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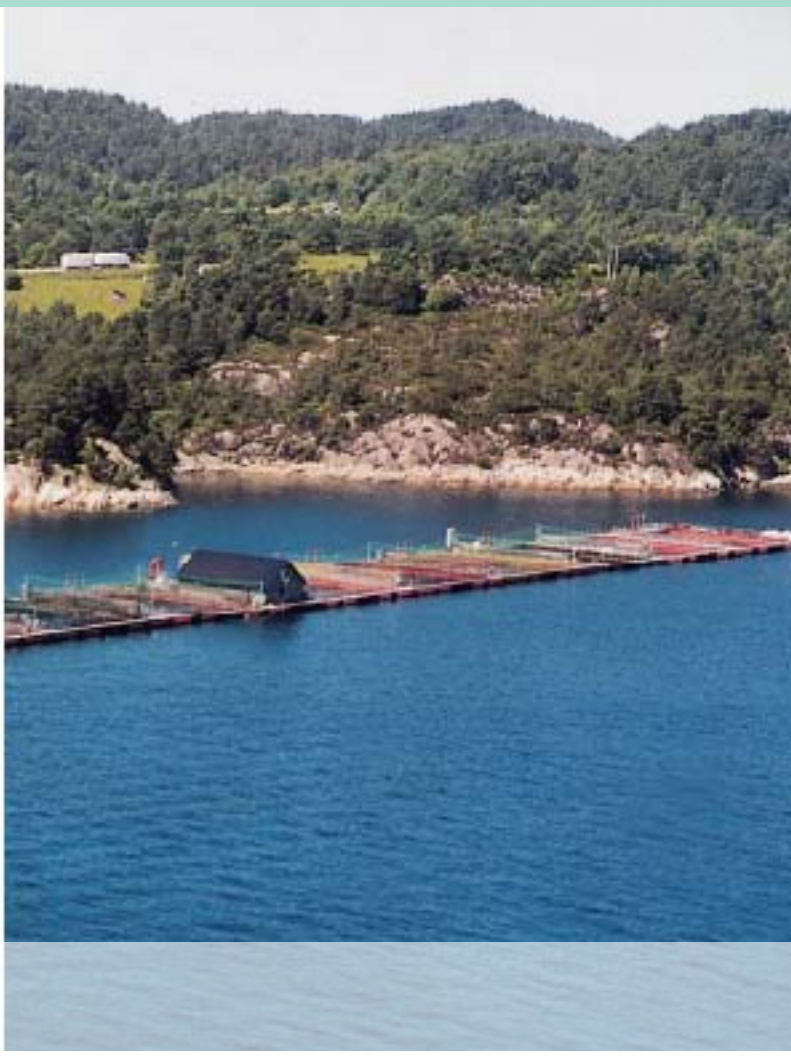
Application of risk assessment in the fish industry



Cover photographs:
Left: Fish processing plant in Latvia. Right: Norwegian salmon farm. Courtesy of EUROFISH.

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PREPARATION OF THIS DOCUMENT

The Fishery Industries Division of the Food and Agriculture Organization of the United Nations (FAO) has produced this document to help those concerned with fish safety and quality to better understand about risk (microbiological and chemical) in the seafood industry and to be able to carry out work on risk assessment.

It aims at assisting those involved in any of the following:

- assessing the effectiveness of existing legislation;
- measuring the effect of a change in legislation on public health;
- measuring the effectiveness of a given safety assurance system;
- protecting an export market;
- assessing safety of imported seafoods;
- assessing equivalence between regulatory systems;
- identifying high risk products and pathogens;
- responding to outbreaks of food poisoning from a specific product and hazard;
- identifying where in the food chain control steps can best be applied.

The text works through examples of how risk analysis can be used for any of the above reasons. Dr John Sumner and Dr Tom Ross prepared this paper with assistance from Dr Lahsen Ababouch. The three have been associated with the work of FAO–World Health Organization (WHO) on microbiological risk assessment; the first two authors prepared risk assessments for the Australian seafood industry. Using their practical knowledge of the fish industry in Asia, the Pacific, South America, Africa and Europe, the authors attempted to demystify the concepts and provide a practical guide, written in simple language and using practical examples, to illustrate the exercises. The photographs were provided by Mr Masanami Izumi.

The authors wish you well in using this paper and the associated CD-ROM and welcome any comments and feedback you have so that we might make any necessary improvements.

