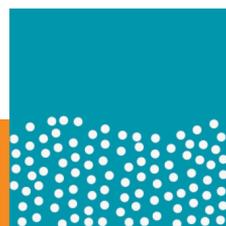


VULNERABILITIES IN THE FOOD CHAIN

A STAKEHOLDERS' GUIDE



How to identify and address vulnerabilities
Theoretical background and perspectives

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Edited by:

H.J. Cnossen, M.A. Wassens, H.L. Heeres, N.B. Lucas Luijckx

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Preface

Food Safety: A Global Challenge

With global distribution of animal feed, human food and ingredients countries have never been more dependent on each other for the safety of their food supply. A united approach with consistent standards based on sound science and robust controls is required to ensure consumers' health and consumers' confidence is adequately protected.

The increasing power of the analytical chemists and forensic microbiologists means that more and more contamination incidents will continue to come to light. Some of these can be major public health threats whereas others may be technical breaches of the legislation that are unlikely to contribute to adverse health affects. Furthermore there is a spectrum of incidents between these two extremes and they all require different risk management approaches. In addition to a globally distributed food and feed supply we have a global media that is open for business 24 hours per day, seven days per week. Often the first casualty of breaking news is perspective so effective and consistent risk assessment and communication is essential if incidents are to be managed effectively and in proportion to the public health consequences.

Appropriate process controls, bio security, adequate traceability and good hygiene practices are the prerequisites for every food business. As businesses increase in size and complexity the risk profile changes and the controls must be adapted accordingly. One negligent, or criminal, operator can damage the output of a complete sector or a country's entire exports so it behoves the regulatory agencies and food businesses in every jurisdiction to be vigilant as the consequences of an untoward event can have disastrous consequences both in economic and public health terms. Brands and reputations that take years to build can be damaged overnight by being associated with a contamination incident.

Science based risk assessment should underpin the food safety control measures applied across the globe and it is important that the risk assessment bodies in the different jurisdictions share data and use similar risk assessment methodologies. Standard setting in food safety is an international issue and consistency is important with the focus on consumer protection and not creating barriers to trade. No country can afford to be complacent, or arrogant, as mistakes can happen in the best systems and all our futures are interdependent.

Staff are a food business's greatest asset but untrained staff can be a company's greatest liability therefore awareness and education initiatives are key to creating a greater understanding of the rationale behind good food safety practices which will assist in achieving greater compliance. Staff should receive supervision, or training, commensurate with their responsibilities.

A chronology of outbreaks, and contamination incidents, has occurred across the globe in the last few years which, at times, have undermined the public's confidence in the safety of food, in industries' commitment to produce safe food and in the regulatory agencies' ability to police

the global food chain. Regulators and industry stakeholders, in all jurisdictions, need to share experiences and learn about best practices from each other. The lessons from incidents, factors that contribute to the occurrence of crises, how they could have been prevented and how they were subsequently managed need to be shared.

The Sigma Chain project demonstrates the benefits of collaborative working as the challenges faced are similar in every country. The use of case studies permits people to learn from the mistakes of others and the development of a framework to identify and prioritise risks along the food chain is essential to target finite resources appropriately.

Professor Patrick Wall

University College Dublin, Ireland

Associate Professor of Public Health

Former Chief Executive Irish Food Safety Authority

Former Chairperson European Food Safety Authority

Preface

Securing of food safety along the whole food chain is for consumers as important as ever before, despite unquestionable improvement of the situation in this area.

An aspect of food safety, although often not considered under food safety aspects, is food nutritional quality, e.g. the risk for consumers posed by too salty food products or too fat products. In this respect food industry is taking more responsibility and more and more food products with diminished level of added salt appear on the market. It is unquestionable that there are chain aspects in the management of nutritional value of products.

More traditional risks for consumer health posed by food of inappropriate quality involve food contaminated by bacteria, viruses, and also by fungi and moulds producing carcinogenic substances. It applies also to potential contaminations of food or ready-cooked meals, such as heavy metals like lead, cadmium, etc., organic chemical substances like dioxins, polycyclic aromatic hydrocarbons, or heat toxicants, originating in food mainly due to thermal processing like acrylamide, and trans-fatty acid isomers.

The molecular research findings seem to substantiate the hypothesis that some adult age diseases with high epidemic spread are a remote function of diet contamination exposure during life, but also during pregnancy.

The Sigma Chain Stakeholders' Guide comprises a set of accessible recommendations how to act so that the food consumer can be satisfied with its safety and quality. The guide aims at providing advice how to control effectively food-born hazards, and by the same token how to enhance consumer health protection in each phase of food production, processing and trade, but focuses in particular on vulnerable phases where food safety of a product is compromised, due to contamination.

The guide provides enough evidence that rational combination of practice and science is essential, even if the effective food safety system seems to be effective on formal and legal grounds. The guide specifies interestingly examples of the assessments of potential vulnerabilities of the food safety system requiring more effective measures.

The second part of the guide contains a set of eight problem-specific articles crucial for the safe food producer.

To sum up this book is one of the best prepared publications in this category and is recommended for food producers, consumers and official food control bodies in all EU Member States.

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General introduction

Food chains are understood as the collective links of production (including raw material production), processing and distribution of food. These include global trade and import, storage, transport, and sale or supply to the final consumer. Food chains are becoming more and more complex networks in a dynamic and global environment. Food is a basic need and its safety of great importance to consumers. It is the responsibility of actors in the chain to ensure this safety and to be aware of the vulnerability of complex systems. Risk management is a broad responsibility that reaches beyond legal compliance and where precaution might be necessary. As with any decision also risk management decisions are made taking into account relevant (legitimate) factors. Every factor considered can and will change, and new information or evidence will be produced. A risk management process requires a constant alertness and regular review of decisions.

People expect the food they eat to be safe and suitable for consumption. Food borne illness and food borne injury are at best unpleasant; at worst, they are fatal. But there are also other consequences, such as decreasing consumers' confidence, producers' and manufacturers' profits, trade, tourism and employment. Added to that, though not a safety subject, food spoilage is wasteful and costly.

In a three year EU-funded research project "Sigma Chain", partners inside and outside the EU took on the challenge to define a strategy for stakeholders to identify, assess and address vulnerabilities in the food chain. A stepwise procedure was created that guides practitioners through a systematic process carried out within the applicable regulatory framework and existing practices. The research project and its results address only food safety related vulnerabilities.

Vulnerability identification and assessment according to the Sigma Chain approach can be used to investigate the whole food chain or specific parts of it in order to minimize risks or optimize production and processing. Firstly, vulnerabilities are defined as any contamination with a dangerous substance, either chemical, microbiological, or physical. But secondly, the application of a process or procedure dealing with contamination can result in a vulnerability, mostly through wrong or insufficient application. An example is the loss of information regarding the product on its journey through the chain, so knowledge of contamination or processes applied is lost and subsequently not dealt with adequately.

This book, the Sigma Chain Stakeholders' Guide, is the result of a combined theoretical and practical approach to food chain vulnerability. Theoretical models were studied and developed and merged with practice as studied in four case studies. These case studies were chosen to serve as examples of a batch mixing chain (milk powder), long geographical chains (chicken and farmed salmon), and a rapid contamination chain (drinking water).

Reading guide

There are two major parts in this book. Part I is the actual guide, containing a set of consistent 'how to guides' with an elaborate introduction explaining the systematic thinking behind the process. Part II gives more background to part I on selected issues in a set of theoretical chapters. Part II can be read separately, as it puts important issues in thinking on food safety in chains and responsibilities of food business operators in a broader perspective.

Abbreviations

ADI	Acceptable Daily Intake
BMP	Best Manufacturing Practices
BRC	British Retail Consortium
BSE	Bovine Spongiform Encephalopathy
CCP	Critical Control Points
EC	European Community
EU	European Union
FAO	Food and Agriculture Organization
FBO	Food Business Operator
FDA	United States Food and Drug Administration
FMEA	Failure Mode and Effects Analysis
GFL	General Food Law
GMO	Genetically Modified Organisms
GMP	Good Manufacturing Practices
HACCP	Hazard Analysis and Critical Control Points
IFS	International Food Standard
ISO	International Organization for Standardization
MRL	Maximum Residue Level
OLF	Other Legitimate Factors
PAHs	Polycyclic aromatic hydrocarbons
PCBs	Polychlorinated biphenyls
QA	Quality Assurance
RASFF	Rapid Alert System for Food and Feed
RFID	Radio Frequency Identification
TDI	Tolerable Daily Intake
pTWI	Provisional Tolerable Weekly Intake
VPN	Vulnerability Priority Number
WHO	World Health Organization



VULNERABILITIES IN THE FOOD CHAIN

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Part I

How to identify and
address vulnerabilities

Introduction

Part I explains the process to identify and address vulnerabilities in a series of 'how to guides'. These guides cover only food safety related vulnerabilities. This implies that the focus is on contaminants, mainly chemical and microbiological, and on processes and procedures that deal with contamination or information on safety related issues.

The theory of the Stakeholders Guide starts from the viewpoint of collecting as much unbiased information as possible, then followed by an intelligent set of filtering and prioritization steps to arrive at the relevant (vulnerability) information. This information is assessed and the resulting vulnerabilities are addressed and prioritized, taking into account the applicable regulatory framework and other legitimate factors. It should be noted that the priority to deal with a certain food safety issue might be higher for an individual operator if consumers are highly concerned, despite the fact that (scientific) risk assessment leads to low priority. Reiterating this process regularly will enhance the quality of food safety systems and allow for efficient use of risk management budget. Priorities will change over time.

The first step in the identification and assessment is to map the chain (part) to allow a systematic review of the information to be collected. Mapping should go into great detail, although the actual extent is difficult to define. Information then collected consists of contaminants, best (manufacturing) practices, chain information, and more. It is important to be aware of any intended or unintended bias when collecting this information, since it is impossible to be complete. Therefore, this process is always teamwork and requires impartiality, 'out of the box'-thinking, and often independent consultancy.

The next step is to identify vulnerable links in the chain. Main focus is on entry points of contamination and points where information might get lost (loss of tags e.g.). From the entry point of a contamination next the dynamics and control of contaminants in the chain can be assessed. Successful targeting of the contaminations' entry points, spreading routes, behaviour and detection points within the food supply chain are vital for the application of successful control measures in the production of safe food. This should not only be known at the level of the individual chain link or food business, but also over the entire chain. This can be best realized by considering the chain or parts of it, rather than individual companies of chain links, when reviewing and checking best manufacturing practices (BMPs), control measures, corrective actions, monitoring plans, and testing and sampling strategies in place at the respective chain links.

Several food safety and quality management systems are available and used to manage, prevent and control the occurrence of contaminants within food businesses, (e.g. HACCP, ISO, BRC, and IFS). None of these explicitly includes the entire food production chain. In these systems, monitoring activities are necessary to ensure that the process is under control and that the products are safe. BMPs can also be used as a basis in the assurance that the product does not pose any harm to the consumer's health as a result of contamination. BMPs also involve

the understanding and implementation of monitoring plans, corrective actions and control measures as contamination can occur at any point in the food chain.

In addition to the identification of contamination, it is important (and legally binding) to trace and track products and to find and address relevant information on products and their sources. The Sigma Chain approach automatically leads to exceeding the existing legal compliance by performing tracking and tracing beyond one step. Potential gaps in the documentation give rise to increased vulnerability, simply because you do not know what to look for. Documentation can be divided into documents and records. Documents describe procedures, practices, statements of intent etc. Records are databases with e.g. process control data (temperature, pressure) or activities/events specific to an identified group or batch or stock. Documentation can be paper based or electronically based. In our assessment process the document and record keeping trail is established and the weaknesses or potential vulnerabilities assessed, both at each step in the chain (i.e. where information is lacking or where there is a risk of loss in identification/traceability) and the weaknesses in the flow of information along the chain, where information is not transferred.

Identifying potential vulnerabilities from the data analysis of chain maps, contaminants, document flow and procedures is a crucial step in the assessment. But the real challenge is to assess and rank the different types of vulnerabilities into priorities, and to identify options for control to be able to support the food business in making sound risk management decisions. The assessment of the potential vulnerabilities is based on the Failure Mode and Effects Analysis (FMEA), and adds a priority number to them once identified. Each potential vulnerability is rated according to three criteria: severity, likelihood of occurrence, and likelihood of detection/recognition, which is not necessarily instrumental analysis only. This last factor is less used in risk matrices currently for risk analysis in food businesses (HACCP). Obviously the application here for chains, rather than individual companies, is a novelty.

The basic scheme for identification and assessment of (potential) vulnerabilities in the chain is provided in Figure 1. A general recommendation is to carry out verification of the collected information, preferably on site, and/or in consultation with experts. Figure 1 equals the order of the chapters in part I.

