Food safety and public health risks associated with products of aquaculture

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ABSTRACT

The Sanitary and Phytosanitary (SPS) Agreement within the framework of the World Trade Organization emphasizes the need to apply risk analysis as a basis for taking any SPS measure. With the adoption of the food-chain approach for food safety, the responsibility for the supply of safe food is shared along the entire food chain from primary production to final consumption. Thus the application of risk analysis to the aquaculture sector, which produces nearly half the fish that is consumed worldwide, has become very important. Guidelines for performing risk analysis have been brought out by the Codex Alimentarius Commission or Codex. Risk analysis is a process consisting of risk assessment, risk communication and risk management. Risk assessment is the scientific evaluation of known or potential adverse health effects resulting from human exposure to foodborne hazards. This consists of four steps: hazard identification, hazard characterization, exposure assessment and risk characterization. The output of risk assessment may be a qualitative or a quantitative (numerical) expression of risk as well as attendant uncertainties. Hazard identification considers epidemiological data linking the food and biological/chemical agent to human illness and the certainty associated with such effects. At the hazard characterization step, a qualitative or quantitative description of the severity and the duration of the adverse health effect that may result from the ingestion of the micro-organism/toxin/chemical contaminants is made. During exposure assessment, an estimate of the number of bacteria or the level of a biotoxin or chemical agent consumed through the concerned food is made. The Codex defines the risk characterization step as the process of determining the qualitative and/or quantitative estimation including attendant uncertainties of the probability of occurrence and the severity of the known or potential adverse health effect in a given population based on hazard identification, exposure assessment and hazard characterization. As an example of a risk assessment, the Food and Agriculture Organization of the United Nations/World Health Organization risk assessment for choleragenic *Vibrio cholerae* in warmwater shrimp in international trade is presented. Risk management is the process of weighing policy alternatives in the light of the results of risk assessment and if required, selecting and implementing appropriate control options, including regulatory measures. Risk communication is an interactive process of exchange of information and opinion on risk among risk assessors, risk managers and other interested parties. Examples of risk management measures adopted based on risk assessment are presented.

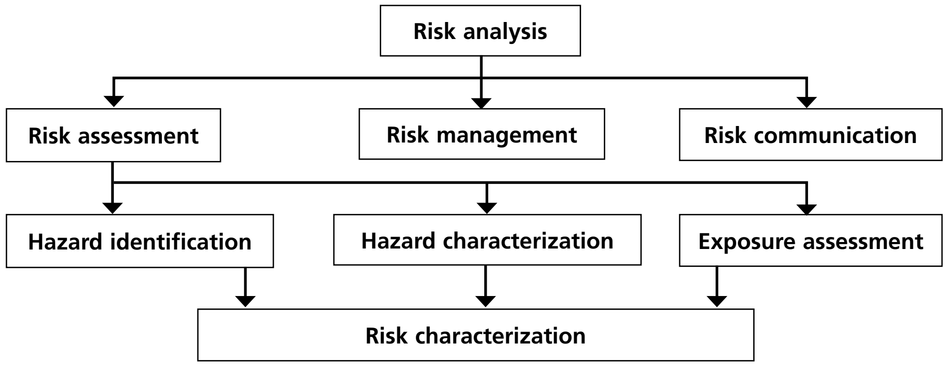
INTRODUCTION

Outbreaks of food-borne illnesses continue to be a major problem worldwide, and international trade in food products is increasing. According to World Health Organization (WHO) estimates, 1.8 million deaths related to contaminated food or water occur every year. Traditionally, food safety programmes have focused on enforcement mechanisms for final products and removal of unsafe food from the market instead of a preventive approach. In such a model, the responsibility for safe food tends to concentrate on the food-processing sector. The Food and Agriculture Organization of the United Nations (FAO) is recommending a food-chain approach that encompasses the whole food chain from primary production to final consumption. In such a system, the responsibility for a supply of food that is safe, healthy and nutritious is shared along the entire food chain by all involved in the production, processing, trade and consumption of food. Stakeholders include farmers, fishermen, processors, transport operators (raw and processed material) and consumers, as well as governments obliged to protect public health. In order to protect public health and facilitate international food trade, the member countries of the World Trade Organization (WTO) have signed the Sanitary and Phytosanitary (SPS) Agreement. Under this agreement, member countries have a right to take measures to ensure that consumers are supplied with safe food, but they also have the obligation to ensure that their food safety regulations are based on risk analysis and are not arbitrary and used as a means to protect domestic producers from competition. Considering that nearly 50 percent of the fish traded in international markets comes from aquaculture, it is important to ensure that the aquaculture sector is producing safe food. The food-chain approach to food safety is based on five important aspects:

