reports from ministries of health, national public health institutes, WHO regional and country offices, WHO collaborating centres, civilian and military laboratories, academic institutes, and nongovernmental organizations (NGOs). The WHO also uses informal sources to ensure that their data collection system is as comprehensive as possible. Indeed, informal sources account for approximately 60% of initial outbreak reports. The information gathered is primarily focussed on communicable diseases (e.g. haemorrhagic fevers, cholera, meningitis, salmonellosis and encephalitis) but also identifies related conditions such as food and water safety, and chemical events. Most reporting now uses electronic media to ensure the information is collated and disseminated as rapidly as possible.

The Global Public Health Intelligence Network (GPHIN) is a good example of the application of modern electronic communications in an early warning rapid alert system. The GPHIN initiative started in 1997 as part of a co-operation between Health Canada (*i.e.* Centre for Emergency Preparedness and Response) and WHO and is managed by the Agency's Centre for Emergency Preparedness and Response (CEPR), which is part of the Public Health Agency of Canada. The GPHIN system is a secure internet-based multilingual early-warning tool that continuously searches global media sources for information about disease outbreaks and other public health events.

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Once the raw information has been gathered it is then processed to determine whether or not the outbreak is of international consequence and when relevant made available to users worldwide (i.e. non-governmental agencies and organisations, government authorities for example WHO, FAO, OIE ect). The data evaluation enables four  
5 different filtering levels (i.e. an automated “top scoring”, an “expert scoring”, “relevance scoring” and “user scoring”) producing tailor made output fulfilling the different users needs and requirements (EFSA, 2006).

10 Formenty and co-workers (2006) mention that GPHIN has detected 39% of the 636 epidemic events verified by WHO during the period 2001-2003, signifying the importance of informal information sources, such as the Internet, for news on infectious diseases. In addition, particularly the recent outbreak of sudden  
15 asymptomatic respiratory syndrome (SARS) is mentioned as an example of the effectiveness of the GOARN network. The first incidences of SARS were observed in China in November 2002, and rumours about what appeared to be avian influenza picked up by GPHIN that time. Nonetheless, it has lasted until February 2003 before the disease spread to other nations and more information about the true nature and  
20 dimensions of SARS emerged (Buckeridge and Cadieux, 2007). This subsequently prompted GOARN to take a series of measures in collaboration with the local authorities and the influenza reporting system FluNet, including the deployment of teams in the areas affected but also the surrounding areas that had still been unaffected. Travel advice has been issued and efforts undertaken towards  
25 characterization of the virus involved, so as to facilitate its detection, which initially has had to rely upon detection of symptoms such as elevated body temperature. It is noted, though, that the hardest hit areas where SARS initially disseminated had low representations of GOARN and FluNet participants, and that SARS could have been reported earlier by the local authorities (Buckeridge and Cadieux, 2007; Michelson, 2005).

30 Furthermore, WHO’s new International Health Regulations adopted in 2005 require that member states establish disease surveillance networks within their nations. Contrary to the three diseases that had not be notified previously, *i.e.* cholera, plague, and yellow fever, the new regulations have a more extensive list of notifiable diseases of various categories, which are considered as being of international importance.  
35 These different categories include diseases that should always be reported, such as SARS, as well as those above a certain background as determined by dedicated algorithms. In addition, unusual or unexpected cases may have to be reported. Members should also be able to respond to consultations by WHO within 24 hours, such as inquiries into reports on incidents of diseases causing concern (Rodier et al.,  
40 2006).

### **2.2.5 WHO Surveillance Programme for Control of Foodborne Infections and Intoxications in Europe**

45 In 1980, a surveillance programme for the Control of Foodborne infections and intoxications in Europe was established as collaborative WHO and FAO initiative. This centre serves as an international focal point for the collection and dissemination of data and related information for all concerned. Its mandate is to improve national food control programmes including surveillance by:

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- identifying the causes of food-borne diseases and delineating factors contributing to the spread of these diseases
- dissemination of relevant surveillance information
- facilitating cooperation with national authorities in identifying programme priorities and the use of resources to meet both emergency and other needs in the prevention and control of foodborne diseases.