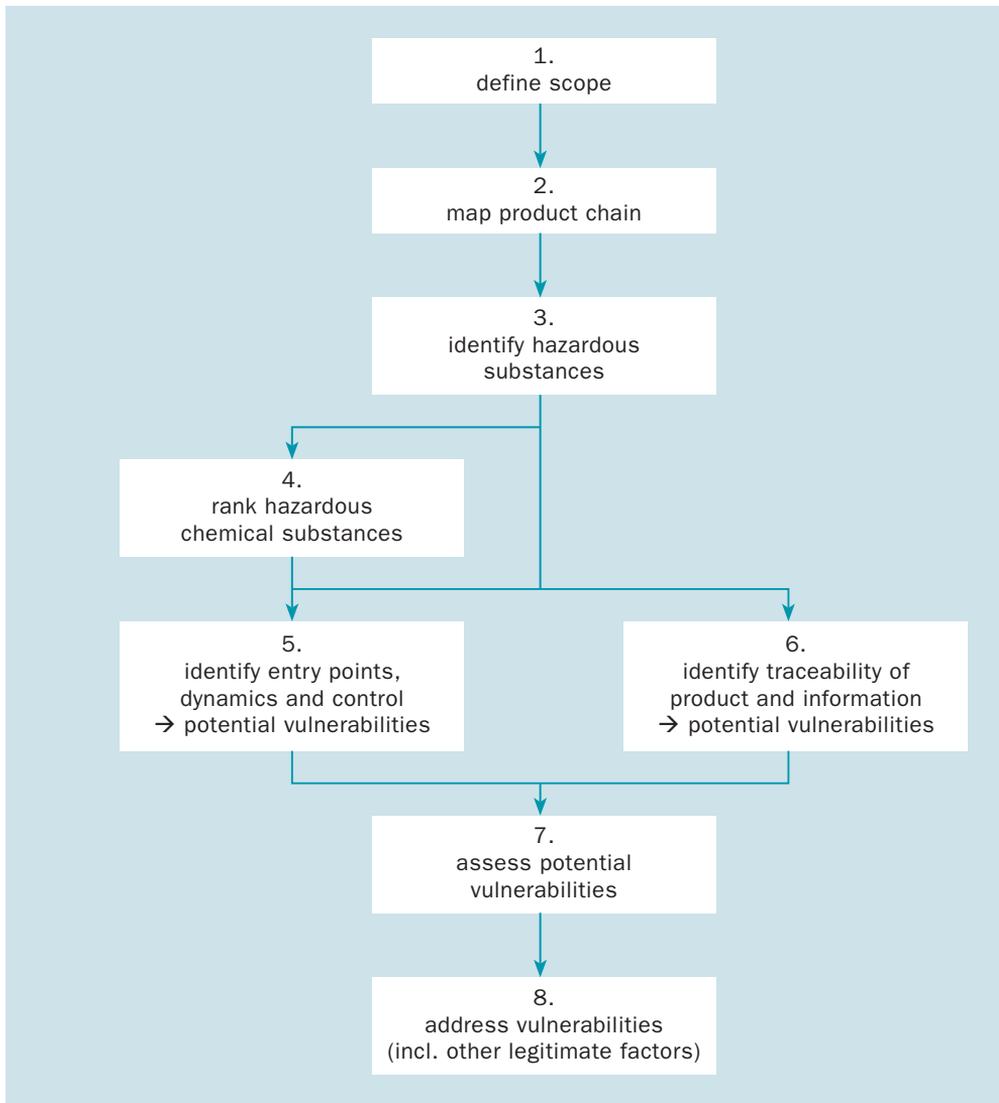


Figure 1 Basic scheme of the process for identification and assessment of vulnerabilities in food and feed chains

The respective steps in the process for identification and assessment of vulnerabilities are elaborated in eight How to Guides, for which a common format is used. Each step starts with an explanation of the objective and the required input. Then, the process is described and at the end the output is defined.

How to Guide 1

Define scope

The objective is to define the scope of the chain vulnerability assessment.

1.1 Input

A food business needs:

- the company's senior management commitment and support to the chain vulnerability assessment team;
- to be open minded towards risk management in the food chain;
- a reason for assessment, e.g. food safety legislation, results from internal and external audits, customer needs or complaints, responsibility for consumer's health, etc;
- to define, by the chain vulnerability assessment team, specific products and/or processes that are the subject of the chain vulnerability assessment.

All relevant information needed to conduct the chain vulnerability assessment needs to be collected, maintained, documented and updated. The food business will ensure that the chain vulnerability assessment is based on comprehensive information sources, which are referenced and available on request. This may include the following types and sources of information.

Internal:

Available information of the food chain from the Food Business Operator (FBO) about:

- technical flow charts of production processes;
- supply chain maps;
- HACCP plans;
- quality assurance (QA) systems;
- expert knowledge of responsible persons in the food business.

External if required:

- available information from suppliers;
 - expert knowledge of persons or consultants involved in the given food chain and/or food safety;
 - customer requirements;
 - existing and/or published production flow charts and chain maps;
 - historical and known hazards associated with specific food products;
 - monitoring data on concentrations of contaminants in food, and, if available, exposure data;
 - legislation and regulations of products and processes throughout the chain, where relevant including those of countries of origin, transfer and destination;
 - generic QA systems;
 - recognized guidelines, e.g. codes of practice, best manufacturing practices (BMP);
-

- guidelines/newsletters of national and international Food Safety/Control Authorities, scientific institutions and professional associations;
- recall notices and alerts from national databases;
- alert internet services and daily press in order to identify emerging hazards;
- latest scientific literature or other internet information through general search.

A list of information sources (not exhaustive) is in Annex 1.

It should be noted that the extent and content of legislation and regulations in force depend on the particular time the assessment is performed. It is important to be aware of this and document the dates of searches, using consolidated legislation. The user must also become acquainted with rapid alert systems, notifications and other systems that individual countries and the European Commission (EC) may have in order to address (novel) harmful substances and contaminants. Such substances may or may not be addressed by standard legislation.

1.2 Methodology

1. Organize an assessment team encompassing all necessary skills and knowledge covering the full chain

Establish contacts or a network outside the FBO/company to cover the whole chain.

2. Make an inventory of cases/items that give reason for a vulnerability assessment and discuss these

3. Identify the products, main processes and process steps that are to be included in the assessment and decide on the scope of the assessment

4. Determine which information sources are needed based on the scope defined

5. Identify gaps in your own expertise and get help from experts in the field where relevant

1.3 Output

The scope of the assessment, i.e. [product] x [chain] combination, should be laid down, clearly defined and not ambiguous. It is the starting point for the identification of vulnerabilities and their assessment.

Example of a scope:

We, company X, want to assess the vulnerabilities associated with the poultry chain, from breeding chickens in Brazil up to, and including, retail sales of chicken boneless breast meat in Germany.

How to Guide 2

Chain mapping

The objective is to map the food chain based on the scope defined.

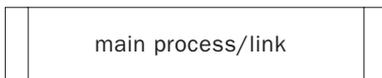
2.1 Input

Detailed knowledge is needed about the technical aspects of the food chain, such as raw materials, products, processes, procedures, storage, transport, food contact materials, in order to map the respective food chain and to identify and select relevant contaminants, as well as their entry points later on.

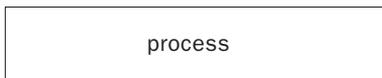
Information can be collected from the sources as listed in How to Guide 1 and Annex 1.

The actual level of breaking down the information must be sufficient to identify vulnerabilities in the food chain and is to be decided in accordance with the set scope. Criteria for chain maps are the relevance for the given problem as well as the given food chain, consistency of inputs and outputs, potential entry points of contamination etc. The minimum level of detail should allow drawing a logical, consistent chain map.

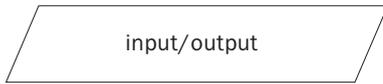
Chain maps should preferably be drawn using the flow chart symbols, as generally applied in HACCP Recommended symbols (ISO 5807:1985) are:



A *link* or *main process* in the food chain can usually be seen as a production plant or an economic activity. An individual process or a combination of several links can be a food business, i.e. any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of production, processing and distribution (including transport) of food. Examples of a link in a food chain are a slaughterhouse or a producer of compound feed.



A *process* or *process step* is an individual method, event or unit operation within a food chain link that results in a transformation of the respective product. Examples are heating, de-boning, evaporating, slicing, and (internal) transport.



Input and *output*, respectively. Inputs are any ingredient, processing aid, packing material, disinfection agents, etc entering the chain at an individual process step or used/ utilized at an individual process step. Outputs are any waste, side product, used processing aid leaving the chain at an individual process step.

2.2 Methodology

1. Note each main process/ link of the food chain and generate a generic overview of the given food chain in a chain map
2. Distinguish individual process steps for each link or main process
3. Generate an overview of these respective process steps in detailed chain maps
4. Add inputs and outputs
5. Carry out a verification of the chain map, e.g. on-site, via literature or experts

2.3 Output

The result is a detailed map of the chain as defined in the scope, giving a clear description of the food chain, and (preferably) a generic overview of the whole chain.

The chain map has to be appropriately detailed, clear and relevant. The resulting chain map should allow identification of contaminants entry points, to follow the contaminant's dynamics through the chain and to allocate all relevant information.

Generic and detailed chain maps are illustrated in Figures 2 and 3.

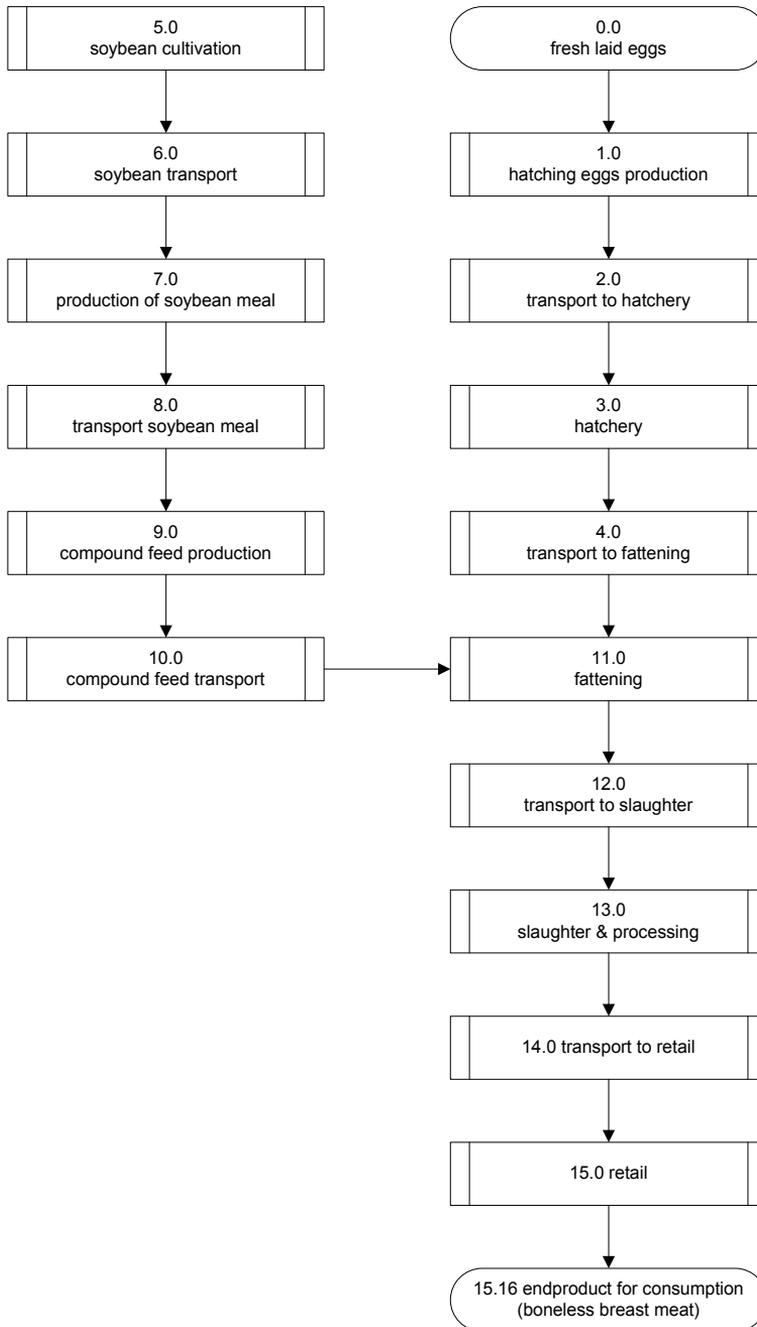


Figure 2 An example of a generic chain map for poultry meat production. Step 11.0 is elaborated into a detailed chain map (see Figure 3)

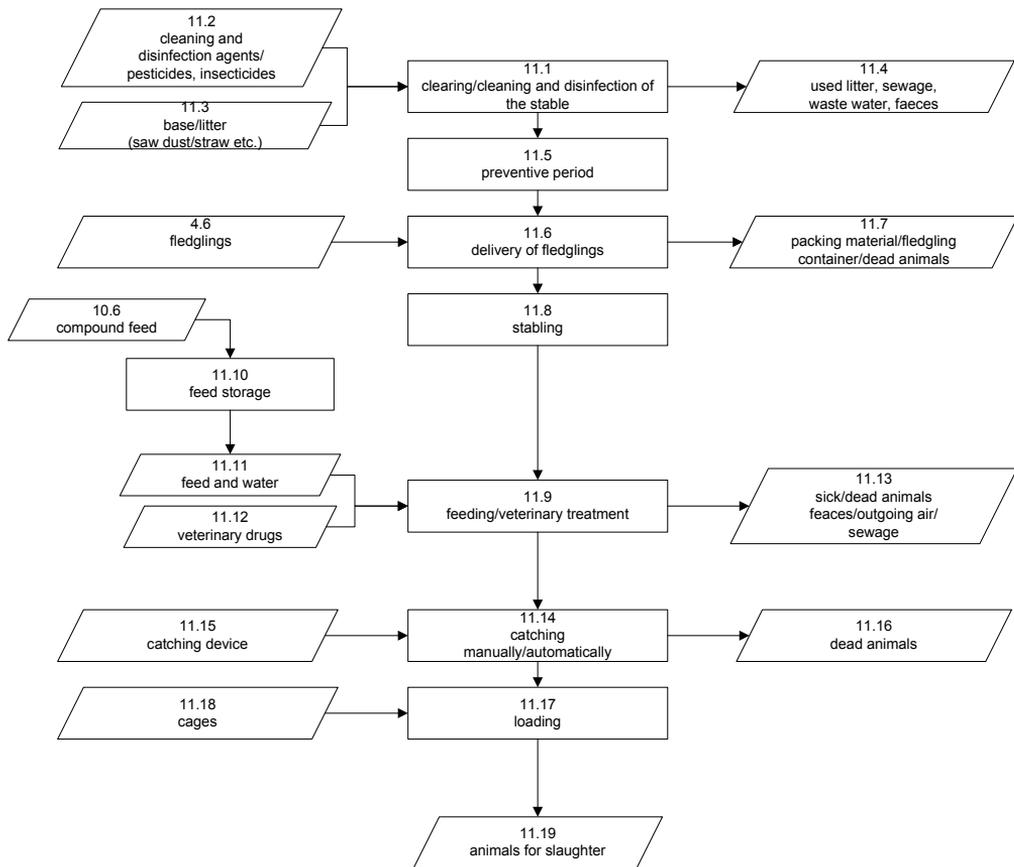


Figure 3 An example of a detailed chain map for the fattening of chicken (Elaboration of step 11.0 of the generic chain map in Figure 2)

How to Guide 3

Identification of hazardous substances

The objective is to identify hazardous substances that might be a risk for the consumer and to classify them based on the scope defined.