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March 2004

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ABSTRACT

In recent years, the concept of risk has become paramount in international food regulation. Industries are increasingly required to undertake product risk assessment, particularly in the export arena. This publication has been developed as a complete "How to" package on risk assessment for seafood technologists, regulators and health professionals. It is designed in five parts and takes the user from a basic knowledge to being able to conduct credible risk assessments:

1. The basics of risk assessment: definitions and language of the discipline
2. How to perform risk assessments: stepwise progression
3. How to use risk assessments: risk management, Hazard Analysis Critical Control Point (HACCP), risk profiling
4. Risk Ranger – how to use it
5. Examples of risk assessments: an interactive setting for the reader

This publication also includes the Resources Bank, a CD-ROM, which provides a large amount of additional information for the would-be risk assessor.

Distribution:
FAO Fisheries Department
FAO Regional and Subregional Fisheries Officers
FAO Representatives
Infoservices
Fish Technology Centres
Authors

FOREWORD

The emerging world trading system is committed to transparent rules relating to food safety and quality based on the principle of equivalence and a scientific approach. This is particularly important for fish and fishery products, which today are more internationally traded than any other food product.

Whereas the concept of risk and food safety has been around for some time, it was the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) of the World Trade Organization (WTO), which came into effect in 1995 and set the stage for a risk approach to food control measures. It states that safety and quality rules should, where possible, reflect international standards, such as those of the Codex Alimentarius, but different national standards can be applied as long as they are scientifically based using risk assessment.

The risk approach to food safety embraces the fact that whereas carefully designed preventive systems, such as HACCP, can produce safe foods, complete safety cannot always be guaranteed at all times for all people. Therefore, communicating the risk associated with consumption of different foods becomes of prime importance.

The Codex Alimentarius Commission (CAC) has identified microbiological risk assessment for foods as a priority. Subsequently, the Codex Committee on Food Hygiene (CCFH) has identified 21 pathogen-product pairs for which it requires expert advice based on risk assessment. Of particular relevance for fishery products are risk assessments for *Vibrio* spp. in seafoods and *Listeria monocytogenes* in ready-to-eat foods – both of which are now near completion.

The Fishery Industries Division of FAO takes pride in helping the fish industry in developing countries to build capacity related to fish safety and quality with a focus on practical approaches. This publication explains the basics of microbiological and chemical risk assessment for seafoods to help "demystify" the area of risk assessment. It should primarily be seen as a working tool that allows for systematic ranking of the risks associated with different product categories – thus allowing for a more focused approach to producing safe aquatic foods. It has been widely used in Australia to profile entire segments of the food industry.

Grímur Valdimarsson
Director
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CONTENTS

ACRONYMS

AIDS	acquired immune deficiency syndrome
AOAC	Association of Official Analytical Chemists
AQIS	Australian Quarantine and Inspection Service
CAC	Codex Alimentarius Commission
CCFH	Codex Committee on Food Hygiene
CFP	ciguatera fish poisoning
EU	European Union
EHEC	enterohaemorrhagic *Escherichia coli*
EPA	Environmental Protection Agency
FAO	Food and Agriculture Organization of the United Nations
FDA	Food and Drug Administration (United States of America)
HACCP	Hazard Analysis Critical Control Point
HAV	Hepatitis A virus
HFP	histamine fish poisoning
HIV	human immunodeficiency virus
IFT	Institute of Food Technologists
JECFA	Joint Expert Committee on Food Additives
NACA	Network of Aquaculture Centres in Asia–Pacific
NAS	National Academy of Sciences (United States of America)
pTWI	provisional tolerable weekly intake
PCB	polychlorinated biphenyls
RfD	reference dose
SPS	Sanitary and Phytosanitary [Agreement]
SRSV	small round structured viruses
TBT	Technical Barriers toTrade [Agreement]
WHO	World Health Organization
WTO	World Trade Organization

Introduction

The use of risk assessment has gained steadily in importance and recognition as the scientifically-based approach for the development of food safety and quality standards. During recent years there has been increasing use of the word "risk" in connection with food safety, in general, and seafood safety in particular. There are statements such as *"regulations must be risk-based", "a risk analysis must be done"* and *"we need to communicate the risk to all stakeholders".*

Where has this emphasis on risk come from? Probably it is a logical extension of the Hazard Analysis Critical Control Point (HACCP) revolution that swept the industry in the 1980s and 1990s. HACCP Principle 1 states that a hazard analysis must be done. First those hazards that are likely to occur are identified, then an assessment is made of the severity of each hazard, followed by an evaluation of its likelihood to occur. These two factors (severity and likelihood) tell us about risk.