Each member country has a designated contact point(s) (usually the national authority responsible for the surveillance and control of communicable diseases) to provide information to the collaborative centre on foodborne disease investigation and findings including the causal agents (a list of agents is provided), epidemiological and clinical investigation data, vector or vehicle of transmission, cost benefit analysis (if done) and prevention and control measures.

The Collaborating Centre reviews the data received from the participating countries. This review includes analysis for regional and international trends and reports its findings back to the national centres. The report particularly identifies causes of food-borne diseases occurring in Europe, delineates the factors contributing to the illness and outlines preventive actions.

For example, Tirado and Schmidt (2001) provide an account of the trends observed in the data from the seventh report covering the period 1993-1998. Among others, *Salmonella* and *Campylobacter* constituted the most important pathogens involved with food infections. In addition, in 85% of the reports, the location at which the food had been contaminated or consumed was family homes or places where groups of consumers are served, e.g. mass caterers, restaurants, medical facilities, and schools. Incorrect temperature treatment, either by cooled storage or by heat processing, accounted for 32% of the reports. Faulty food preparation at home was also highlighted as the cause of botulism and trichinellosis, the latter following consumption of meat from wild boars or domestically slaughtered pigs. These authors noted, however, variability in the numbers of report between seasons as well as between nations. Based on these observations, the authors recommend, among others, education of domestic food processors and harmonization of surveillance and reporting systems (Tirado and Schmidt, 2001).

### **2.2.6 WHO International Food Safety Authorities Network (INFOSAN)**

At the beginning of this millennium, various international organizations, including FAO, WHO, OIE, and Codex alimentarius, acknowledged that globalization increases the likelihood that locally initiated food safety incidents can attain international dimensions. In addition, Codex alimentarius issued guidelines on how national authorities should handle food safety emergencies. Among others, these guidelines require the establishment of a national contact point for such emergencies. These developments have led to the foundation of the International Food Safety Authorities Network (INFOSAN) in 2004 (WHO, 2006).

Member states have to appoint national focal points, which disseminate information from INFOSAN within their own country, and maintain contacts regarding food safety issues with the INFOSAN secretariat and other members. Each member state may assign multiple focal points, given the fact that, for example, different ministries have oversight over distinct parts of the food manufacture chain (WHO, 2006).

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In addition, one emergency contact point has to be established in each member state, which, besides the tasks of a focal point, is able to identify emergencies and to act on behalf of the national authorities. The emergency contact points has to inform INFOSAN about the import and export of contaminated foods and to indicate if it needs assistance in solving the issue. Both reports on hazards (presence of a contaminant in foods and feeds) or endpoints (reported food poisonings) can be reported. The INFOSAN secretariat then takes a decision whether to take action or not, based on consideration of factors including the distribution of the hazard and the impact on public health and society. The decision may entail the contacting of other specific INFOSAN members that might have been affected or the entire network. In addition, INFOSAN can provide support with advice and support for international product recalls. Approximately ten reports are handled each month by INFOSAN, of which one is further processed as an alert to INFOSAN members (WHO, 2006).

The member states' task of emergency reporting partially overlaps with that of their reporting duties under the International Health Regulations (IHR), which also cover foodborne diseases (see section 2.2.4 on WHO systems). National focal points should therefore establish links with their national IHR counterparts. In a similar fashion, the reporting of zoonotic diseases may overlap with the duties under the OIE's Terrestrial- and Aquatic- Animal Codes, for which FAO, WHO and OIE recently established the Global Early Warning Systems (GLEWS).

The INFOSAN network not only serves as an emergency response network, but also provides a forum for exchange of information between its members, including the publication of notes on topics of particular interest. The notes that have been published on its website cover topics such as, among others, avian influenza, biotechnology, *Salmonella*, and acrylamide (WHO, 2007a).

The usefulness of INFOSAN and national reporting systems in mitigation of international dissemination of foodborne disease is illustrated by a recently published note on an outbreak of food infections in the US. In particular, this involved the infection of consumers with *Escherichia coli* O157:H7 following consumption of spinach. A combination of modern pathogen characterization techniques, identification of spinach as the source of infection, and precocious warning of other potentially affected nations, in part through INFOSAN, contributed to a timely response (WHO, 2007b).