3.1 Input

Use the information sources as listed in How to Guide 1 and Annex 1 in order to identify the hazardous substances.

3.2 Methodology

1. Generate a list of relevant hazardous substances, within the scope defined i.e. [product] x [chain] combination

The criteria for identification of hazardous substances are that they:

- must have been shown to be directly or indirectly associated with the food chain or;
- are, or have the potential to become hazards in the food chain (even if they are not or are not yet considered as such currently).

Potential or existing hazardous substances are identified using documented evidence, expert opinions and best practices.

The elaborated chain, together with common sense, can be used to identify potential or unforeseen hazardous substances and contaminants, for example previous cargo loads in ships being used for transportation.

Together with information about the hazardous substance, in most cases there will also be information available about the possible sources of contamination, and information about interactions with other contaminants. Whenever available, this information can be recorded in a database with any other information available for the identified substance.

2. Classify the hazardous substances according to type

Chemical substances

Consider:

- toxins, mycotoxins, pesticides, antibiotics and other veterinary drugs, dioxins, PCBs, volatile organic compounds, PAHs, heavy metals, etc.;
 - the nature of regulation for these chemical substances (see How to Guide 4).
-

Biological substances

Consider:

- the type of (micro)organisms (bacteria, viruses, parasites, fungi, ...);
- pathogenicity;
- the ability of biological contaminants to produce toxins, and under what conditions. Control measures differ depending on these characteristics (see also How to Guide 5);
- regulation of these biological substances.

Physical substances

Consider:

- product foreign particles arising from processing, coming from the supply chain (e.g. sand, stones), and other foreign material like glass or metal particles, cigarette butts, etc.;
- regulation of these physical substances.

3.3 Output

The result is a list of classified hazardous substances and contaminants that may occur in the [product] x [chain] combination, i.e. contaminants of concern.

NB: the list of hazardous chemical substances can be huge. Therefore, before identification of entry points, dynamics and control of contaminants, an intermediate ranking of hazardous chemical substances can be done as an initial priority screening. This can be an essential activity if the resources required for the assessment are to be minimised. If this assessment is carried out on all identified contaminants within the process, it may take up a lot of resources.

The requirement to rank hazardous biological (and physical) substances is not as significant as the requirement to rank hazardous chemical contaminants, as generally the number of bacterial pathogens is much smaller than the number of chemical contaminants associated with a particular foodstuff. For most products there is also a well established body of (expert) information to derive a listing of biological hazards of significance for a particular product.

How to Guide 4

Ranking of hazardous chemical substances

The objective is to rank hazardous chemical substances.

4.1 Input

Use the list of classified hazardous chemical substances (from How to Guide 3) and information sources as listed in How to Guide 1 and Annex 1.

4.2 Methodology

1. Assess the legal status of chemical substances

Consider:

- prohibited substances;
 - authorised substances, e.g. veterinary drugs, pesticides;
 - regulated substances, e.g. through legal limits such as maximum residue levels (MRL);
- If the substance is not prohibited, authorized or regulated, then label the substances as 'other'

2. Identify health advisory values for all chemical substances

Consider e.g. tolerable daily intake (TDI), provisional tolerable weekly intake (pTWI) for all categories.

NB: If there is no health advisory value, the substance is a potentially high ranking hazard.

3. Calculate the ranking score of the chemical substance if a health advisory value exists

The ranking score can be expressed as follows:

$$\text{Ranking score} = [\text{exposure intake}] / [\text{health advisory value}]$$

4. Categorise the chemical substances from the full list primarily based on their legal status and ranking score

5. Note if other considerations or remarks have to be taken into account

Consider e.g. zero tolerance policies on prohibited substances. The substance may then be a potentially high ranking hazard based on qualitative issues.

6. Identify those contaminants which can be used for further assessment

Consider the evaluation and remarks from steps 1-5 together with information of the FBO and/or experts, and literature.

NB: a fixed limit for yes/no further consideration cannot be given. This depends among other factors on the scope defined and resources available for the assessment.

4.3 Output

The result is a list of categorized chemical contaminants of concern, that may occur in the [product] x [chain] combination, including a ranking score based on their legal status and health advisory value.

The categorization of chemical contaminants of concern is illustrated in Table 1

Table 1 Ranking of chemical contaminants of concern (fictitious)

CHEMICAL CONTAMINANT	CATEGORY	HEALTH ADVISORY VALUE	RANKING SCORE	COMMENTS
Contam-bdf	0.8	
Contam-mjh	0.6	
Contam-unj	regulated	available	0.4	
Contam-yrd	0.2	
Contam-eku	0.05	
Contam-kfn	prohibited	available	0.03	'Zero tolerance' on prohibited substance; so even though it has a low ranking score it is to be categorised as high ranking
Contam-emz	0.01	
Contam-hgr	not possible	No exposure data available
Contam-gfd	...	none available	not possible	Carcinogen with no ADI

The addition of the 'comments' column allows qualitative issues to be raised and so flag contaminants that should be categorised as high ranking contaminants even though there may be a lack of data to allow the ranking process to be carried out. Highlighted (■) chemical contaminants need to be categorised as high ranking or at least requiring further consideration or scenario analysis.

How to Guide 5

Contaminants of concern in the chain: entry points, dynamics and control

The objective is to identify entry points, dynamics and control of contaminants of concern in the chain.

5.1 Input

Use the output of How to Guide 2: the chain map and related information on processing, and the output of How to Guides 3 & 4: the contaminants of concern. In order to review dynamics and (current) control of the contaminants of concern information should be collected from the sources listed in How to Guide 1 and Annex 1.

5.2 Methodology

1. For each contaminant of concern identify entry points in the food chain

Consider:

- information on possible interaction with other contaminants as it is of relevance to identify and follow a contaminant in a chain;
- the preceding and following steps in the food chain.

Criteria for contaminants entry points or entry route are:

- that they must have been shown to have occurred in a real life case or;
- to have a clear potential to be an entry route, even if it has not been occurred in real life.

2. Identify the dynamics of the contaminants (e.g. growth, spreading, reduction, and exit routes) in the actual situation with current control measures in the food chain. Thus identify the possibilities for control of the respective contaminants in the actual situation (e.g. prevention, elimination or reduction)

Consider:

- survival of micro-organisms of concern throughout the process chain in case no current kill step (cooking/smoking/drying/chlorine wash/etc) is applied in the process;
 - multiplication of micro-organisms of concern especially at process steps that involve a 'delay' or storage step. Remember that all chilled/frozen/transport storage steps may fail if the power source fails and must be considered as a potential 'growth' step;
 - presence of toxins within the product from using contaminated raw materials;
 - further production of toxins within the process chain. Micro-organisms of concern can produce toxins depending on the conditions like humidity, temperature, and so on. The conditions under which the toxins will be produced will be very specific and vary greatly from one
-

micro-organism to the next. A detailed understanding of each micro-organism and the conditions required for toxin formation is essential;

- if the process uses any product as ‘rework’ from one batch to the next batch, consider the potential risks from among others the use of rework product-allergen cross contamination, transfer of (chemical) contaminants, growth of microorganisms, survival or toxin production;
- if there is any process step within the process where the contaminant can be controlled by adequate known control measures;
- if there is any step within the process where the contaminant can be reduced or eliminated by using known adequate corrective actions.

3. Identify where in the process the contaminant of concern is currently being tested for in relation to entry points and dynamics and identify where in the process it thus can be detected and therefore controlled

Consider:

- the adequacy of monitoring plans available at among others the company to get detailed knowledge on presence of contaminants in the food chain, the type of analytical method used, limit of tolerance, number of samples, and analysis results;
- if there is any step within the process where the contaminant is tested for in a laboratory by using appropriate analytical techniques;
- if there is any step within the process where the contaminant is tested by other means of monitoring or control i.e. visual/sensory evaluation, pH, water activity, temperature change etc.;
- records being kept from analysis results;
- information with regard to test/analysis results being made available to others, elsewhere in the food chain;
- note any contaminants that are not tested for. Ask why these contaminants are not tested for. Reasons might include cost, lack of method, lack of laboratory facilities, lack of risk of hazard occurring, etc.

Table 2 Example table. Identification of potential vulnerabilities in the milk powder chain

PRIORITY CONTAMINANT	CONTAMINANT ENTRY POINT: STEP NO.	CONTAMINANT PRESENCE, MULTIPLICATION OR ACCUMULATION: STEP NO.	IS THE CONTAMINANT CURRENTLY TESTED FOR Y/N
<i>Enterobacter sakazakii</i>	Via: processing environment. Step 3.19 (spray drying)	Yes (multiplication)	No
<i>Listeria monocytogenes</i>	Via: Raw milk. Step 3.1 (raw milk)	Yes (multiplication)	Yes
Lead	Via: Raw milk. Step 3.1 (raw milk)	No	Yes

4. Assess historical data against own standards including legal requirements

Consider:

- trend analysis whether or not contaminants exceed the standard(s);
- hygiene, i.e. aspect of control: trend analysis whether or not hygiene requirements for the process or product exceed the standard(s).

5. Identify potential vulnerabilities at the respective process steps on the basis of steps 1 to 4

Consider:

- the specific process step where the contaminant enters the chain;
- the dynamics and current control within the subsequent process steps;
- the contaminants of concern which are not tested for or otherwise not likely to be detected within the current process;
- the control measures in place for contaminants which are not tested for;
- the process steps in the food chain with multiple input of contaminants.

5.3 Output

The result is a list of potential vulnerabilities at process steps identified based on the entry points of the contaminant, its dynamics and where and whether or not this contaminant is under control given current practices, including testing.

An example of the identification of potential vulnerabilities is illustrated in Table 2.

TESTING STEP NO.	DETAILS OF TESTING (ROUTINELY TESTED, ON REQUEST ETC.) Y/N	ANALYTICAL METHOD AVAILABLE - Y/N
N/A	No	Yes
Step 3.6 (milk intake and batch mixing); Step 3.27 (skim milk powder)	Yes	Yes
Step 3.27 (skim milk powder)	Yes – Tested yearly or biannually through National residue monitoring plan.	Yes

How to Guide 6

Traceability of product and information in the food chain

The objective is to consider the information of the origin, history and process activities of the product along the chain in order to identify the potential for loss in information and traceability which may result in vulnerability.

6.1 Input

Detailed knowledge about each step in the food chain is needed. Use the chain map from How to Guide 2 and collect additional information from the sources listed in How to Guide 1 and Annex 1.

This should include an assessment of supplier information and traceability, of internal information and traceability and of the distribution of products to customers.

6.2 Methodology

1. Identify and review the adequacy of available information on the raw materials and ingredients, including packaging material. Distinguish between origin of materials, products in process, and finished and distributed products

Consider:

- are all supply possibilities known and documented;
- is there a supplier approval procedure, is it adequate and is it followed;
- is there information on contractors to suppliers;
- additional service providers that may have an impact of food safety.

2. Identify and review the adequacy of available information of activities at each step in the chain which may support the safety of product

Consider:

- is there an adequate recording and documentation system in place;
 - are records legible, accurate and retrievable – consider specifically records relating to HACCP – Critical Control Point monitoring, verification and validation;
 - supplier specifications and verification records;
 - monitoring programmes intended to verify the safety of supplies, in-process and finished products.
-

3. Identify and review the responsible parties and transfer of ownership of product

Consider:

- all responsible parties at each process link in the chain, external and internal;
- responsibilities of the distribution and warehousing steps- is there potential for product abuse, loss of identity through mixing or contamination from other materials.

4. Identify and review the adequacy of information from suppliers, within the organisation and to immediate customers

Consider:

- the response time of suppliers and your response time to internal requests and customers;
- the accuracy and suitability of information at verifying the traceability and traceability of product from suppliers, within the organisation and to immediate customers;
- the presence and adequacy of emergency/contingency plans of suppliers, your organisation and your customers.