Another important drive towards risk assessment is the increase in international trade, which has raised new safety and quality challenges. Newer proactive quality and safety approaches have been developed to address the risk of cross-border transmission of infectious and hazardous agents and to deal with emerging food-borne diseases and quality problems. This has required the development of a new safety and quality regulatory framework that culminated with the entry into force, in 1995, of the Sanitary and Phytosanitary (SPS) and the Technical Barriers to Trade (TBT) Agreements of the World Trade Organization (WTO). Two provisions of these Agreements are of paramount importance to fish safety and quality:

- National SPS and quality requirements should reflect standards agreed on in the international standards setting bodies i.e. Codex Alimentarius for food quality and safety.
- Domestic standards, different from international ones, can be developed given they are scientifically based using risk assessment.

Risk assessment of microbiological hazards in foods has been identified as a priority area by the Codex Alimentarius Commission (CAC.) At its thirty-second session in 1999, the Codex Committee on Food Hygiene (CCFH) identified a list of 21 pathogen-commodity combinations that require expert risk assessment advice. In response, FAO and the World Health Organization (WHO) jointly launched a programme of work with the objective of providing expert advice on risk assessment of microbiological hazards in foods to their member countries and to the CAC. This involved establishing expert drafting groups to examine four priority pathogen:product pairings:

- *Listeria monocytogenes* in ready-to-eat food;
- *Salmonella* in eggs and broiler chickens;
- *Campylobacter* spp. in broiler chickens;
- *Vibrio* spp. in seafoods.

In view of all this, risk assessment is important throughout all aspects of the seafood industry – for companies, national governments and for international regulators. It does not matter where you operate in the seafood industry, risk assessment either already is an important part of your activity, or it soon will be. It can also be an expensive exercise, but in the end it should be worth the resources mobilized.

This paper is presented in five parts:

1. The basics of risk assessment
2. How to perform risk assessments

3. How to use risk assessments
4. Risk Ranger – how to use it
5. Examples of risk assessments

In addition, there is a CD-ROM, the Resource Bank, which provides selected back-up resources if an extensive library or online facilities are not available. It also includes a spreadsheet tool, Risk Ranger, to facilitate semi-quantitative risk assessments and risk profiles.

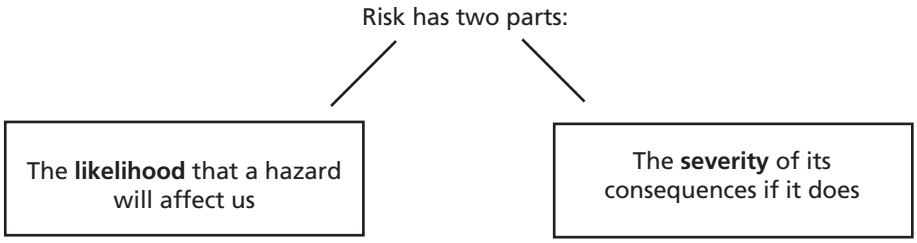
1. The basics of risk assessment

1.1 RISK AND RISK ANALYSIS IN PLAIN LANGUAGE

Risks from microbiological and chemical hazards are of serious concern to human health. As the discipline of risk analysis matures, it is developing its own tools and language, and this paper explains what those tools can do, in simple language. To begin, the definitions and terms used in risk analysis are set out in the CAC *Principles and guidelines for the conduct of microbiological risk assessment* (CAC/GL-30, 1999). The Codex words are in italics and some explanatory words are in normal type.

Risk

A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food.



Hazard

A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.

There are two very useful books that give information on seafood hazards:

- *Assessment and management of seafood safety and other quality aspects* (FAO, 2004).
- *Fish and fisheries products hazards and controls guide (*FDA, 2001).

Risk analysis

A process consisting of three components:

- *risk assessment*
- *risk management*
- *risk communication*

A common question is "Which of the three elements do I do first?" In most cases, the risk managers identify the need for a risk assessment and select an assessment team. Ideally, they should also begin the risk communication process as early as possible so that all interested and affected groups know what is happening from the first day. Tactically, it is a mistake to keep people uninformed – even if they agree with the assessment they will be displeased to have been excluded from the process.