### **2.3 Hazard-focused systems**

The examples provided below pertain to systems that collate the reports by control authorities of consignments that do not comply with food safety standards (EU RASFF); evaluate the implementation of such control systems in member states and identify possible points that are amenable to improvement (EU FVO); or monitor veterinary diseases, including those that may become a human health issue, such as through consumption of derived edible products (OIE).

#### **2.3.1 FVO Early Warning Activities**

The European Commission is responsible for ensuring that Community legislation on food safety, animal health, plant health and animal welfare is properly implemented and enforced. This task is the primary role of the Food and Veterinary Office (FVO)

The mission of the FVO is to:

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- promote effective control systems in the food safety and quality, veterinary and plant health sectors;
- check on compliance with the requirements of EU food safety and quality, veterinary and plant health legislation within the European Union and in third countries exporting to the EU;
- contribute to the development of EU policy in the food safety and quality, veterinary and plant health sectors,
- inform stakeholders of the outcome of evaluations.

10 The FVO must also audit/inspect food safety control systems in countries exporting to the EU to ensure compliance with EU standards. While the role of the FVO does not include early warning activities, the inadequacies of food safety control in different countries subject to FVO audit could be used as an indicator/early warning of future food safety problems and the FVO recommendations (all of which are published in the FVO reports) could be used as preventative measures. The latter includes recommendations to national authorities but also to the European Commission on legislative changes that may be required to prevent or reduce the likelihood of foodborne illness in the future through European food law

### 20 **2.3.2 (European) Rapid Alert System on Food and Feed (RASFF).**

The European Food Safety Authority (EFSA) hosts the Rapid Alert System on Food and Feed (RASFF), as required by the General Food Law (EU regulation 178/2002/EC). Whilst a centralized EU reporting system had existed previously, the provisions in the General Food Law ensured that reporting by RASFF members was mandatory and done in a timely fashion. Members, including national food control authorities, are obliged to report their measures regarding food safety to RASFF, such as recalls of food and feed products and detention of imports that do not comply with food safety standards. These notifications can be divided into two types. First, the observations or measures that may have implications for other members are designated “alert” notifications. On the other hand, “information” notifications pertain to products that are considered to be without consequences for other members, for example in case the product has not been marketed elsewhere. Various types of food hazards are commonly reported through RASFF, including chemical, microbiological, and physical hazards. Members of the RASFF system will consider the possible implications of these notifications for their own national food safety policy and, if needed, undertake any measures.

Weekly summaries and annual reports of the RASFF alert and information notifications can be found on the European Commission's website. In addition, it publishes annual reports of the notifications which, besides an overview of the numbers of reports in a particular year, provide accounts of noteworthy developments within that year ([http://europa.eu.int/comm/food/food/rapidalert/index\\_en.htm](http://europa.eu.int/comm/food/food/rapidalert/index_en.htm)).

We have investigated the potential use of these reports for predicting trends in food safety issues in an early stage by analyzing reports starting from mid 2003 in retrospective. While the details of this study are reported elsewhere (Kleter et al., this issue), several issues that emerge from the data reported by RASFF are discussed below.

Distinctive trends occurred for items that are not foods *per se* but that may come into contact with foods and thereby transfer external agents into food. For example, a number of reports in 2005 pertained to heavy metals migrating from kitchen utensils.

This was followed by a sudden rise in reports of the presence of the substance 2-isopropyl-thioxanthone (ITX), which is a component of ink applied in printing of packaging, in predominantly baby food and fruit juices. As regards ITX, EFSA has assessed the safety aspects of its presence in foods and both national authorities and industries have taken various risk-mitigating measures (EFSA, 2005). In more general terms, the EU is preparing to extend its current legislation on substances that may come into contact with food (Regulation 1935/2004/EC), so that, among others, a number of additional components that were recently detected in foods are included within its scope.

Another noteworthy development was the occurrence of unauthorized dyes, predominantly in spices and condiments, as well as in oils and fats. Sudan dyes, which have not been authorized for food use, initially accounted for most of the notifications, while their share in all dyes reported appeared to decrease progressively. Another dye that has gone through a temporary “blip” in 2005 is Para Red, which, like Sudan dyes, is commonly used for non-food purposes but has not been authorized for food. Para Red has mainly been found to occur in spices and condiments. Both Sudan dyes and Para Red have been recognized as a problem in the EU (EC, 2005; FSA, 2005). These developments may be indicative of a trend towards the increased occurrence of non-authorized alternatives of Sudan dyes.