5. Evaluate the legal compliance of traceability systems within the organisation, of suppliers and of customers

6. Where feasible conduct a simulation of traceability requests and recall procedures to validate the findings from this How to Guide

6.3 Output

The result is the identification of vulnerable steps in the food chain associated with the absence of information that will reduce the ability to trace the product or confirm/verify the safety of the products supplied.

A loss or lack of traceability within a feed/food chain does not in itself have a potential to cause consumer harm. As a consequence, examples of vulnerability of chains to inadequate traceability must be linked to a potential contaminant of food safety concern.

How to Guide 7

Assessment of potential vulnerabilities

The objective is to assess the potential vulnerabilities and determine the priority (number) of the individual vulnerabilities.

This is the crucial step to arrive from the data analysis of chain maps, contaminants, document flows and procedures to vulnerabilities. The challenge is to rank the different types of potential vulnerabilities into priorities to be able to support food businesses operator in making risk management decisions.

7.1 Input

Use the result of How to Guide 3: the contaminants of concern, the result of How to Guide 5: potential vulnerabilities per process step identified based on presence of contaminants and whether or not these are controlled, and the result of How to Guide 6: potential vulnerabilities associated with loss of information.

In addition, use ratings for Severity, Likelihood and Detectability as given in Table 3.

7.2 Methodology

- 1. List the process steps with potential vulnerabilities based on entry and/or presence of contaminants and whether they are controlled or not based on current control measures**
Use the information collected in How to Guide 3 to complete the assessment table.
 - 2. List the process steps with potential vulnerabilities based on assessment of traceability of product and information and tags**
Use the information collected in How to Guide 5 to further complete the assessment table.
 - 3. Assess the Severity (Sev) of the potential vulnerabilities**
 - 4. Assess Likelihood (Lik) of the potential vulnerabilities**
 - 5. Assess Detectability (Det) of the potential vulnerabilities**
 - 6. Calculate the Vulnerability Priority Number (VPN) for each vulnerability**
The priority number is the product (between 1-150) of multiplication factors for Severity x Likelihood x Detectability.
-

Individual vulnerabilities are now ranked according to priority number. All vulnerabilities that have an individual high rating in either severity (8 and 10), or likelihood of occurrence (5, sometimes 4), or a likelihood of detectability (3) need further investigation or addressing, no matter what the rating in the other factors is.

7.3 Output

The result is that the vulnerabilities are prioritised based on assessment of severity, likelihood and detectability.

Examples of the assessment table are given in How to Guide 8, Tables 4 and 5.

Table 3 Ratings for severity, likelihood of occurrence and detectability

SEVERITY	
10	Immediate effects and/or serious effect on health, including precautionary principle application
8	<ul style="list-style-type: none"> Effect on human health is expected at relevant (possible) exposures and the effect is serious, including prohibited substances / fraud Loss of information
5	<ul style="list-style-type: none"> Effect is expected but not serious =curable disease or longer term (slight) discomfort. Possible loss of information
3	Effect is not expected, but if occurring effect is curable disease (though not serious)
1	No impact expected at all
LIKELIHOOD OF OCCURRENCE	
5	Occurs on a frequent basis, historically shown
4	Can occur frequently
3	Can occur
2	Will probably not occur
1	Will not occur (circumstantial exceptions accepted)
DETECTABILITY (LIKELIHOOD OF DETECTION)	
3	Unlikely to be detected: no procedure is applied (not procedurally covered vulnerability)
2	Possibly detected: procedure applied but reliability and frequency not appropriate or not known
1	Likely to be detected: procedure applied frequently and is reliable (enough) → Needs substantiation!

$$\text{Vulnerability Priority Number (VPN)} = \text{Severity} \times \text{Likelihood} \times \text{Detectability}$$

Severity

Severity is the rating of the hazard associated with the vulnerability, in the sense of damage to public health. For this assessment it may be necessary to use toxicological or other scientific data for which professional assistance might be useful. Severity of chemical hazards might have been assessed already to some extent in How to Guide 4.

A serious effect (ratings 8 to 10) is:

- actual disease, curable but disabling for more than a few days;
- longer term illness;
- injury (physical contamination);
- effects on organs or physiological systems that may show only after a longer period (including mutagenicity, teratogenicity, carcinogenicity, etc).

If information loss is identified as vulnerability, severity will be rated 8 or possibly 5. Since the direct hazard resulting from information loss is often not known, the uncertainty implies a higher severity.

The severity scale ranges from 1 to 10, but not every number has been defined. Any number can be used however based on subjective or qualitative judgment. An example is that some chemicals arouse more suspicion than others, while the objective data are practically the same.

Likelihood of occurrence

The likelihood of occurrence indicates the frequency of a vulnerability event happening. The frequency can come from either case history or careful data analysis. Please remember that past performance is no predictor for the future, only indicative, so one should stay alert. Occurrence is not the likelihood of exposure, which is addressed earlier and is related to severity. Occurrence is largely independent of severity or exposure. Occurrence is the frequency of exceeding the Health Advisory Value or comparable practical values.

The scale here has 5 defined points. To substantiate the rating data sharing within sectors or branches, or the chain, will have added value. Be aware that data of occurrence can be geographically unevenly distributed.

The subtle difference between ratings 2 and 1 lies in the measures already in place. If specific control or corrective measures for reduction or avoidance (i.e. not testing) are in place, rating 1 can be applied. Testing procedures do not influence occurrence. Any measure obviously can fail and this is acceptable. Recognition or detection procedures at a certain point in the chain can cover that.

Rating 1 will in practice in this guide be of no practical value because the rating is performed for potential vulnerabilities already identified.

Detectability

Detectability or likelihood of detection/recognition refers to whether the vulnerability or event happening will be noticed or detected given the current control measures. Factors to include here are whether any method or procedure is applied, the procedure's reliability and frequency of application. There is a 3-point scale for detectability.

Frequency of application is interdependent with likelihood of occurrence. It is either given in time or number of batches, related to production volume.

Rating 1 will in practice in this guide be of no practical value because the rating is performed for already identified potential vulnerabilities.

In most current procedures for ranking (such as HACCP) this likelihood of detection factor is not used. It adds value however because it assists prioritisation to focus on the vulnerabilities 'less' covered.

How to Guide 8

Address vulnerabilities

The objective is to address the vulnerabilities by identifying a set of control measures for reduction or elimination of vulnerabilities.

8.1 Input

Use the list of prioritised vulnerabilities identified in How to Guide 7. These vulnerabilities will be addressed using additional information from the sources listed in Annex 1 for identifying options for better or more advanced control measures.

8.2 Methodology

Review the priority of the vulnerabilities

- 1. Review the vulnerabilities starting with the highest priority number**
- 2. Always review vulnerabilities with a high individual score even if the priority number is not that high**
Consider severity scores 10 and 8, likelihood score 5 and detectability score 3.
- 3. Review the assessment table and identify those process steps that have multiple vulnerabilities**
Consider e.g. process steps with multiple contaminants not controlled. Accumulation of vulnerabilities may result in weak links in the chain. Those process steps may need extra attention.
- 4. Review vulnerabilities that relate to the same problem**
Consider e.g. contaminants that occur at multiple process steps.
- 5. Review the specific notes and remarks made per process step and/or per vulnerability when reviewing the process at the food business**
Consider additional information which is not in the assessment tables, and take into account the results of the assessment of the regulatory status, i.e. qualitative assessment of the outcome of the steps above.

Identify control options in order to reduce vulnerabilities

- 6. Review Best Manufacturing Practices to identify additional control measures**
Consider BMPs and other information sources and experts (see Annex 1) to identify whether or not additional control measures or corrective actions are available that could be applied in order to reduce or eliminate the vulnerability due to presence of contaminants. Document results in the assessment table (see Table 4 as example).
-

7. Review analytical techniques to identify if other/additional methods for analysis of contaminants in a specific product matrix are available that could be applied

Consider the information sources and criteria as listed in Annex 2.

8. Review other possible methods of product tracking available

Consider:

- methods being used in another industry with similar processing conditions;
- paper tags (with or without RFID or other readable information), paper labels on cartons (with or without RFID or other readable information), embedded electronic micro chips or other biological tracing systems (lipids, proteins and DNA).
- Any such identification method must have been shown to have been used within this food chain somewhere in the world and to have a clear potential to be used within this food chain, even if it has not currently been the case within the industry.

9. Determine new values for likelihood and detectability

Consider the new measures and determine new values for likelihood and detectability – severity remains the same – according to the procedure described in How to Guide 7. Take into account that applying new measures in order to reduce a/one vulnerability may have an effect on other vulnerabilities in the same process step or in other process steps, e.g. heating kills several pathogens.

10. Calculate the NEW Vulnerability Priority Number (VPN) for each vulnerability

11. Review the NEW VPNs and assess if the new control measures give enough effectiveness

If this is not the case, start again with step 6 (the review above).

12. Consider the need for a safety assessment

In case no legislation/regulation applies and vulnerabilities were identified, the need for a safety assessment for the presence of contaminant x in product y at level z needs to be considered.

8.3 Output

The result is a list with prioritised vulnerabilities and a set of (optional) control measures for reduction or elimination of vulnerabilities.

In the end the food business needs to consider the respective options together with additional information regarding costs and benefits of the respective control measures, taking into account stakeholders' views and other legitimate factors, in order to set his risk management policy and take risk management decisions.

An example of the other legitimate factors is: consumers want GMO free products, while current scientific assessment indicates that GMOs as such are no risk to the consumers' health. The food business may then decide to take measures in the field of communication strategies to show that they are aware of consumers' concern.

Examples of vulnerabilities and their priorities related to contaminants and loss of information in the water chain and the salmon chain are given in Tables 4 and 5.

Table 4 Assessment table. Example illustrating the assessment of some potential vulnerabilities related to contaminants in the water chain

NO. OF POTENTIALLY VULNERABLE CHAIN STEP	DESCRIPTION OF CHAIN STEP	POTENTIAL FAILURE (contaminant name or tag/ documentation failure)	CAUSE OF FAILURE	1. SEVERITY (SEV)
116	Distribution network	Lead	Corrosion of pipework	8 Lead is a cancer causing agent
111	Water storage after disinfection step with chlorine (111)	Trihalo-methanes (THMs)	Prolonged storage	3 THMs family members are human carcinogens

Table 5 Assessment table. Example illustrating the assessment of some potential vulnerabilities related to contaminants and loss of information in the salmon chain

NO. OF POTENTIALLY VULNERABLE CHAIN STEP	DESCRIPTION OF CHAIN STEP	POTENTIAL FAILURE (contaminant name or tag/ documentation failure)	CAUSE OF FAILURE	1. SEVERITY (SEV)
5.2	Feeding	Melamine (emerging chemical contaminant)	Entry through fish feed ingredients manufacture	8 Whilst little data on transfer from feed to humans Melamine and derivatives can cause liver/organ damage
10.5	MAP/Tray packing	Documentation failure/loss in traceability	Inadequate traceability of individual packs/ production to harvest batch	10 Precautionary principle applied, assuming worst case scenario regarding consumer health

2. LIKELIHOOD (LIK)	3. DETECTABILITY (DET)	VPN 1	NEW CONTROL MEASURES THAT COULD BE PUT INTO PLACE	1. SEV	4. NEW LIK	5. NEW DET	VPN 2
2 Remote occurrence: may occur once a year or more	1 Contaminant regularly tested within industry	16	- pH correction - Use of Orthophosphate - Pipework replacement	8	1	1	8
2 Remote occurrence: may occur once a year or more	1 Contaminant regularly tested within industry	6	- Reduced storage period	3	1	1	3

2. LIKELIHOOD (LIK)	3. DETECTABILITY (DET)	VPN 1	NEW CONTROL MEASURES THAT COULD BE PUT INTO PLACE	1. SEV	4. NEW LIK	5. NEW DET	VPN 2
3 Although isolated in salmon chain has occurred in other chains on occasional basis in 2008	3 No detection procedure is routinely applied.	72	Increased control on supply of feed raw materials. Risk assess supply chain, control supply chain. Surveillance testing of purchased materials	8	2	2	32
3 Occasional event: 1 per month	2 Annual traceability and mock recall audit	60	Improved traceability system applied to pack- allowing traceability to harvest batch and production time. Increased internal audits – quarterly traceability and mock recall to test and refine procedures	10	2	2	40



VULNERABILITIES IN THE FOOD CHAIN

A STAKEHOLDERS' GUIDE

Part II

Theoretical background
and perspectives

1. Global perspectives on food production

Nelson Beraquet, Mariana Castrillon (ITAL, Brazil)

Internationally-traded food products are part of our daily life. The water we drink may be bottled in one country and sold to consumers in another. Even if the meat we eat is produced domestically, there is a great chance that some element in the feed composition has originated from a distant country or region. Just as consumers do, stakeholders in the food industry are currently forced to deal with transnational concerns on a daily basis in order to avoid loss of consumer trust, government sanctions, and economic losses.

The longer distances transnational products have to travel before reaching the consumer means that they spend longer periods of time being transported and in storage, both factors which might increase the risks of pathogen growth and food spoilage. In order to reduce these risks, stakeholders and food chain actors must develop logistic planning that allows for the shortest possible storage and transportation times, equipment that allows for the maintenance of optimal storage and transportation conditions, and reliable recording of all processes and transactions.