- The three fundamental concepts of **risk analysis** – risk assessment, risk management and risk communication – should be incorporated into food safety. There should be an institutional separation of science-based risk assessment from risk management, which is the regulation and control of risk.
- **Traceability** from the primary producer (including fish feed) through post-harvest treatments, food processing and distribution to the consumer should be improved.
- **Harmonization of food safety standards** is necessary; this implies increased development and wider use of internationally agreed-upon, scientifically based standards. The Technical Barriers to Trade (TBT) Agreement of WTO tries to achieve this by ensuring that arbitrary standards do not become barriers to international trade.
- **Equivalence of food safety systems** that achieve similar levels of protection against food-borne hazards, whatever means of control are used. This is a requirement under the SPS Agreement.
- Increased emphasis on **risk avoidance or prevention at source** within the whole food chain – from farm or sea to plate – is necessary to complement conventional food safety management based on regulation and control.

Complementing the current emphasis on regulation and control of the food safety system with preventive measures to control the introduction of contamination at source requires the adoption of practices in food production, handling and processing that reduce the risk of microbiological, chemical and physical hazards entering the food

FIGURE 1
The risk analysis process



chain. There are some hazards such as chemical contaminants and biotoxins in shellfish that cannot be simply removed from foodstuffs. The adoption of sound practices along the food chain based on principles defined in Good Aquaculture Practices (GAP) and in-plant control of food processing based on hazard analysis and critical control point (HACCP) analysis is important to prevent such hazards from entering the system. By using a risk-based approach to the management of food safety, food control resources can be directed to those hazards posing the greatest threat to public health and where the potential gains from risk reduction are large relative to the resource use. Establishing risk-based priorities requires sound scientific knowledge and effective systems for reporting the incidence of food-borne diseases.

Guidelines for performing risk analysis have been brought out by the Codex Alimentarius Commission (CAC). According to Codex, risk analysis is a process consisting of risk assessment, risk management and risk communication. Risk assessment is a scientifically based process involving the following four steps: hazard identification, hazard characterization, exposure assessment and risk characterization (Figure 1).

THE RISK ANALYSIS PROCESS

Hazard identification

This involves identification of biological or chemical agents capable of causing adverse health effects that may be present in a particular food or group of foods. Products of aquaculture include freshwater and marine finfish as well as shellfish (molluscs and crustaceans). Hazard identification considers epidemiological data linking the food and biological/chemical agent to human illness (CCFH, 1998) and the certainty and uncertainty associated with such effects. Data from national surveillance programmes, microbiological and clinical investigations, and process evaluation studies are important (Fazil, 2005). At the hazard identification step, a qualitative evaluation of available information is carried out and documented. The characteristics of the organism/toxin/chemical agent, including its effects on the host and mode of action, are considered. Table 1 lists known or potential hazards associated with products of aquaculture. Based on epidemiological evidence, only a few microbial agents are known to be involved in foodborne illnesses; however, only a small number of outbreaks have been adequately investigated. Therefore, limitations of hazard identification with respect to biological agents include the expense and difficulty involved in outbreak investigations, and the difficulties involved in the isolation and characterization of certain pathogens such as viruses. However, for most chemical agents, clinical and epidemiological data are unlikely to be available. Since the statistical power of most