In addition to the chemical hazards described above, also other types of hazards, including mycotoxins and microbial hazards, have been considered in the study on RASFF data, which are discussed in more detail in the report of the study elsewhere (Kleter et al., this issue).

The EU and national authorities have already taken measures against various observed trends towards higher frequencies of notifications for hazards linked with certain products and substances. These trends in RASFF data combined with information on the potential impact on health and trade nevertheless can provide a useful basis for identifying hazards that are likely to increase in future.

### 2.3.3 OIE World Animal Health Information System

The “Office International des Epizooties” is an international organization that sets standards for sanitary practices in trade, husbandry, breeding, therapy and diagnosis of diseases in animals and animal products. These standards serve as reference for the World Trade Organization in case of international trade disputes over animals or animal products, as set out by the SPS agreement on sanitary and phytosanitary measures. Member States of this organization have to notify certain veterinary diseases that have been listed by OIE. A number of these diseases, such as bovine spongiform encephalopathy (BSE), are also relevant to food safety of animal edible products.

In addition, there may be occurrences of animal diseases that require urgency, for which alerts are issued. Conditions of urgency include, for example, the first occurrence of a certain pathogenic strain in a geographical region; an unanticipated or unexplained sudden increase in disease or death among animals; or the emergence of a disease with substantive impact. Exceptional notifications are also published weekly in the journal *Disease Information*, which is also available from the OIE’s website ([http://www.oie.int/eng/info/hebdo/A\\_INFO.HTM](http://www.oie.int/eng/info/hebdo/A_INFO.HTM)). These reports include information on the location where a disease has been observed; the number of animals that have been affected and possibly destroyed; methods of diagnosis that have been used and their outcomes; and measures that have been taken to control the disease.

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Recently, the OIE information system was upgraded by the introduction of the electronic World Animal Health Information System (WAHIS). OIE members can enter data electronically through WAHIS, which increases efficiency compared to paper-form-based notifications and which allows other members to follow these notifications in real-time. The Internet interface summarizes the information using maps to illustrate the geographical distribution of the diseases. In addition, the information available through the website to the general public has also become more extensive (Vallat, 2006).

### 3. Predictive Early Warning; Emerging Risk Systems

#### 3.1 Introduction

While 'early warning systems' for threats to public health are reasonably well developed and in operation, there is a dearth of 'predictive early warning systems'. There is little doubt that the former will always command the greater resources as public expectation will require public health agencies to deal with the threats already present before tackling threats which may (or may not) emerge in the future. Regardless, given the potential decrease in human fatalities, suffering and economic loss which might be prevented by a relatively small investment in predictive activities, there is little doubt that these activities should and will increase in the future. The need for the development of "Emerging Risk Identification Systems" has been acknowledged and recommended by the participants of the FAO/WHO pan-European conference on Food Safety and Quality (FAO, 2002).

To date several emerging risk identification systems are operational and others are in development. These and the potential to use existing monitoring systems as emerging risk identification system will be discussed in this section. The examples below provide an account of systems that are either focused on specific food hazards, such as the mycotoxin warning systems, and those that are broadly-oriented, such as "horizon scanning".

#### 3.2 Early warning systems for mycotoxin in maize and/or wheat

The major mycotoxin-producing fungal genera are *Aspergillus*, *Fusarium* and *Penicillium* (Whitlow and Hagler, 2005). Molds can grow and mycotoxins can be produced at pre-harvest, or during storage, transport, processing or feeding. The initial colonization of plants (wheat and maize) in the field by molds and their growth and mycotoxin production are related to plant stress caused by weather extremes, to insect damage, to inadequate storage practices and to faulty feeding conditions (Whitlow and Hagler, 2005). Many predictive models for the occurrence of *Fusarium* head blight and the mycotoxin deoxynivalenol (DON), zearalenone (ZEA), fumonisin B1 on wheat and/or maize have been developed and are being used in several countries for management control of these natural toxins (Moschini et al., 2001; Hooker et al., 2002; Hooker et al., 2003; De Wolf et al., 2004; Madden et al., 2004; Rossi et al., 2003a,b; Detrixhe et al., 2003). The computer models operational are generally based on weather variables (temperature, rainfall and moisture) and in some cases plant development stage is included as well.