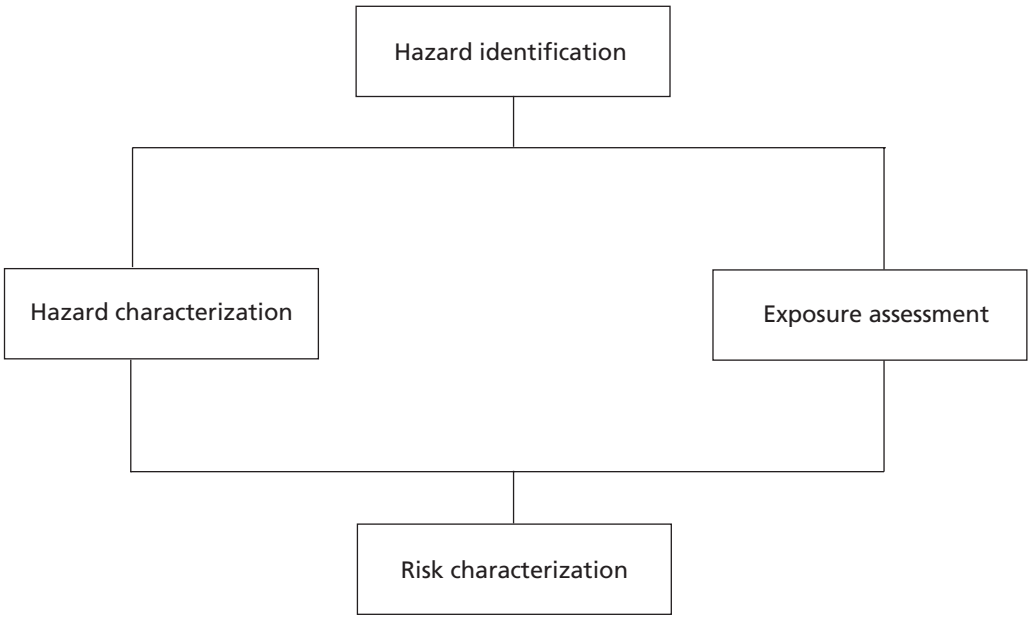
Risk assessment

A scientifically based process consisting of the following steps:

- *hazard identification*
- *hazard characterization*
- *exposure assessment*
- *risk characterization*

The aim of risk assessment is to estimate the level of illness that may be expected in our target population from a product or group of products.

The information flow for the four components in a risk assessment is shown below:



Hazard identification

The identification of biological, chemical and physical agents capable of causing adverse health effects and that may be present in a particular food or group of foods.

This is the first stage in risk assessment and is a screening process to make certain that the hazard really does exist in this particular product. For example, *Clostridium botulinum* is readily identified as a hazard in canned, smoked and vacuum-packed seafoods, but is unlikely to be a hazard for any other seafood product. So hazard identification is a primary screen that allows risk managers to eliminate product: pathogen pairs that are of no concern.

You will find material on hazard identification for all of the hazards associated with seafoods in the Resources Bank.

Hazard characterization

The qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with biological, chemical and physical agents that may be present in food. For the purpose of microbiological risk assessment the concerns relate to micro-organisms and/or their toxins.

There are two parts to hazard characterization:

- a description of the effects of the hazard (micro-organism or toxin);
- the dose-response relationship (if it exists).

Dose-response assessment

The determination of the relationship between the magnitude of exposure (dose) to a chemical, biological or physical agent and the severity and/or frequency of associated adverse health effects (response).

For any particular individual, dose-response links the amount of the hazard you ingest (dose) with the chance of your becoming infected and the scale of the illness if you do. For example, most healthy individuals can consume large numbers of *Listeria monocytogenes* (maybe as many as 100 million cells) without becoming seriously ill. By contrast, in susceptible people (foetuses, the aged or individuals with impaired immune

systems) a much smaller dose (maybe as few as 10 000 cells) can cause serious illness and, in around 30 percent of cases, death. In the Resources Bank you will find a list of dose-responses for several micro-organisms and their toxins.

Exposure assessment

The qualitative and/or quantitative evaluation of the likely intake of biological, chemical and physical agents via food as well as exposures from other sources if relevant.

To carry out an exposure assessment you need data in two areas:

- number of servings of potentially dangerous food eaten;
- level of contamination with the micro-organism or toxin at the time of consumption.

To arrive at these types of data you will probably follow the micro-organism or toxin through the processing–food preparation chain and estimate changes that occur to the hazard throughout the chain.

Risk characterization

The process of determining the qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterization and exposure assessment.

When you do the risk characterization, you integrate hazard identification, exposure assessment and hazard characterization to provide an estimate of the risk.

Risk estimate

Output of risk characterization

This may vary from a qualitative estimate (high, low, medium) to a quantitative estimate where you predict the number of people you expect will become ill from the particular product:hazard pairing. Alternately, your risk characterization may be semi-quantitative and you make a risk ranking that is a number in a specific range, 0–100, for example.

Risk management

The process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant to the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options.

Risk managers have a difficult responsibility because they must take into account the views of various groups. Trying to find compromises between the views of scientists, industry, consumer groups, politicians and lawyers is almost impossible, but it is what risk managers are required todo.