TABLE 1
Biological and chemical hazards associated with aquaculture products

Known or potential hazard	Product likely to be affected	Epidemiological evidence
BIOLOGICAL AGENTS		
Bacteria		
Vibrio vulnificus	Molluscan shellfish	Strong
V. parahaemolyticus	Shellfish	Strong
V. cholerae	Fish and shellfish	Very weak
Salmonella	Fish and shellfish	Very weak
Viruses		
Norovirus	Molluscan shellfish	Strong
Hepatitis A virus	Molluscan shellfish	Strong
Parasites		
Fish-borne trematodes *(Opisthorchis viverrini, Clonorchis sinensis)*	Finfish	Strong
Biotoxins		
Paralytic shellfish poisoning (PSP)	Molluscan shellfish	Strong
Diarrhetic shellfish poisoning (DSP)	Molluscan shellfish	Strong
Amnesic shellfish poisoning (ASP)	Molluscan shellfish	Strong
Neurotoxic shellfish poisoning (NSP)	Molluscan shellfish	Strong
Chemical agents		
Polychlorinated biphenyls (PCBs)	Finfish and shellfish	Epidemiological data lacking
Pesticides	Finfish and shellfish	

epidemiological investigations is inadequate to detect effects at relatively low levels in human populations, negative epidemiological evidence is difficult to interpret for risk assessment purposes. Where positive epidemiological data are available, consideration should be given to variability in human susceptibility, genetic predisposition, age-related and gender-related susceptibility, and the impact of factors such as socio-economic and nutritional status. Due to a paucity of epidemiological data, hazard characterization may have to rely on data derived from animal and *in vitro* studies.

Some examples of hazard identification are given in Box 1.

Exposure assessment

At this step, an estimate of the number of bacteria or the level of a biotoxin or a chemical agent consumed through the concerned food is made. This involves documenting the sources of contamination, frequency, concentration and estimation of the probability and the concentration that will be consumed. This requires information on the pathogen (e.g. ecology of the microbial pathogen, distribution, growth, inhibition or inactivation during handling and processing), on the food (food composition – pH, water activity, nutrient content, presence of antimicrobial agents, competing microflora; processing practices; handling at retail and consumer preparation practices), and on the consumer (population demographics, food consumption patterns).

Primarily, exposure assessment is concerned with estimating the likelihood of being exposed to the hazard through consumption of the food under consideration and the amount or dose to which an individual or population is exposed. Microbial hazards are much more dynamic as compared to chemical hazards because of the potential of micro-organisms to multiply in foods or their numbers being reduced due to handling, processing or storing (e.g. freezing) of foods and consumer preparation (e.g. cooking) steps that may inactivate them. With respect to microbial toxins, a combination of the microbes' characteristics and the chemical-like effects of the toxin are to be considered. Data on the concentration of the pathogen in the food at the time of consumption are rarely available and therefore, it is necessary to develop models or assumptions to estimate the likely exposure. For bacteria, the growth and death of the organism under the predicted handling and processing conditions of the food are considered in the model, which would take into account the effects on the pathogen due to time, temperature, food chemistry and the presence of competing microflora. However, biological agents like viruses and parasites do not multiply in foods. In these cases, handling, storage and processing conditions may affect their survival.

BOX 1

Some examples of hazard identification

Vibrio vulnificus occurs in warm estuarine environments all over the world and three biotypes have been reported (Bisharat and Raz, 1997; Bisharat *et al.,* 1999; Strom and Paranjpye, 2000). Nearly all human cases resulting from seafood consumption are due to Biotype 1. Biotype 2 is associated with infections in cultured eel and Biotype 3 is limited to wound infections associated with handling cultured fish in ponds. Annually, about 30–40 cases of primary septicaemia due to Biotype 1 are reported from the United States of America, but there is little epidemiological evidence of cases in other countries. Nearly all cases are associated with consumption of raw oysters harvested from the Gulf coast. Although foodborne *V. vulnificus* infections are rare, case fatality ratio is high, exceeding 50 percent (Hlady and Klontz, 1996; Mead *et al*., 1999). Individuals with pre-existing liver diseases are at the greatest risk of contracting primary septicaemia and subsequent mortality, but other chronic illnesses and immunodeficiency conditions are also associated with increased risk. *Vibrio vulnificus* is not a hazard that is specific to aquaculture products. Natural beds of oysters, mussels and clams may contain this organism. As the organism is not derived from faecal contamination, its presence is not higher in polluted environments.