Reasonably successful predictive systems have been developed in this way particularly in the United States, where disease prediction models for *Fusarium* head blight of wheat were revised based on weather, crop growth stage and disease observations from seven states located in both spring and winter wheat production areas. The final models used hourly temperature, humidity and rainfall to predict the

risk of disease severity greater than 10%. The model deployed in 2004 also contained variables that allowed users to specify type of wheat (winter vs. spring) and whether winter wheat was planted into corn residue. Model accuracy was estimated to be near 80% based on data used to validate the model. The model was deployed for 23 states in 2004 as part of the National *Fusarium* Head Blight Prediction Center ([www.wheatcab.psu.edu](http://www.wheatcab.psu.edu)) (De Wolf et al., 2004).

Current research concerns the validation of the system, and the development of more accurate models for scab risk prediction, based on additional scab observations, weather data for different time windows, and the integration of empirical observations of epidemics with results from field and laboratory studies on scabs. Consideration is being given to predicting the risk of other disease severities or of DON level in grain. The current system was generally accurate in field testing, but improvements in accuracy are needed (Madden et al., 2004).

### 3.2.1 Limits of predictive mycotoxin models

Although successes in the prediction of the presence of mycotoxins in wheat and maize can be reported, further development is needed in order to reach the accuracy needed for a broad implementation in risk management. It is anticipated that inclusion of variables on agronomic criteria such as crop rotation, crop variety, tillage etc, human behaviour (e.g. habits, customs) and field and storage practices may improve the present models.

### 3.3 European Commission's Scientific Committee on Emerging and Newly Identified health Risks (SCENIHR)

The European Commission's Directorate on Public Health and Consumer Affairs (DG SANCO) recently established the Scientific Committee on Emerging and Newly Identified health Risks (SCENIHR). This Committee consists of independent scientific experts that provide advice in response to questions from the Commission and other EU institutions, in addition to issues that the Committee itself considers relevant.

As part of the transparency pursued by the European Commission, agendas, meetings minutes, opinions etc. of this Committee are published on its website ([http://europa.eu.int/comm/health/ph\\_risk/committees/04\\_scenih/04\\_scenih\\_en.htm](http://europa.eu.int/comm/health/ph_risk/committees/04_scenih/04_scenih_en.htm)).

Topics that have been considered by this Committee include West Nile Virus, variant Creutzfeldt Jakob's disease, electromagnetic fields, and nanotechnology. Whereas these topics are not particularly confined to the area of food safety, some of them, such as vCJD and nanotechnology, have cross-cutting issues.

### 3.4 DEFRA - Horizon Scanning

The UK Department for Environment Food and Rural Affairs (DEFRA) has developed a strategy for "horizon scanning" which is defined by DEFRA as "*The systematic examination of potential threats, opportunities and likely future developments which are at the margins of current thinking and planning. Horizon scanning may explore novel and unexpected issues, as well as persistent problems or trends. Overall, horizon scanning is intended to improve the robustness of Defra's policies and evidence base.*"

With horizon scanning, DEFRA aims to focus on areas of scientific research that are not traditionally considered and that may provide information on potential hazards and opportunities. This may pertain, for example, to unexpected or emerging issues,

as well as to an analysis of existing trends within DEFRA's remit. External sources can provide ideas for research, which are evaluated for their pertinence to the objectives of the horizon scanning program. In addition, for the prioritization of issues, input will be used from workshops and other channels of communication. A description of the activities on horizon scanning is provided on a dedicated website (<http://www.escience.defra.gov.uk/horizonsscanning>).