Risk communication

The interactive exchange of information and opinions throughout the risk analysis process concerning hazards and risk, risk-related factors and risk perceptions among risk assessors, risk managers, consumers, industry, the academic community and other interested groups, including the explanation of risk assessment findings and the basis of risk management decisions.

Communicating risk is a very difficult task because it involves the full range of stakeholders. A major problem is informing consumers that no food product is risk-free and, as a consequence, they must be prepared for X deaths and Y illnesses each year from this particular product. Risk communication includes changing perceptions of stakeholders so they all move towards some central positions that are not far removed from each other.

Quantitative risk assessment

A risk assessment that provides numerical expressions of risk and indication of the attendant uncertainties (WHO, 1995).

A typical quantitative risk assessment (QRA) was carried out by Lindqvist and Westöö (2000) for smoked fish in Sweden, where the predicted annual number of illnesses varied between 47 and 2 800 (mean 168) for consumers at most risk.

Qualitative risk assessment

A risk assessment based on data which, while forming an inadequate basis for numerical risk estimations, nonetheless, when conditioned by prior expert knowledge and identification of attendant uncertainties, permits risk ranking or separation into descriptive categories of risk.

A typical qualitative risk assessment was done by Huss, Reilly and Ben Embarek (2000), who estimated the risk as high for consumption of molluscan shellfish, fish eaten raw, lightly preserved fish and mildly heat-treated fish. Low-risk products were chilled/frozen fish and crustaceans, semi-preserved fish and heat-processed (canned) fish. Dried and heavily salted fish were considered to have no risk.

Risk profile

A description of a food safety problem and its context developed for the purpose of identifying those elements of a hazard or risk that are relevant to risk management decisions. This approach has been used in Australia to profile entire food industries.

Risk profiling can be a way of quickly identifying those products within a particular sector that are of most concern. This is exactly what Huss, Reilly and Ben Embarek (2000) did in the previous example for the seafood industry, as a whole. If you did a risk profile of your industry you might find some difference in risk rating. For example, dried and heavily salted fish usually have no risk. But what if the rainy season led to mould formation and the moulds were able to produce aflatoxin? The risk rating will no longer be zero.

A recent report of a joint FAO/WHO (2002) consultation defines that the purpose of a risk profile is to enable a decision on what will be done next and whether resources should be allocated to a more detailed scientific assessment. A risk profile comprises a systematic collection of information needed to make a decision, and is the responsibility of the risk manager (although it may be commissioned out to appropriate parties).

Transparency

Characteristics of a process where the rationale, the logic of development, constraints, assumptions, value judgements, decisions, limitations and uncertainties of the expressed determination are fully and systematically stated, documented and accessible for review.

Whenever risk assessments are submitted for peer review or public comment, the reviewers often comment that there is a lack of transparency. This means that they were not able to find important data, or they could not understand a calculation, or the risk assessors did not fully explain their logic.

Uncertainty analysis

A method used to estimate the uncertainty associated with model inputs, assumptions and structure/form.

Risk assessments almost always contain a statement specifying that insufficient data were available in one or more areas and, as a result, a certain amount of caution should be attached to the estimate. Caution, as a result of lack of precise information, leads to uncertainty and you should always record the data gaps that lead to uncertainty. Later, if that knowledge becomes available, the level of uncertainty will be reduced so that the risk estimate becomes more accurate.

Principles and guidelines for risk assessment

In 1999 the CAC set out general principles and guidelines for the conduct of microbiological risk assessment (FAO/WHO, 2001). As we also consider non-microbiological hazards, these principles have been amended from the Codex Principles for Microbial Risk Assessment by omitting "microbiological" where appropriate. The principles state that:

1. Risk assessment should be soundly based upon science.
2. There should be functional separation between risk assessment and risk management.
3. Risk assessment should be conducted according to a structured approach that includes hazard identification, hazard characterization, exposure assessment and risk characterization.
4. A risk assessment should clearly state the purpose of the exercise, including the form of risk estimate that will be the output.
5. The conduct of a risk assessment should be transparent.
6. Any constraints that impact on the risk assessment, such as cost, resources or time, should be identified and their possible consequences described.
7. The risk estimate should contain a description of uncertainty and where the uncertainty arose during the risk assessment process.
8. Data should be such that uncertainty in the risk estimate can be determined; data and data collection systems should, as far as possible, be of sufficient quality and precision that uncertainty in the risk estimate is minimized.
9. A microbiological risk assessment should explicitly consider the dynamics of microbiological growth, survival, and death in foods and the complexity of the interaction (including sequelae) between human and agent following consumption, as well as the potential for further spread.
10. Wherever possible, risk estimates should be reassessed over time by comparison with independent human illness data.
11. A risk assessment may need re-evaluation as new relevant information becomes available.