Another critical concern relates to international trade spreading contaminants, which can harm both human and animal health, and which has the potential to severely affect a country or region economically. Transnational food products have the potential to spread pathogens and substances that are either foreign or previously controlled in other countries or regions. This occurred in the case of the worldwide concern regarding the spread of Foot and Mouth disease, Bovine Spongiform Encephalopathy (BSE), and Avian Influenza. In order to avoid international spread of contaminants, Food business operators (FBO) must always keep track of the origin of raw materials and ensure that there is compliance with legislation and policies regarding contaminants in all countries involved in the production chain. It is also important that due account of differences in national legislation is taken into account. It is strongly recommended that stakeholders work with Best Manufacturing Practices (BMP) and maintain a strict control of contaminants through reliable and frequent analytical detection tests.

Food producers have to demonstrate that their product is safe, both domestically and internationally, in order to be able to sell it. Certificates are used for this purpose and are provided by third-party organizations, for example the audit standards established by the International Organization for Standardization (ISO). In order to be certified, FBOs must be able to provide records that demonstrate compliance with laws and regulations, and that they have followed procedures such as those of BMP and HACCP. Certificates are intended to provide assurance that the information provided by the producer is correct. Many government agencies provide certification of compliance with their own domestic regulations. In addition, government agencies

in certain importing countries also inspect products while still in their country of origin, checking for compliance with their own sanitary requirements. Very often, transnational companies have inspectors to audit sanitation, animal welfare and product quality in the plants of their suppliers abroad.

Tracking and tracing are important in all chains but are particularly important for transnational ones. There must be a strict control of all raw materials and processes used, as well as a rigorous control of the transportation and storage conditions, to the point where the product reaches its final destination. Recent technical advances, such as RFID, have increased the volume of information and detail that may accompany the product to its final/following destination. It is important to know where ownership/responsibility for the product begins and ends (for instance, once the product is on board a vehicle for transportation, the responsibility for the product integrity usually lies with the carrier). The paper flow accompanying the product must provide means of finding this information, or provide it. (See also section 5).

Consumer confidence in the food they buy may be raised by certification and by tracking and tracing procedures. It has been demonstrated that consumer groups are able to bring pressure onto governments in terms of issuing legislation, (as was the case in the 1989 European Union ban on animal growth hormones). Also consumer confidence can affect the sales of a specific product positively or negatively. Consumer shopping habits, cultural differences and country-specific concerns in the destination country must also be addressed, as these may affect the type of certification required and/or the type of information printed on the package, for example.

FBOs should get information about the relevant legislation, technical requirements and economic policies that might represent trade barriers in each of the countries involved in the production/distribution of the product. Economic policies, such as those regarding interest rates, labour force, and taxes, must be taken into account for all countries involved. Economic and commercial agreements among all involved countries must also be considered. FBOs should be aware of international guidelines such as those provided by the WHO and standards such as those provided by the Codex Alimentarius Commission (Codex). In some cases an expert may be needed in order to overcome any difficulties with the interpretation of legislation, including problems in understanding language and/or jargon.

Information exchange among all FBOs, as well as between FBOs and consumers, is crucial. A language specialist may be needed in order to avoid misunderstandings, as well as to adapt product descriptions, for example, according to cultural/legislative preferences and requirements. It is worth mentioning that raw materials and products provided by vertically integrated businesses (integrated chains) are often more trusted, since such chains are better equipped for risk identification and communication.

2. Other legitimate factors and precautionary principle in food safety

Niels Lucas Luijckx (TNO Quality of Life, the Netherlands)

As for all kinds of decision making, food safety risk management decisions may incorporate all types of arguments. Some people might dismiss certain arguments used by others, either based on values or different perspectives on knowledge and information. In food safety discussions, in the Codex Alimentarius and in the EU it has become customary to use the term Other Legitimate Factors (OLF) to describe arguments for risk management decisions that are not directly food-safety related. These arguments might be based on social, economical, ethical or political considerations and may originate from governments, industry or consumers.

Risk management in food safety is the process of translating risk assessment data from the natural sciences into practical measures and policy. Risk analysis is the governance practice applied to food safety, and has been developed by international organizations such as Codex Alimentarius and FAO/WHO. Risk analysis comprises risk assessment, risk management and risk communication. This process starts with science providing data regarding the health impact of a risk (exact figures) which can be used by risk managers in decision-making. Practice is however more complicated, science might not be as exact as it is presented and it might not be completely value-free. Other types of arguments may have influenced the science-based risk assessment, and these will in turn influence any risk management decision.

Both Codex Alimentarius and the European Commission have produced papers, standards and legislation on this subject to allow for a systematic and regulated use of OLF in the food safety risk analysis process.

The pivotal word is 'legitimate'. If one can underpin the legitimacy of the argument, it can be used in the decision making process. The agenda or perspective of one party can colour the legitimacy, but it remains legitimate as long as it can be underpinned or sufficiently convincing. In the end all different (legitimate) arguments need to be weighed to reach a decision. An example of a societal argument: citizens or consumers can demand a producer to take (risk management) action although risk assessment (science) favours the producer by stating there is no / little appreciable risk. The argument of the consumer might be emotional or irrational from an assessment perspective. In view of business continuity, action can still be necessary (cf. the case of GMO ingredient contamination). Or, if a government takes an action, but the difference here is that for a producer legal compliance is the only option left.

Some of the other legitimate factors (source: Codex Alimentarius)

- Economic costs associated with the establishment of maximum levels of contaminants (by government) or quality systems (by producers) and methods of analysis
- General technical and technological need and feasibility
- Availability of resources to undertake analyses and enforce standards
- Prevention of environmental contamination through the use of Source Directed Measures
- The proper use of labelling to inform consumers about health and safety issues, to prevent them from being misled, or to respond to their concerns;
- Good Agricultural Practices
- Good Manufacturing Practices
- Consumer concerns related to the safety of food additives and contaminants
- Traditional, cultural, national and regional differences in food intakes and consumption
- The effects of processing on contamination of food
- Enforceability of maximum levels
- Control of pathogens
- Impact on nutrition
- Prevention of any practices that may mislead consumers and of unfair trade practices in international trade

2.1 OLF in the general food law

The EU has legalized the use of OLF in food safety through the general food law, Regulation 178/2002. This Regulation defines the crucial processes and responsibilities around food safety in the EU. In article 3 ('other definitions') risk management is defined as:

*.... the process, distinct from risk assessment, of weighing policy alternatives in consultation with interested parties, considering risk assessment and **other legitimate factors**, and, if need be, selecting appropriate prevention and control options.*

The wording and intention here is primarily directed towards governments and authorities, but it is clear that in risk management the EU recognizes OLF as a part of the risk management decision process, even an obligatory part. As written in article 6 on risk analysis:

*Risk management shall take into account the results of risk assessment, and in particular, the opinions of the Authority referred to in Article 22, **other factors legitimate** to the matter under consideration and the precautionary principle*

2.2 Precautionary principle

The EU has also introduced here a specific type of OLF: the precautionary principle, to be used when risk management decisions have to be taken quickly on the basis of (very) limited knowledge. This is, in particular, directed towards governments and authorities. The precautionary principle is mentioned in the considerations of the General Food Law as means for health (and life) protection in the case of scientific uncertainty associated with risk assessments.

The precautionary principle is laid down in article 7 of the General Food Law (GFL):

- 1. In specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment.*
- 2. Measures adopted on the basis of paragraph 1 shall be proportionate and no more restrictive of trade than is required to achieve the high level of health protection chosen in the Community, regard being had to technical and economic feasibility and **other factors** regarded as **legitimate** in the matter under consideration. The measures shall be reviewed within a reasonable period of time, depending on the nature of the risk to life or health identified and the type of scientific information needed to clarify the scientific uncertainty and to conduct a more comprehensive risk assessment.*

The key words here are 'provisional' and 'proportionate'. Further it appears clear that other legitimate factors have to be taken into account, when applying the precautionary principle, they are well interlinked.

As in any (risk) management decision, there needs to be a weighing of relevant (legitimate) factors, including technical risk assessment. In other words:

- any risk management decision may be interpreted as a form of precaution;
- every management decision is provisional until new factors (or information) arise or new evidence has been produced;
- any management decision requires review.

Both the precautionary principle and OLF are, or can be, used to take account of stakeholders' views, in particular those of the consumer, relating to food safety and associated concerns.

3. Stakeholder involvement, issues and concerns regarding vulnerabilities and contaminants in the food chains

Lynn Frewer, Swaroop Kher (Wageningen University, the Netherlands)

A stakeholder is generally defined as any individual, end-user or organisation who has an interest in a particular issue. It is important to take into consideration the views and concerns of relevant stakeholders in policy making as:

- stakeholders' issues and concerns represent indicators of policy demands;
- stakeholders' concerns help to identify useful insights, and values which may be included in the policy making process;
- taking stakeholder concerns into account may increase societal trust in risk management practices and the safety of the food supply.

3.1 Major stakeholders in the domain of food safety

Consumers represent major stakeholders with regard to food and food safety. Other important stakeholder groups include non-government organizations such as consumer associations, environmental groups, industry groups, individual food industries, policy makers, risk managers, risk assessors, risk communicators, public and private research organizations, and the media. All can be said to have a 'stake' in food safety.

In the context of the Sigma Chain project, an initial stakeholders' guide to identification of vulnerabilities of food chains to dangerous agents and substances was developed. In order to address stakeholder concerns, it is important to understand what these actually are. One of the activities in the Sigma Chain project focused on understanding consumer concerns regarding food chain vulnerabilities, together with their preferences for risk mitigation priorities. A second activity focused in understanding the views of food chain actors regarding food chain vulnerabilities, and the perceived relevance of the sigma-chain approach to mitigating any food safety problems. Taken together, the views of both consumers and food chain actors have been used to refine the stakeholder guide in line with stakeholder preferences.

3.2 Methods applied in understanding views of Sigma Chain stakeholders

Two widely used techniques were used in the sigma chain project to understand stakeholder views. Consumer views were understood using focus group methodology. Expert stakeholder views were captured through application of an on-line polling methodology, the Delphi technique. A brief overview of these two methods is presented here along with the advantages and

limitations to give an impression of the way such techniques are used in stakeholder research (see also Annex 3).

1. Focus Group studies

- Focus groups are a widely used technique in qualitative research. In the Sigma Chain project, they were to develop insights into consumer concerns about food safety, food chain vulnerabilities, and food and ingredient traceability;
- Focus groups are carefully planned discussions designed to obtain peoples views about an area of interest in a “permissive, non-threatening environment”;
- Focus groups share the following characteristics:
- Participants are recruited against a pre-defined criteria;
- A focus group involves about 8 to 12 participants who discuss their views and opinions about a particular topic under the directions of a moderator;
- The duration of a focus group is about 2 hrs;
- Open-ended questions are used to allow the participants to express their opinions, which would not be possible if closed questions were used;
- Focus groups are an efficient way to gather information about areas or topics about which little is known;
- Focus group data may be valuable in its own right, or provide the basis for development of surveys or other quantitative methodologies that can be used to investigate the opinions of more representative groups of individuals.

Advantages:

- Focus groups can be used to efficiently collect data from participants in a cost-effective manner;
- They provide a means of direct interaction between the moderator and participants. This allows for clarification and exploration of responses if needed;
- Respondents can react to other members of the focus group, and build upon their responses.

Limitations:

- The views of a small number of participants are analysed, and so their views are not representative;
- The results from the focus groups can be biased or influenced by the opinions of dominant members (although a good moderator should prevent this happening);
- The moderator may bias the results by providing cues about the type of responses desired (although this will not happen if the moderator is effective);
- Although the results are not representative in a statistical sense, the views expressed by participants could be typical for the particular target group included in the research, but this cannot be assumed.

2. The Delphi technique

- The Delphi methodology allows a group of individuals to consider complex problems. For example, through developing majority or minority consensus views within the group);
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- The primary objective of the method is to obtain a reliable consensus of opinion within a group of stakeholders or experts, or at least to identify where disagreements occur. Normally participants in the research answer questionnaires, which are presented in a series and combined with controlled opinion feedback. As a first step, a questionnaire, either structured or unstructured, is given to a group of individuals who have usually been identified as 'experts' in their field, or representative of the group of people whose opinions are required. Their responses are then collated and a second round questionnaire developed on the basis of their answers to the first round;
- The process is repeated for a pre-determined number of rounds or until pre-determined criteria for 'consensus' have been fulfilled. Sometimes the results are discussed at a 'workshop';
- The primary purpose is to reach consensus, or identify minority and majority views, about a particular issue or issues. Delphi can also provide insight into the extent to which a group or groups of people, for example expert and lay people, agree on a specific issue.

Advantages:

- The Delphi method represents an efficient way of obtaining consensus opinion across a wide range of issues;
- Iteration or replication of 'rounds' helps in obtaining consensus or opinions from participants without social pressure, because responses are anonymous;
- The method has the potential to gather large quantities of information if desired;
- Delphi methodology can be utilized as an alternative to group discussions to avoid the problems of social pressure and the influence of differences in participant status that these discussions may bring;
- More communication through feedback in successive rounds of questioning allows participants;
- to review and amend their opinions and responses.

Limitations:

- There is no formal definition of the meaning of 'consensus' – for example, it is not agreed how many participants must agree for consensus to be reached;
- The feedback from participants might not be fully interpreted or passed on to the other participants by the researcher, which might limit the results;
- Inclusion in a Delphi survey requires a relatively high commitment and contribution from the participants, especially when the number of rounds increases or the length of the questionnaire is considerable.