### 3.5 FAO Global Information and Early Warning System (GIEWS)

The Global Information and early warning system (GIEWS) is a world wide information exchange system connecting 115 governments, 61 non-governmental organisations (NGOs), research and media institutions, in which issues related to food security are shared. (<http://www.fao.org/giews/english/index.htm>). The main objective of GIEWS is to support policy-makers and policy-analysts with timely warnings of possible changes in the food supply and demand and/or related aspects to allow effective measures to prevent the potential problem. An interesting example of the use of information by GIEWS is that of satellite information to create an inventory of agricultural land status and to forecast crop harvest yields. Whereas this example does not pertain directly to food safety hazards, it provides an excellent example of an approach towards integration of information from different sectors influencing agricultural production with alerts by science-based monitoring systems and scientific findings by experts working in the field.

The most recent FAO Programme Implementation Report describes the progress in GIEWS (programme 223P6), noting that the GIEWS website has been overhauled in 2004. GIEWS has alerted 28 impending food security crises, mainly in Sub-Saharan Africa, in 2004-05. Positive developments are also reported for the quality and timeliness of information provided through the website (FAO, 2007).

## 4. Emerging Risk Systems based on a holistic approach

As many factors inside and outside the food production chain (such as human behaviour, trade, climate, regulation, technology, etc) may have direct and/ or indirect influence on the emergence and development of foodborne hazards, a systemic approach (often referred to as "holistic" approach) that includes these variables may result in predictive system for the identification of an emerging food safety risk in an early stage. Such predicting systems would allow authorities to take preventive actions before the hazard has been picked up by monitoring and survey systems. OECD argues for the potential of such an approach (e.g. systemic in the report "Emerging Systemic Risks in the 21<sup>st</sup> century: an agenda for action (OECD, 2003)). It is emphasised that the changes that will affect risks and their management in the future will occur in four contexts: demography, the environment, technology and socioeconomic structures. The feasibility of a systemic approach to identify emerging risks in the food and feed chain is currently being explored in several European projects (EU 6<sup>th</sup> Framework projects, PERIAPT ([www.periapt.net](http://www.periapt.net)), SAFE FOODS ([www.safefoods.nl](http://www.safefoods.nl)), SAFEFOODERA ([www.safefoodera.net](http://www.safefoodera.net)) and EMRISK ([http://www.efsa.eu.int/science/sc\\_commitee/sc\\_meetings/1132/sc\\_minutes\\_14thplen\\_meet1.pdf](http://www.efsa.eu.int/science/sc_commitee/sc_meetings/1132/sc_minutes_14thplen_meet1.pdf)) as well in a Dutch project funded by the Dutch Ministry of Agriculture, Nature and Food Quality (Emerging risk in the Dutch food chain, [www.kenisonline.wur.nl](http://www.kenisonline.wur.nl)).

5 Within the PERIAPT project nine sectors have been identified that have direct or  
indirect effect on the development of a food safety hazard . The sectors identified  
were i) Science, technology & industry: ii) Nature and environment: iii) Government  
and policies: iv) Consumer behaviour: v) Culture and demography: vi) Public health  
10 and welfare: vii) Agriculture: viii) Economy and ix) Information (Noteborn & Ooms,  
2005) which have been later modified by the EMRISK project (EFSA, 2006). The  
sectors proposed by EMRISK are generally the same, albeit that industry has been  
separated and combined with trade as an additional sector entitled “industry and  
trade.” In addition, consumer behaviour and welfare have been combined with culture  
15 and demography to form the sector entitled “population and social conditions.”  
Within these sectors, critical factors (such as, for example, weather conditions for the  
sector nature and environment) occur that may trigger the development of a hazard.  
Hence such critical factors, referred to as “indicator”, are measurements and or  
observations that provide information (reliable, sensitive, quantifiable) on the nature  
20 of a hazard (agent/process involved) and the source of the risk (EFSA, 2007). By  
studying recent food safety crises, attempts are undertaken to identify such  
quantitative indicators. The major challenge in such studies will be to identify the most  
important determinants. This concept has been applied by research teams in the  
EMRISK project funded by the EFSA (EFSA, 2006), studying five recent (food)  
25 safety incidents (acrylamide, avian influenza, BSE, aflatoxicosis, and  
semicarbazide). In this study in total 217 indicators were identified divided over 9  
different sectors. The sectors having the most indicators were agriculture, population  
& social conditions and environment & energy, comprising 44% of all indicators  
found. Based on this outcome a “holistic” emerging risk system was proposed by the  
researchers.  
Research teams in the EU 6<sup>th</sup> FP SAFE FOODS project and the Dutch project  
“Emerging risk in the Dutch food chain” further explore this concept.