1.2 TYPES OF RISK ASSESSMENT

There are several types of risk assessment that fall under three broad categories:

- qualitative risk assessment;
- semi-quantitative risk assessment;
- quantitative risk assessment.

All three categories provide useful information and your choice of assessment will depend on the speed and complexity you require from your assessment.

1.1.1 Qualitative risk assessments

These are the simplest and quickest to do, but they can be rather subjective, which reduces their value. Every HACCP plan contains simple qualitative risk assessments in the HACCP worksheet.

For every hazard, an estimate of risk is made by inserting high, medium or low in answer to questions on the severity of the hazard and the likelihood of it occurring. A basic problem is that the three descriptors (high, medium, low) are often inadequate. For example, suppose the process step is retorting in fish canning and the hazard is *Clostridium botulinum*. Almost everyone will describe the severity of the hazard as high. But how likely is the hazard to occur? Most people will put low because billions

Type 1: Hazard control worksheet

Process step	Hazard	What can go wrong	Risk		Hazard control
			Severity of hazard	Likelihood of hazard occurring	
	BIOLOGICAL				
	CHEMICAL				
	PHYSICAL				

of cans of fish are manufactured each year with no sign of the hazard. High severity and low likelihood – how would you link these to estimate risk?

Another type of qualitative risk assessment is shown below, in which the risk estimate is a risk ranking – high, low and medium.

Type 2: Qualitative risk ranking

Hazard	Product	Severity of hazard	Likelihood of occurrence	Exposure in diet	Linkage with epidemiology	Risk ranking

This assessment is based on factors which are linked with exposure assessment (likelihood of occurrence and exposure in the diet) plus one which is linked with hazard characterization (severity of hazard). If the hazard:product pairing has some linkage with epidemiology (it has caused food poisonings), this serves to remind you that there is some probability that it will happen again.

So, in Type 2 (above) we can make some assessment of exposure from our responses to likelihood of occurrence and exposure in the diet. Suppose we are considering ciguatera in two different populations, e.g. people in a Pacific island atoll community and the population of the United Kingdom. For the Pacific you would probably say the likelihood of occurrence of ciguatera is high. For the United Kingdom, you would probably say likelihood of occurrence is very low. There are strong links with epidemiology in atoll communities where the hazard is more or less accepted as an unavoidable fact of life; in contrast, ciguatera only rarely occurs in the United Kingdom from imported reef fish.

When all the information is brought together into a risk ranking you probably have a high or very high ranking for the Pacific and a low or very low ranking for the United Kingdom. The ranking will have value if you need a clear-cut answer in a relatively short time. To get the answer you will need to research the hazard and discover that it may have a cumulative effect but that it is rarely fatal. You will also look into epidemiology of the two target consumer groups – a few thousand atoll residents and 60 million United Kingdom residents. If you can find a recent review of ciguatera, especially one that is written in a risk assessment context, you could complete your research in a short time.

Another qualitative scheme for categorizing risk from seafoods has been developed by Huss, Reilly and Ben Embarek (2000) who ascribe pluses to hazard, then rank risks as “high” (four or more pluses) or “low” (less than four pluses). The scheme takes into account epidemiology (bad safety record) and then focuses on the process, searching for a critical control point (CCP) for each hazard and assessing possibilities for growth and death of microbial hazards.

Type 3: Qualitative risk assessment based on the process

Risk criteria	Raw molluscan shellfish	Canned fish	Dried fish
Bad safety record	+	+	-
No CCP for the hazard	+	-	-
Possibility of contamination or recontamination	+	+	-
Abusive handling possible	+	-	-
Growth of pathogens can occur	+	-	-
No terminal heating step	+	+	+
Risk category	High	Low	No risk

Source: after Huss, Reilly and Ben Embarek (2000).

So, as shown in Type 3, molluscan shellfish, fish eaten raw, lightly-preserved fish and mildly heat-treated fish are considered "high" risk, while chilled/frozen fish and crustaceans, semi-preserved fish and heat-processed (canned) fish are considered "low" risk; dried and heavily salted fish are considered to have no risk.

1.1.2 Semi-quantitative risk assessment

In qualitative risk qssessment, we estimated risk according to subjective terms such as high, low or medium. In semi-quantitative risk assessment we obtain a numerical risk estimate based on a mixture of qualitative and quantitative data. To do this type of assessment you need much of the data that will be used in a full quantitative risk assessment. There is a great deal of work involved, but not as much as for a full quantitative risk assessment.