3.3 Concerns of Sigma Chain stakeholders

The stakeholders have been categorised here according to their type of 'expertise' (for example, as risk managers in the food industry, or primarily as risk assessors), or as consumers or non-expert stakeholders. The results suggest that risk perceptions and risk mitigation priorities vary between the expert and non-expert stakeholders. The results of the Delphi study and the consumer focus group studies are summarised below.

Concerns and views of 'expert' stakeholders

1. Prioritisation of different contaminants

- Expert stakeholders prioritised microbial risks because they are associated with a relatively higher probability of occurrence compared to chemical contamination;
- Expert stakeholders considered consumer handling of food products to play a major role in food contamination (for example, through cross-contamination in the domestic environment).

2. The need for harmonisation of food safety standards across industries and food chains

- Expert stakeholders identified the need to develop uniform food safety standards, and for these to be implemented across different food businesses and food chains;
- The view was expressed that strict regulatory enforcement of these rules need to be applied by the relevant authorities.

3. The role of traceability

- Expert stakeholders suggested that the implementation of effective traceability systems for foods and ingredients could help to reduce both microbial and toxicological contamination of food chains;
- Expert stakeholders considered traceability to potentially have role in increasing consumer confidence in food safety, but did not agree on whether food recalls increased or reduced consumer confidence.

4. The costs of implementing traceability

- The costs of traceability were perceived as being disproportional high for smaller companies;
- Most expert stakeholders expressed the view that traceability would not be economically burdensome if implemented according to harmonised standards that are uniform across different industries and food chains.

Concerns of consumers

1. Chemicals in food products

- Consumers prioritised risk mitigation of chemical contaminants, in comparison to microbiological risks, as they associated these chemical contaminants with long term irrecoverable effects, and perceived a lack of personal control over whether they are exposed to them or not;
- Consumers are concerned about the presence of antibiotics, hormones and vaccines in meat and dairy products;
- Consumers consider microbial contamination to be manageable through application of personal hygiene and domestic cleanliness. This implies that perceived personal control is an important factor influencing consumer concerns about microbial contamination.

2. Length of food chains

- Consumers consider longer supply chains to be highly vulnerable to contamination from both microbial and chemical contaminants;
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- Long distance transportation, extensive handling, and variation in storage conditions during transport are perceived by consumers to negatively affect product quality and safety, and increase the chances for contamination;
 - Consumers prefer to have information about product origin, as they feel insecure about the safety systems enforced through the entire food chain;
 - Consumers prefer shorter food chains over the longer ones.

3. Processing

- Consumers perceive extensive processing to affect the “naturalness” of food products, and to be a source of potential chemical contamination;
- Consumers prefer natural and less processed products;
- Food processing is usually associated by consumers with negative effects on public health and the environment.

4. Sustainability

- Food ‘sustainability’ is considered to be negatively affected by long food production chains;
 - Consumers are concerned about the use of chemicals in agricultural production (pesticides etc.) due to their role in environmental contamination.
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4. Regulatory framework

Heereluurt Heeres, (TNO Quality of Life, the Netherlands)

Most countries have national legislation regarding food and feed. The legislation of several countries can apply throughout production and transport of food and feed, whereas these products are often produced in long geographical chains. The extent of food and feed legislation differs from country to country and supra-national legislation may exist. Food legislation can therefore be a complex matter. Food legislation is, however, often based on the standards laid down in the Codex Alimentarius.

4.1 Codex Alimentarius Commission

The Codex Alimentarius Commission was created in 1963 by FAO and WHO to develop food standards, guidelines and related texts such as codes of practice under the Joint FAO/WHO Food Standards Programme. The main purposes of this Programme are to protect health of the consumers, to ensure fair practices in the food trade, and to promote coordination of food standard elaboration from international governmental and non-governmental organizations.

4.2 European Community

The European Community (EC) is an example of a supra-national body that lays down legislation for the Member States. A product in an EC Member State is firstly affected by the European legislation, because of the harmonization of Member State legislation. A considerable number of EC statutory regulations and guidelines on the safety of food and feed were published during recent years. However, EC Member States still can have additional legislation. There are also non-EC countries, like Norway, that implement or follow legislation from the EC.

The most important standard regarding food and food safety in the European Community, is the General Food Law (Regulation 178/2002/EC; GFL). This regulation lays down, among others, the general principles and requirements of food law.

Food safety, Article 14 GFL

- This article states: Food shall not be placed on the market if it is unsafe. It shall be deemed to be unsafe if it is considered to be injurious to health or unfit for human consumption. There are criteria to determine whether a food is unsafe, injurious to health and unfit for human consumption. Regard shall be given to:
 - the normal conditions of use of the food by the consumer;
 - the normal conditions at each stage of production, processing and distribution;
 - the information provided to the consumer, including information on the label or other information generally available to the consumer on potential health effects.
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Responsibilities of the food business operator, Article 19 GFL

When a food business operator considers or has reason to believe that a food which it has produced, distributed or imported is not in compliance with the food safety requirements, the FBO shall immediately initiate procedures to withdraw this food from the market where the food has left the immediate control of that initial food business operator. They also have to inform the competent authorities thereof. If the food may have reached the consumer, then the food business operator shall effectively and accurately inform the consumers of the reason for its withdrawal, and if necessary, recall from consumers products already supplied to them when other measures are not sufficient. It should be clear that the FBO responsibilities do not stop when the food has changed ownership or is out of their direct control.

Traceability, Article 18 GFL

Traceability of food, feed, food-producing animals, and any other substance intended to be, or expected to be, incorporated into a food or feed shall be established at all stages of production, processing and distribution. Therefore food business operators should be able to identify their suppliers and their customers. FBOs shall have in place systems and procedures which allow for this information to be made available to the competent authorities on demand.

Food and feed products placed on the market or likely to be placed on the market in the (European) Community shall be adequately labelled or identified to facilitate its traceability, through relevant documentation or information. In the case of product liability it is essential for a food business operator to have in place systems to trace food and for adequate labelling.

4.3 Contaminants, residues, hygiene and traceability

The presence of contaminants or residues from pesticides or veterinary drugs, in food and feed products, raw materials and semi-processed products, may result in an unsafe product depending on the amount and the nature of the contaminant. Maximum levels for some contaminants and residues are laid down in legislation that is continually changing due to new (risk assessment) insight, emerging risks and political agendas. The production, processing and distribution of the products, should be done hygienically to ensure food safety. Mostly legislation includes general and specific rules for food business operators regarding hygiene standards for food products.

To assess the regulatory status of a contaminant, a residue, the hygiene and traceability, any user needs to access the legislation of the countries concerned, such as the country of origin, the countries of destination and in some cases the countries in which the food was transported or in transit.

4.4 RASFF

The EU rapid alert system (RASFF) is essentially aimed at the rapid exchange of information between Member State authorities in the event of a serious and immediate risk to the health or safety of consumers. The purpose is to provide the authorities with an effective tool to take measures ensuring consumer protection. The European Commission publishes a weekly overview of all notifications (alerts and information) and border rejections on the internet.

5. Traceability and vulnerability in the food and feed chain

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5.1 Introduction

Traceability can be viewed in the following ways:

- internal traceability (within the organisation);
- supplier traceability (supply of goods and services);
- customer traceability (the traceability by an organisation of goods and services to its customers).

Traceability in the feed-food chain can be defined by ISO 22005 (Standard for Traceability in Feed-Food Chains), as the “ability to follow the movement of a feed or food through specified stage(s) of production, processing and distribution”.

A traceability system is an essential tool to assist a food/feed business with respect to tracing materials, goods, services and processes into, within, and out of a food business. The traceability system is influenced by regulations, product characteristics, customer expectations and the objectives of the business. Good traceability requires the management of successive links between what is received, produced, packed, stored and shipped across the entire supply chain. If traceability of one of the partners in the supply chain is inadequate, it may result in the weakening of the information chain and lead to a loss in traceability.

Although virtually every traceability chain is different, they are essentially made up of a number of characteristic components. The first component is the data. The second component is the data management (capture, collation, storage and retrieval). The third is the transfer of that data to another enterprise. This process at its simplest can be completely paper based with the data written by hand at every stage and the transfer of data completed by a human handing over a copy of the document that someone else at another enterprise has written down. At its most sophisticated this system can collect data from product/animal tags, scanable box labels, scanable micro chips, RFID tags, biological samples (DNA, proteins and lipids) and process them using industry standards such as Tracecore (created by the TraceFish project) and transfer the data via a web based product such as TraceTracker (from Norway), TracePlace (from the Faroe Islands), Trace Assured (from UK/N.Ireland), or Trace Register (US).

Ease of access and retrieval should also be identified as key requirements of a traceability system and therefore, how information on the goods supplied, processed and distributed is collected, and collated, are important components of the system. Traceability systems should be able to contribute to the search for the cause of nonconformity and the ability to withdraw and/or recall products if necessary. Therefore, they can play a major role in preventing contaminated

products from reaching the consumer market by their identification and elimination before entry into the consumer market. However, it is important to note that a traceability system in itself does not guarantee food safety. Traceability is, however, an essential component of the totality of food safety measures and food safety systems in place for the protection of the consumer.

In addition to food safety, traceability adds to consumer protection and concern as it extends into a myriad of product claims in particular regarding functionality, production method, origin and ingredients. Examples are Organic Product, GMO free, Additive Free, Welfare Friendly, Free Range, Geographic Indication/Origin (Parma Ham, Product of Germany).

Credible and effective traceability is a key requirement from food retailers and food buyers because of multiple points of product movement between suppliers, logistics service providers, contract manufacturers and distributors in order to protect the interests of consumers and the business from potential harm from food scares and scandals.

The complexity of the traceability system can vary depending on the features of the product and the objectives to be achieved. The implementation by an organization of a traceability system depends on technical limits inherent to the organization and products (i.e. nature of the raw materials, size of the lots, collection and transport procedures, processing and packaging methods), and the cost benefits of applying such a system.

5.2 Traceability and Vulnerability

Information transfer interfaces may represent vulnerable parts of the chain, where information systems from different organizations or parts of the same are often not compatible.

Traceability is challenged at the major interfaces or nodes where there is a physical transfer of product and hence a need to transfer information. Transfer interfaces may represent the more vulnerable points in food chains because of this higher risk to loss in traceability.

This risk to a loss in traceability may also be influenced by the organizational structure; integrated, multi-national, discrete and stand alone. Vulnerability to loss in traceability will also be influenced by the information management systems used within the traceability system. These may vary from simple hand written formats to fully automated, electronic data capture, storage and retrieval systems. Rarely, does one exist in isolation and, in reality, information systems are a mixture of paper based records combined with electronic, computer based data generation, collection and records including bar code scanners and in some cases, RFID technology.

During the Sigma Chain case studies, rarely were fully electronic data recording and storage capabilities observed throughout the entire food supply chain except during the processing steps in the chain where bar codes and scans were evident which recorded standardized information, allowing good control of daily production, stock and distribution records. Mixing of individual batches of product can occur at points throughout the supply chain. When it does, it is essential that the identification of each batch is recorded and linked to the product identification code of the 'mixed consignment'. This ensures that, even if physical traceability of the

individual batches is lost, the identities of the component batches within a mixed batch are known and retained.

Case – Melamine contamination in feed-food chain

For emerging contaminants such as melamine in the feed and food chain where there is little data on the transfer of contaminant and health risks of contaminated feed fed to food production animals, a precautionary principle approach should be applied whereby, the avoidance (zero tolerance) of melamine in the feed-food chain is the only, socially and legally acceptable limit.

Elimination of potentially contaminated material from the feed-food chain is the most appropriate avoidance mechanism, since testing regimes are not in place and would only constitute surveillance measures given the quantities and batch sizes/batch mixing occurring in normally traded protein based feed materials (these are considered most at risk to melamine adulteration).

Thorough understanding and control of the feed material chain is essential in order to protect the chain from potential contamination. Improved control may be brought about by direct sourcing and reducing the sourcing steps in the chain - eliminating the intermediary steps of raw material chains. Some may be necessary and play an important distribution role but consider that trading entities may not have sufficient control on batch identification, separation and segregation increasing the vulnerability to contamination of 'unknown' sources of feed materials. Larger organisations may exert more control of the distribution chain through ownership and partnership, contract and exclusivity arrangements which may reduce the vulnerability of the supply chain.

Lack of control and purchasing on an open market (often necessary during contract negotiation, supply shortages from existing suppliers and economic circumstances) may be a more vulnerable activity with respect to traceability.

Batch size limit and traceability may also allow improved isolation of potentially contaminated batches and reduce exposure to increased product recall and financial and reputation damage.

At the farm unit level, lack of documentation of feed batches delivered and their allocation to definable and identifiable batches of stock which can be segregated in production and also post distribution through effective labelling of products. This may also result in increased exposure and high financial consequences associated with product recall.

6. Risk ranking of contaminants in relation to vulnerability

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Where contamination of food can occur, the production chain becomes vulnerable, because contaminants can be a hazard, possibly causing harm to human health. As defined in HACCP, a hazard is a biological, chemical, or physical substance that can cause harm to human health, at levels that are reasonably likely to occur if not controlled. When assessing vulnerability of the chain, all kinds of possible contaminants emerge and a system for priority setting with which to deal first is required. Such a basic system of ranking the risks, as a function of chance and effect, is provided in the Stakeholders' Guide.