30 Although the above mentioned studies are still ongoing and the results are to be  
published it is evident that economic factors, (scientific) innovations and human  
behaviour often are linked to the development of a hazard or risk and that these  
factors will be used in “holistic” based emerging risk systems Furthermore, it is clear  
that the output of the conceived “holistic” emerging risk identification system will not  
35 be a simple straight forward signal that can be used directly by the risk manager to  
design interference strategies. Instead, analyses by scientific experts of the detected  
signals and anticipated food safety risks, most probably with experts of different  
disciplines, will be an essential step in the “holistic” emerging risk system. Large  
expert databases such as developed in the SAFE FOODS project  
40 ([www.safefoods.nl/expert](http://www.safefoods.nl/expert)) may be very useful in the selection of the most appropriate  
expert.

## 5. Conclusions

Worldwide, various early warning systems exist for early identification of human and  
animal diseases, of which only a limited number are specifically dedicated to the early  
45 identification of foodborne hazards. From examples described in this study, such as  
the INFOSAN network, it is apparent that besides the challenges of timely detection  
of a hazard also rapid information exchange to relevant parties is a crucial element in  
such systems. If warnings do not reach the relevant authorities in time, this may  
hinder timely and adequate prevention, intervention, and control activities . The use of  
50 advanced early warning systems such as GPHIN may help circumventing this

problem, for example by continuously collecting relevant information from the worldwide web. Besides collecting information, analysing the collected data and selecting the most relevant information may also be automated, but it is evident that additional expert judgement will in any case be needed.

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Furthermore, institutions in charge of systems aiming to identify emerging foodborne hazards in an early stage should not only focus on the technical requirements to collect and process information but should also describe how and where it should be used, taking into account that a dynamic interaction between the risk assessor and the risk manager in the various stages of process is needed. The challenge for such systems will be to generate outputs that allow the risk manager, in consultation with the risk assessors and involved stakeholders, to define the problem and set the terms of reference for the scientific risk assessment, the first step in the risk analysis framework (FAO/WHO, 1995, 1997).

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In our investigation it became apparent that little public accessible information is available on the performance of operational early warning or emerging risks systems. It is not clear whether such evaluations have not be performed or whether they have not been published. Recent studies have shown that transparency of institutions involved in the food safety governance has potential to increase the public trust in these institutions (van Dijke et al., in press) and that the consumers expect these organisations to act pro-actively (van Kleef et al., in press).

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The authors realise that it will be difficult to quantify the success of preventing a food safety incident to occur without the knowledge what would have happened if nothing was done. Nevertheless, defining sets of criteria to evaluate the performance of early warning and emerging risk identification systems is a prerequisite to justify the investments made. This is most eminent for the “holistic” emerging risk systems which are being developed. A detailed cost-benefit analysis of the systems considered in this review, however, is out of the scope of this article.

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In addition, the assignment of the responsibility for early identification of emerging risks is a factor to be considered. The initiatives considered by this review have been under the responsibility of international organizations, regional authorities (*e.g.* EU) and national governments. This likely relates to these institutions’ remit to protect public human and animal health. It is conceivable that also the private sector can contribute to the early warning of foodborne hazards or factors influencing these hazards. This may be done through the monitoring of hazards through the Hazard Analysis Critical Control Points (HACCP) approach, which can also align with the current trend towards verification of in-company safety controls by governmental food inspection agencies. Furthermore, for the parallel, analogous topic of natural disasters, the United Nations International Strategy for Disaster Reduction envisages an effective functioning of early warning systems based on a combination of risk knowledge among the stakeholders involved; monitoring of- and warning against-hazards; timely and understandable communication and dissemination of information on these hazards, and the capability to build a response to the identified hazards [UNISDR, 2006]. This also involves participation of- and communication with- the local and international authorities, private sector, and citizens in order to better prepare them for response to threats. The effectiveness of the early warning systems

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therefore not only relies on the accurate and timely identification of hazards, but also on the risk management measures taken to mitigate or prevent the identified hazards from becoming a real risk or even a disaster.

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