Ross and Sumner (2002) developed a simple spreadsheet tool to describe the risk that emerges from pathogens in products manufactured by typical processes (canning, chilling, cooking, etc). Table 1 lists risk criteria needed for a semi-quantitative risk assessment. These are simple questions and they can be answered qualitatively in terms such as "high" and "low". But the researchers found it possible to insert a quantitative basis to the answers. The tool is in Microsoft® Excel spreadsheet software and uses standard mathematical and logical functions. You can mouse-click your qualitative inputs, and the software will automatically convert them into quantities for calculations.

You must generate some data in order to answer the eleven questions in Table 1. To help you make your inputs as objective as possible, and to maintain transparency of the model, descriptions of the subjective descriptors are provided and many of

TABLE 1
Typical risk criteria in a semi-quantitative risk assessment

Risk criteria	Input
Dose and severity	
1. Hazard severity	
2. Susceptibility	
Probability of exposure	
3. Frequency of consumption	
4. Proportion consuming	
5. Size of population	
Probability of infective dose	
6. Probability of contamination	
7. Effect of process	
8. Possibility of recontamination	
9. Post-process control	
10. Increase to infective dose	
11. Effect of treatment before eating	

the weighting factors are specified in the lists of descriptors. Alternatively, where the options provided do not accurately reflect the situation being modelled, you can enter a numerical value that is appropriate.

The details behind the model can be read from the publication of Ross and Sumner (2002). Section 4 gives details about the tool, called Risk Ranger, and you can use it to work through some examples. The most robust risk estimates from Risk Ranger are a risk ranking (score from 0 to 100) and the number of illnesses per annum. This tool was used to provide a risk profile for the Australian seafood industry; later we will show you how its estimates were used to focus on those products and pathogens which required most attention from the industry.

1.1.3 Quantitative risk assessment

Quantitative risk assessments (QRAs) are done for specific purposes and provide numerical risk estimates to answer questions that were posed by the risk managers who originally commissioned the assessment. In the seafood area there have been three QRAs:

- *Listeria monocytogenes* in smoked fish in Sweden (Lindqvist and Westöö, 2000);
- *Vibrio parahaemolyticus* in oysters in the United States (FDA, 2000);
- *Listeria monocytogenes* in a range of seafoods in the United States (FDA, 2001).

The United States risk assessments were very large, taking more than one year to prepare and then moving to a 1–2 year review period of public comment. The *L. monocytogenes* risk assessment involved more than 30 people arranged in six teams, each of which was assigned specific tasks; more than 50 additional participants were acknowledged for their assistance. It must be stressed that this QRA involved a range of foods, not just seafoods, but the QRA of *V. parahaemolyticus* in oysters also involved more than 20 people who received information from scientists at more than 20 institutions in the United States and internationally. The Swedish QRA had two authors and acknowledged the help of two collaborators.

The resources invested in the two United States risk assessments were undoubtedly in response to large outbreaks of food poisoning in that country. In 1997 and 1998 there were two incidents involving *V. parahaemolyticus* in oysters involving more than 700 cases of illness, which led to the commissioning of the QRA. Also in the late 1990s there were two listeriosis incidents in the United States involving hot dogs and delicatessen meats in which more than 130 were seriously ill and 28 died.

Setting objectives – statement of purpose

In a QRA, it is vital to define what you want the work to achieve, and to do this right at the beginning. This is called a Statement of Purpose. In the United States, the risk managers stipulated that, for *V. parahaemolyticus* in oysters, the risk assessors:

1. produce a mathematical model of the risk of illness incurred by consumers of raw oysters containing pathogenic *V. parahaemolyticus*;
2. provide the regulators with information to assist with reviewing current regulations to ensure that they protect public health by evaluating:
   - current criteria for closing and reopening shellfish waters to harvesting;
   - preventive and intervention measures for controlling *V. parahaemolyticus* in oysters;
   - current guidance on allowing up to 10 000 cfu/g of *V. parahaemolyticus* in oyster meat.

For *L. monocytogenes*, the Statement of Purpose was to examine available scientific data systematically in order to estimate the relative risks of serious illness and death that might be associated with consumption of different types of ready-to-eat foods that might be contaminated with *L. monocytogenes*. The work produced mathematical models to predict contamination at the retail level and in the home, and different

consumer groups were included in the assessment. The result was predicted rates of listeriosis from various foods for various at-risk groups.