After a classification based on legal status, further ranking derives from hazard evaluation and exposure assessment of the food hazard. This stage is qualitative rather than a thorough scientific risk assessment, but some elements of risk assessment are used to underpin the estimate of the risk as a function of both its effect and exposure. Often (as under Codex Alimentarius HACCP recommendations), a risk assessment grid is used to evaluate hazards. The grid compares the severity (low, medium, high) and exposure likelihood (remote, low, medium, high). See Table 6 as an example. However, it is always unclear how to deal with midrange hazards, and other factors might influence the final decision.

Table 6 Codex Alimentarius grid for ranking food hazards

SEVERITY	LIKELIHOOD OF OCCURRENCE			
	Remote	Low	Medium	High
High	H/R	H/L	H/M	H/H
Medium	M/R	M/L	M/M	M/H
Low	L/R	L/L	L/M	L/H

There has been some development of risk ranking criteria for microbiological and chemical hazards of food products. Ross and Sumner (2002) and Davidson et al. (2006) provide two examples of risk ranking tools developed for microbiological hazards. A number of papers have been published ranking pesticide risks in foods (Low et al., 2004; Calliera et al., 2006). Generally separate risk ranking criteria are needed for identified microbiological and chemical hazards. While a number of physical hazards are associated with foods, generally the number of these hazards is relatively small and these hazards (and resulting control strategies) can be

considered on a case by case basis rather than attempting to derive risk ranking criteria to accommodate these hazards as well. Accordingly, it is recommended that risk ranking is carried out separately for chemical and microbiological hazards.

A functioning chemical risk ranking model should provide information on the relative risk posed by the presence of chemicals in a foodstuff. The risk posed by a chemical in a foodstuff is a function of both its hazard and the exposure of consumers to the chemical. Without performing full risk assessment or accessing toxicological data, one can often easily find for many chemicals a health based advisory value (e.g. ADI, pTWI). The hazard posed by a chemical can be considered in the first instance to be inversely proportional to this value. Exposure is the simple multiplication of the consumption of the food by the concentration of the contaminant present in the food (based on historical data, using the mean or a maximum value (as a worst case scenario). A simple measure of risk for initial screening of chemical hazards can then be developed as:

$$\text{Ranking score} = [\text{Exposure}] / [\text{Health advisory value}]$$

The requirement to rank bacterial pathogens is not as significant as the requirement to rank chemical contaminants, as generally the number of bacterial pathogens is much smaller than the number of chemical contaminants associated with a particular foodstuff. For most products there is also a well established body of (expert) information regarding the pathogens of significance. If required, a number of published risk ranking tools are available for assessing bacterial risks including Risk Ranger (Ross and Sumner, 2002) and a fuzzy logic algorithm to rank risk (Davidson et al., 2006). Both of these approaches adopt a similar approach by considering risk ranking to be a combination of probability of exposure to a food-borne hazard and the magnitude of hazard in a food when present. In most cases control measures for microbiological contamination are similar (often heating steps). Likewise the kind of effects are similar to some extent, but often the effects are acute as opposed to effects of chemical hazards that mostly will be long term.

In the Sigma Chain Stakeholders' Guide, to progress from a simple risk ranking process to prioritising vulnerability, an FMEA adapted method is provided. In this grid type approach, three dimensions are introduced as follows:

1. severity: this means the type of effect (damage to human health) the substance causes at a certain level (exposure), so severity is rated according to the realistic and relevant effect that it might cause when consuming the product under study.
2. likelihood of occurrence: this means the 'chance' the contamination will happen at the relevant levels as in severity (these are therefore partly interdependent).
3. detectability: this is the likelihood that the contamination will be detected or recognized by any procedure or control measure.

This approach can be applied to chemical and microbiological contamination.

To prioritize vulnerability associated with microbiological contamination, the FMEA method requires first a simple classification decision tree to distinguish between the risks involved with

the respective micro-organisms, although not addressed specifically in the Stakeholders Guide it is useful to identify spoilage contamination and micro-organisms that exert effect through a secondary mechanism, mostly toxins (either bacterial or fungal). Toxins are consequently dealt with as chemical hazards. Finally, being aware of the possibility of viruses and parasites, especially because of globalization, will help putting vulnerabilities in perspective. In principle the FMEA method can be applied in the Stakeholders Guide to any vulnerability, even if it is not a contamination directly.

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7. Malicious contamination in food and feed

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Malicious contamination in the food or feed chain specifically involves and relates to a deliberate act of contamination in the specific aim to harm either an industry (mostly in case of blackmailing) or a community to achieve financial or idealistic goals. This includes, but is not limited to, terrorist acts.

The malicious contamination of food for terrorist purposes is a possibility that responsible governments and private companies cannot ignore (World Health Organization - WHO, 2008). The WHO has defined food terrorism as “an act or threat of deliberate contamination of food for human consumption with chemical, biological or radionuclear agents for the purpose of causing injury or death to civilian populations and/or disrupting social, economic or political stability” (Kennedy and Bunko, 2007; Donaghy, 2006). The biological agents referred to are communicable infectious or non-infectious pathogenic microorganisms, including viruses, bacteria and parasites. The chemical agents in question may be man-made or natural toxins. Physical agents can include a wide range of objects including glass, needles and metal fragments. Radionuclear materials are defined in this context as radioactive chemicals capable of causing injury when present at unacceptable levels. In this regard, food and water are recognized as potential vehicles for disseminating such agents to a broad population (WHO, 2008).

The diversity of food sources, their easy access and widespread availability, as well as the global market, makes prevention difficult. While the effects of unintentional food contamination are theoretically enormous, considering any large foodborne outbreak of disease (e.g. Hepatitis A in China, Halliday et al. 1991; Cooksley, 2000), in practice, those from a threat or deliberate attack are potentially far greater.

Absolute food and water safety is impossible to achieve on account of both the numberless chemical and microbiological hazards potentially entering these chains. Routine methods of detection often fail to detect non-routine contaminants and have to be complemented with other security measures and early warning systems. Research is currently focussing on rapid, sensitive and broad spectrum ranging methods to detect these biological warfare (BW) agents (Khreich et al., 2008) for real time monitoring of food and water distribution system such as sensors arrays (Helbling et al., 2007 & 2008; Hang et al., 2008) but also analytical methods arrays and protocols for an expanded screening of target and unknown microbiological and chemical contaminants in complex food matrices (Ferretti et al., 2007; Charlton et al., 2008).

Throughout recorded history, civilian food supplies have often been targeted for sabotage during military campaigns. Deliberate food sabotage aimed at civilian casualty has however been far less documented. A concise historical review is given by Kennedy and Bunko (2007).

Prevention, although it can never completely be effective, is the first line of defence. The keys to preventing food terrorism are establishing and enhancing food safety management programmes and implementing reasonable security measures. The capacity to prevent deliberate sabotage of food lies mainly with the food industry and should be addressed throughout the food-chain (WHO, 2008). Proactive risk analysis can reduce vulnerability in the same way as analysis of the risks of inadvertent contamination. The risk should be analysed for each link in the food-chain, taking into consideration issues such as vulnerability to sabotage, opportunity for the introduction of an agent, capacity to monitor deliberate contamination as well as to trace and recall suspect products (Kumar & Budin, 2006). The most vulnerable foods, food ingredients and food processes could be most likely the primary target and should be identified, using criteria such as accessibility, tamper proofness (e.g. packaging), distribution characteristic, and supervision of production areas and processes.

Governments have their responsibility towards the general population. They have to be vigilant and aware of the possibility of bio-terrorism. Obviously they should be prepared to handle crisis situations, e.g., as part of the US Bioterrorism Preparedness and Response program. Sobel et al. (2002), at the National Center for Infectious Diseases (Atlanta, USA), describe a framework to prepare for such scenario, combining surveillance, communication between the various disease centers, food safety agencies and the emergency response units. A biological terror attack that targets a food distributed over a wide geographical area could stress, stretch and challenge the assurance of adequate medical supplies and personnel (Dichtwald & Weinbroum, 2008).

Major knowledge gaps exist with regard to the feasibility of current disinfection and inspection methods to protect our food and water against contamination by a number of biological and chemical agents (Khan et al., 2001). For example, municipal water supplies are quite vulnerable to malicious contamination due to the often open nature of the reservoirs. Some water-borne infectious agents such as *Shigella* spp. and *Vibrio cholerae* are obvious water threats and most biotoxins would probably be effective threats to drinking water under suitable conditions (Burrows & Renner, 1999). For most, however, the agent cannot survive in water because of rapid inactivation by standard treatments for drinking water, such as chlorination or aeration, as well as the dilution effect in large reservoirs (Donaghy, 2006).

Nearly all known biological warfare (BW) agents are intended for (area restricted) aerosol application and the threat is primarily to the respiratory tract, not to the digestive system. Although less effective as potable water threats, many are potentially capable of inflicting heavy casualties when ingested. With few exceptions, the dose of any BW agent required to cause adverse health effects through ingestion is of such magnitude as to make essential the targeting of water supplies closest to the consumer; these might include finished water storage facilities, vulnerable points in the distribution system, or even bottled water (Burrows & Renner, 1999).

Sometimes, deliberate sabotage of food might be difficult to distinguish from naturally occurring food outbreaks: e.g. botulism, (US Center For Disease Control, 2008). Several authors, such as Gill (1982), Sobel et al. (2002), Donaghy (2006) and Khan et al. (2001) have compiled very concise and detailed reviews of these potential BW agents.

Indeed civilian panic and disablement of institutional operations are likely to be prominent intentions of any bioterrorist attack. The psychosocial response to the threat or small actual contamination is likely to overshadow the extent of the actual disease or threat. One thing is certain, malicious and bioterrorist threats on food and water supplies are real and currently figure among the top priorities of the developed countries, as suggested by recent literature (WHO, 2008; Edelstein et al., 2008).

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8. Emerging risks from an information management perspective

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With the increasing complexity and globalization of the production of food and the constant flow of (research) papers focused on food safety, the volume and diversity of information grows rapidly and it is becoming more and more difficult to assess vulnerabilities and to identify risks.

In spite of the success of implementing quality and safety assurance systems like HACCP, GMP and others, the feed and food industry, as well as the government are confronted with suddenly occurring food safety risks from time to time.

For example, in 2002 the potential carcinogen acrylamide suddenly hit the news headlines after the discovery that acrylamide is formed while heating carbohydrate rich foods, like potato crisps. In 2004, dioxin was found in milk produced by some Dutch farmers. It appeared that dioxin is present in naturally contaminated kaolinitic clay, which was used in the sorting process of potatoes for French fries production, where the potato peelings with attached contaminated clay were considered a waste stream and consequently sold and fed to cattle which led to the subsequent finding of dioxin in milk (Figure 4).

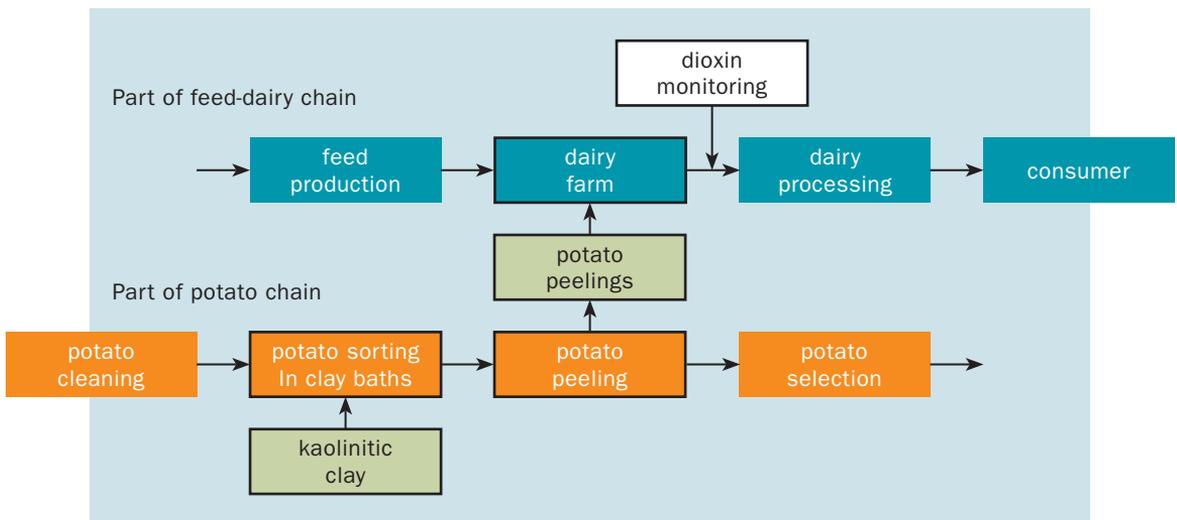


Figure 4 Example of a contaminant crossing chains illustrating looking beyond the obvious

The risks associated with these incidents can be described as ‘emerging risks’. An emerging risk is a risk resulting from a newly identified hazard, or from a known hazard to which a new exposure may occur. The idea is that when it is possible to identify emerging risks one is able to develop timely proactive risk management and mitigation measures.

In the time preceding the actual incident occurrence of the cases of acrylamide (2002) and dioxin (2004), pertinent information in some documents could be identified, but these were hidden in large volumes of scientific literature and news articles.

The acrylamide case (2002) illustrates how new knowledge published earlier (Tareke et al.; 2002) in scientific literature on formation of acrylamide in feed as a result of heating could have its implications on possible human exposure of acrylamide via food. This knowledge was developed and subsequently published. This was not generally accessed by food industry, but appeared to be very relevant to it.