In Sweden, Lindqvist and Westöö (2000) set the objective to develop a QRA for estimating the exposure and risk of acquiring listeriosis from consumption of packaged smoked or gravad salmon and rainbow trout.

Modelling the process

In the seafood industry, the process is usually stretched out from harvesting, storing prior to processing, processing in the seafood plant, storing/distributing, retailing and consumption. Whatever the seafood product you are considering, the hazard may change throughout the process, either in prevalence or in concentration. We need to chart these changes often by making a process flow diagram and then mathematically measure or estimate changes in the hazard at each stage. In risk assessment this is called "modelling". Usually modellers try to make a "farm-to-fork" model that takes in changes to the hazard all along the harvest–process–consumption route. This part of the risk assessment is best done by people who understand the industrial process and combined with microbiologists who understand the hazard and how it reacts to changes, particularly to changes in temperature and time.

When the model of the system has been set, data must be gathered (exposure assessment). Ideally, there would be time to carry out experiments that give you exactly the data you need but, almost always, there are not sufficient resources or time to do this. So you need to investigate all sources of existing data and try to incorporate them into the model. This is where the modeller on your team takes the data and constructs mathematical relationships that describe changes in the hazard throughout the process. The modeller will encounter a number of problems, the most common being variability and uncertainty.

Variability

This occurs because of the diversity in any population, and it cannot be reduced, no matter how much the property is studied. To illustrate, let us use height as an example. In any population there is variability in height. We could do a survey by measuring how tall people are, and we would find most adults are 160–175 cm tall but that some are 220 cm while others are 120 cm. This is an example of variability within a population.

Uncertainty

This is due to our (the risk assessor's) lack of knowledge about a parameter and our inability to measure it. Uncertainty can be reduced if we study the characteristic. Using the same example of peoples' height, we could do a national survey and measure everyone. Then there would be no uncertainty.

Distributions

The risk is never fixed – it varies according to a range of parameters. For example, take the risk of dying in an air crash. For the vast majority of people on this earth the risk is zero because they never fly but, among those many millions who do fly, the risk varies according to how often they fly (likelihood), the airline (some have more crashes than others), the weather conditions (many crashes occur in bad weather) and the country (some have better systems than others). So estimating the risk is difficult because there is a distribution of risk from very low, through average to very high. Often the best estimate of distribution is minimum, most likely (average) and maximum value. For example, we might say the bacterial levels of shrimp landed aboard a trawler ranged from 10/g to 10 000/g, with the most likely count being 100/g.

Type of model
Modellers generally use simulation or stochastic modelling in which data are inserted into a spreadsheet. Computer software is then used to analyse the data. Each analysis is called an iteration where a value is selected from the distribution describing each variable range, more or less at random, but according to the probability distribution of that variable (more likely values are run more frequently than minimum or maximum values). A large number of iterations is run (10 000 is a popular number) and collated; the technique is called Monte Carlo simulation. The result is a distribution frequency of possible outcomes, which forms the basis of the risk estimate.

Risk estimate
The way you estimate the risk in a QRA is usually set by the statement of purpose. For example, Lindqvist and Westöö (2000) estimated the risk of acquiring listeriosis, and so risk estimates included the number of cases per annum and risk of becoming ill on a per serving basis. The researchers used two models and so had two estimates for each output. In the United States, the relative risk of acquiring listeriosis from a range of foods was the estimate, with pâtés, smoked seafoods, soft cheeses and delicatessen meats being the four most likely to cause the illness. For *V. parahaemolyticus* in oysters the single most important factor related to risk of illness was temperature – of air and water (seasonality). The model predicted nationwide illnesses of 4 750 per annum with a range of 1 000 to 16 000 cases. The model also indicated that risk of illness was reduced if product temperature could be lowered soon after harvest.

Reality check
When you have the risk estimates it is a good idea to do a reality check to see that the model is not predicting something that will seem absurd. For example, suppose you are estimating the number of cases of listeriosis caused by consumption of smoked fish and the model predicts the most likely scenario of 1 million cases each year. If your country statistics on illness and death state that there are 1 000 such cases each year, you know there is something wrong either with the model or with the inputs. You have more work to do!

Sensitivity (importance) analysis
As the software grinds through the iterations it also keeps a record of which factors have the biggest effect on risk estimate. This allows you to do sensitivity or importance analysis to identify those factors most influencing risk – either reducing or increasing it. This analysis then points risk managers to those areas where process control can be increased.

Summary
Risk assessments range in complexity from qualitative, through semi-quantitative to quantitative. As assessments become more complex, they also become more expensive and take longer to complete. So before you begin a risk assessment be sure you know exactly what you want or you may end up using resources unnecessarily.