The dioxin case (2004) illustrates how information about an earlier feed incident (FDA, 1997), describing the possible presence of dioxin in some kaolinitic clay pits was very relevant to the dairy chain. Here we see how information relevant to the feed production network appeared to be also relevant to the food production network, but the food sector seemed to be not aware of the information.

In both incidents relevant information was available and could have been interpreted and be used to develop risk management measures well before the actual incident occurred. Identification of emerging risks represents a proactive approach to risk management.

These incidents are not merely co-incidental observations, but are part of the trend foreseen by institutions such as OECD and EFSA which suggest that the number of emerging risks and their impact on society is growing and will continue to so do in the near future.

So there is, and will be, a need for companies within food production networks to proactively identify emerging risks and be able to develop risk management options.

Sensitivity to early warnings and other signals needs to be developed. It is important to have detailed chain information on production and vulnerabilities at hand to be able to interpret early signals. The Stakeholders’ Guide helps to assess this information specifically and so can provide early warning systems for the food industry.

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VULNERABILITIES IN THE FOOD CHAIN

A STAKEHOLDERS' GUIDE

Annexes

Annex 1

Information sources

The following information sources can be used to identify relevant substances of concern as well as their entry points and dynamics, best manufacturing practices, control measures, testing etc. This list is not exhaustive. All websites mentioned were accessed in 2009.

1. Recall notices and alerts from national databases

- EU: <http://ec.europa.eu/food/food/rapidalert>
- EU: <http://www.efsa.europa.eu>
- UK: <http://www.food.gov.uk>
- Ireland: <http://www.fsai.ie>
- France: <http://www.afssa.fr>
- Germany: <http://bfr.bund.de/cd/3992>
- Australia: <http://www.foodstandards.gov.au>
- Canada: <http://www.inspection.gc.ca>
- Netherlands: <http://www.vwa.nl>

2. National scientific institutions, professional associations and industry specific food safety hazard databases and newsletters

- INERIS (Institut National de l'Environnement industriel et des risques): <http://www.ineris.fr>
 - RIVM (National Institute for Public Health and the Environment): <http://www.rivm.nl>
 - RIKILT – Institute of Food Safety: <http://www.rikilt.wur.nl>
 - Irish National Food Residue Database <http://nfrd.teagasc.ie/> & www.nfrd.ie
 - The Canadian Food Agency: <http://www.inspection.gc.ca>
 - USDA/FDA Foodborne Illness Education Information Centre, United States Department of Agriculture Food Safety and Inspection Service and the Food and Drug Administration Centre for Food Safety and Applied Nutrition <http://www.nal.usda.gov/fnic/foodborne/foodborn.htm>
 - Introduction to Foodborne Pathogenic Microorganisms and Natural Toxins: <http://vm.cfsan.fda.gov/-mow/intro.html>
 - UC Davis Seafood HACCP Information <http://www.seafood.ucdavis.edu/haccp/ucd.htm>
 - Seafood NIC Home Page. <http://www.seafood.ucdavis.edu/home.htm>
 - The Seafood HACCP discussion group discussions are available at: <http://listproc.ucdavis.edu/archives/seafood/>
 - Fish and Fisheries Products Hazard & Controls Guidance- 3rd edition <http://www.fda.gov>, then select 'food' then 'seafood' then 'HACCP'.
 - The International Meat Poultry HACCP Alliance <http://www.haccpalliance.org/sub/index.html>
 - <http://www.foodscience.csiro.au>
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- <http://www.health.gov.au/internet/main/publishing.nsf/content/cdi2504-1>, then search for Communicable Disease Intelligence and OzFoodNet
 - Publication 'Seafood Safety Manual' from Safe food NSW Aug 2001
<http://www.foodauthority.nsw.gov.au/industry/news%2Dpublications%2Dand%2Dhelp/>
 - Publication 'A risk ranking of seafood in Australia-Attachment 9' from Food Standards Australian New Zealand in May 2004

3. Legislation

Relevant legislation, standards and guidelines at national and European level containing information about:

- regulatory status of contaminants (substances regulated (or not) with regard to the specific product, including standards), hygiene and traceability
- sampling procedures and analytical methods to be applied for each substance

European Community

- Legislation regarding regulatory status of contaminants, hygiene and traceability:
http://ec.europa.eu/food/food/index_en.htm.
- Important regulations regarding food safety are:
- Regulation (EC) No 178/2002 on food safety: generic standard regarding food safety, no specific standards regarding physical contaminants
- Directive 2002/32/EC on undesirable substances in animal feed
- Regulation (EC) No 852/2004 on the hygiene of foodstuffs
- Regulation (EC) No 853/2004 on specific hygiene rules for food of animal origin
- Regulation (EC) No 183/2005 on requirements for feed hygiene
- Regulation (EC) No 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin
- Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs
- Regulation (EC) No 1881/2006 on levels for certain contaminants in foodstuffs

Codex Alimentarius

- List of food standards and guidelines regarding contaminants, hygiene and traceability:
http://www.codexalimentarius.net/web/index_en.jsp
- The standard regarding the use of HACCP has been laid down: 'Recommended international code of practice, general principles of food hygiene'
- FAO reports: <http://www.fao.org>

4. Databases of scientific literature

Using as key words: the name of the product, the hazards, the generic name of the hazards; "safe*", risk and combinations of these keywords.

Scientific literature using the names of scientists known to be experts and publishing in the field (for the product and related hazards).

- ISI Web of Knowledge
 - Web of Science
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- Pubmed
- Science Direct
- CAB Abstracts
- Scirus

- <http://www.pcs.agriculture.gov.ie>
- <http://www.pan-europe.info>
- http://europa.eu.int/comm/food/fs/sfp/ras_index_en.html
- <http://ec.europa.eu/enterprise/pharmaceuticals/mrl>
- <http://archive.food.gov.uk/maff/archive/food/infsheet>
- <http://www.atsdr.cdc.gov/toxprofiles>
- <http://www.emea.europa.eu/pdfs/vet/mrls>
- <http://www.merckvetmanual.com/mvm>
- <http://www.inchem.org/documents/jmpr>
- <http://www.vet-residuescommitteegov.uk/Reports>
- <http://www.allqa.com>
- <http://www.atsdr.cdc.gov>

5. Search for standards like ISO, BRC, Globalgap and others

6. General search in internet

- Using as keywords: The name of the product, the hazards, the generic name of the hazards; “safe*”, risk, and their combinations
- The homepage of national and international Control Authorities for information about hazards related to the product under investigation
- Search in the homepage of the Control Authorities for information about hazards related to the product under investigation

7. Alert internet services and daily press in order to identify emerging hazards

- <http://www.FoodQualityNews.com>
 - <http://www.seafoodsource.com>
 - <http://www.seafood.net.au>
 - <http://www.SeafoodIntelligence.com>
 - <http://www.isid.org>
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Annex 2

Analytical techniques

In order to identify and to select the relevant analytical techniques, information can be collected from the following sources (in addition to those described in Annex 1):

- experts involved in the food quality control at all stages of the food chains;
- experts in laboratory analyses of foods (microbiological, chemical, biochemical, physical);
- national and European regulations and directives providing information about:
 - a) substances (or contaminants) regulated (or not) with regard to the food product or matrix;
 - b) values/limits set for each contaminant;
 - c) analytical techniques set as reference methods by international or government institutions (e.g. WHO, FDA, CEN) for specific contaminants and food matrices;
 - d) minimum analytical technique performance required when set for particular food matrices;
- search for standards such as ISO, AOAC International, Australian Standards and others;
- National Residue Control Plans, analyzing the information about the analytical methods used for the identification and the quantification of hazards related to food products;
- search in databases, including their internet alert services (see Annex 1) using the contaminant name and, if available, CAS code number as key words;
- general search through internet:
 - a) homepage of Control Authorities for information about hazards and control systems related to the contaminant and the food product under consideration;
 - b) homepage of the institutions carrying out the official routine/control laboratory analyses to detect and/or quantify the relevant hazards;
 - c) homepage of companies producing analytical equipment for the determination of undesirable substances;
 - d) electronic scientific literature using the names of scientists known to be experts and to publish articles in the field as key words.

The analytical techniques must:

- be relevant to the type of food product (or matrix) and to the type of contaminant considered;
- be sufficiently documented, that is, the following information should be made available:
 - a) description of the procedure;
 - b) sampling method and sample preparation;
 - c) type of analytical material required;
 - d) performance (e.g., detection limit, quantification limit, decision limit CC β , detection capability CC β , sensitivity, selectivity, reproducibility, maximum residue level, ...);
 - e) time required for the whole determination process, including sample preparation;
 - f) cost of the analysis;
- be validated;
- be accepted by law (national and EU regulations, directives etc.);
- show performance in accordance with the values/limits imposed according to the food safety context, that is current national, European or international regulations or standards.

Perform a regular search and update of information (e.g. on an annual basis) to take into account the emergence of new contaminants, the development of new methods, and changes in legislations.

The result is a list of selected analytical techniques that can be classified according to their type: reference method, rapid method, method from the literature, or other type.

If different methods are identified for the same contaminant, they can be prioritised according to the criteria mentioned previously, viz. reliability, accuracy, speed and cost of the analytical process (including sample preparation).

Annex 3

Methods used in stakeholder research

Stakeholder involvement and food research

Stakeholder involvement techniques can be used to address a broad range of issues. A variety of methods is used to analyze and understand the role of various stakeholders, and identify implications of their concerns for policy making.

Consumers represent major stakeholders with regard to food and food safety. Other important stakeholder groups include non-government organizations such as consumer associations, environmental groups or associations of industry groups, individual food industries, policy makers, risk managers, risk assessors, risk communicators, public and private research organizations, the media, and various pressure groups.

Some widely used methods in the stakeholder research have been elaborated here providing a brief description of the advantages and disadvantages they offer.

1. Surveys

- Surveys represent one of the most common types of research techniques in stakeholder/consumer research and are an efficient tool for obtaining information and opinions from a representative sample of consumers and other relevant stakeholders regarding an issue of interest;
- Surveys use a standardized questionnaire to explore respondents' responses. Both open ended and/or closed ended questions can be used in the questionnaire;
- Surveys can be administered in a variety of ways (for example, using questionnaires posted in the mail to respondents, telephone interviews, internet questionnaires etc) and can be used in a variety of research disciplines.

Advantages:

- Surveys are useful in describing the characteristics of large population;
- Surveys can be administered from remote locations by means of the internet, the telephone etc.;
- Many questions can be asked about a given issue giving considerable flexibility to the analysis;
- Statistical analysis (for example, significance testing of means comparisons) can be applied.

Limitations:

- The wording of the question can influence the results of the survey (for example through 'framing');
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- 'Person-to-person' interview surveys may result in the interviewer influencing the respondents responses, for example through providing feedback either explicitly or implicitly;
- It is sometimes difficult to obtain enough responses from a given sample to extrapolate to 'nationally representative' sampling.

2. Nominal Group Technique

- An alternative approach to group interviewing;
- Useful when it is not possible to gather particular group(s) of interest on a timely basis (e.g. scientists, senior executives, high level government officials etc.);
- Direct interaction between individuals is not always possible. Group members are often interviewed separately, and summaries of the responses and ideas of others are provided at these interviews;
- Researchers obtain first round data, which are summarised and presented to the members of the group to obtain responses in the second round;
- The aim is to avoid the influence of group opinion on the views of individual participants.

Advantages:

- The method provides opportunities for equal participation for all stakeholders;
- Good way to generate diverse ideas on an issue of discussion.

Limitations:

- Time consuming method;
- Lacks interactions and hence there is lack of spontaneity on parts of respondents.

3. Personal Interviews

- Such interviews involve in-depth questioning of a respondent to understand his opinions about issues of concern and are widely used in consumer research;
- Consumer views can be probed in more details and underlying perceptions can be effectively explored;
- Attitudinal behaviour can also be best observed (respondents gestures, expressions on particular topic);
- It is very expensive and time consuming method;
- Interviewer can influence the response of respondents.

4. Brainstorming techniques

- Brainstorming technique forms a part of group techniques and are designed to generate new ideas, solutions about an issue under discussion from consumers and other relevant stakeholders;
 - Group members work together on developing new approaches and ideas to tackling certain issue and the group may or may not have a moderator;
 - Emphasis of the technique is to produce more ideas so that at least a few work;
 - Brainstorming technique is most likely to be useful for problems that do not have any single best solution.
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5. Consultative groups

- These are designed to bring together key representatives of society (NGOs or consumer organizations etc.), and key actors such as policy makers, political figures etc. to discuss key policy issues and recommendations to assess the feasibility and implementation of such policies;
- They involve a wide range of individuals from within communities, social groups and stakeholders, which reflect the composition of the population and its agencies and organisations of the local area;
- Consultation can help to inform, publicise and promote policy decisions and are also useful in the identification of individual views about particular issues.

6. Consensus conferences

- A small, representative group of stakeholders/citizens is chosen to represent different viewpoints;
- A selected panel of lay people or relevant stakeholders undergoes a learning process to inform them about the issue at hand. At the end of process, the lay panel comes up with a set of questions that they feel need to be addressed so as to be able to form an opinion;
- A panel of selected experts then answers the questions in the form of presentations and responses to panel questions at a public conference that helps in reaching to a consensus.

Advantages:

- Early involvement of stakeholders is achieved;
- The consensus conference acts as an interface between experts and lay people and allows public participation.

Limitations:

- Expensive approach;
 - The small sample of people might exclude minorities.
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