Vibrio parahaemolyticus is a halophilic bacterium found in coastal and estuarine environments throughout the world (Joseph, Colwell and Kaper, 1982). However, most environmental strains are not human pathogens. Strains isolated from clinical cases produce a thermostable direct hemolysin (TDH) or a TDH-related hemolysin (TRH) (Joseph, Colwell and Kaper, 1982; Honda, Ni and Miwatani, 1988). Gastroenteritis, an illness of short duration and moderate severity that is characterized by diarrhea, vomiting and abdominal cramps, is the most common clinical manifestation of *V. parahaemolyticus* infection. Individuals with underlying medical conditions (diabetes, alcoholic liver disease, hepatitis, those receiving immunosuppressive therapy for cancer or AIDS) do not seem to be more susceptible to initial infection, but they may have higher risk of the infection developing into septicaemia. In the United States of America, most infections are associated with consumption of raw oysters; but in other countries, a wide variety of seafood including finfish, crayfish, crabs, shrimp and clams have been involved. In the United States of America, about 4 500 cases occur annually; a much higher number of cases is reported from Japan. While most outbreaks are sporadic, outbreaks with pandemic potential have been reported recently, and the strains involved belong mostly to O3:K6, O4:K68 and O1:KUT serotypes. Cases involving these serotypes appeared in India in 1996 and were detected in Southeast Asia, Japan and the United States of America (Okuda *et al.,* 1997; Daniels *et al.,* 2000). This organism is present in both cultured and wild fish and shellfish and is not derived from faecal contamination of the waters.

Hazards associated with foodborne viruses have been recognized recently. Transmission of norovirus and hepatitis A virus through consumption of raw molluscs has been reported from several countries. The largest outbreak of hepatitis A occurred in and around Shanghai in the People's Republic of China in 1988 in which more than 293 000 individuals became sick after eating clams (Xu *et al.,* 1992). Several cases have been reported from the United States of America, Australia and Europe (Richards, 2006). The bacteriological standards for shellfish-growing waters seem to be ineffective in preventing viral disease outbreaks. An outbreak of hepatitis A occurred in Spain in 1999 with 184 cases from clams meeting European Union standards (Sanchez *et al.,* 2002). Outbreaks of illness due to shellfish-borne norovirus have been reported from the United States of America, Australia, several countries in Europe, China and Japan (Richards, 2006). Unlike the *Vibrio* spp. mentioned above, these viruses are derived from sewage contamination of shellfish-growing areas. There is a high rate of secondary spread of viruses following a food-borne episode. Therefore, it is a challenge to obtain reliable estimates for the proportion of illness that is foodborne.

With respect to chemical hazards, exposure assessment requires information on the consumption of relevant foods and the concentration of the chemical of interest in the foods. Chemical contaminants and pesticides are generally present, if at all, at very low concentrations. Estimation of the dietary intake of chemical contaminants requires information on their distribution in foods that can only be obtained by analysing representative samples of relevant foods with sufficiently sensitive and reliable methods. Guidelines for estimation of dietary intake of contaminants are available from WHO (GEMS/Food, 1985).

Hazard characterization and dose-response analysis

At this step, a qualitative or quantitative description of the severity and the duration of the adverse health effect that may result from the ingestion of microorganism/toxin/chemical contaminants is made. The virulence characters of the pathogen, effect of food matrix on the organism at the time of consumption (factors of the food such as high fat content that may protect the organism by providing increased resistance to gastric acids), host susceptibility factors and population characteristics are considered. Wherever data are available, a dose response analysis is performed. Data for dose response analysis may come from outbreak investigations, human volunteer studies, vaccine trial studies or animal studies. In the example given later in this paper, dose response for choleragenic *V. cholerae* in seafood has been estimated based on data from vaccine trials.

Risk characterization

Codex defines the risk characterization step as the process of determining the qualitative and/or quantitative estimation including attendant uncertainties of the probability of occurrence and the severity of the known or potential adverse health effect in a given population based on hazard identification, exposure assessment and hazard characterization. The output of risk characterization is not a simple qualitative or quantitative statement of risk. Risk characterization should provide insights into the nature of the risk, including a description of the most important factors contributing to the average risk, the largest contributions to uncertainty and variability of the risk estimate and a discussion of gaps in data and knowledge. A comparison of the effectiveness of various methods of risk reduction is also presented.

The output of risk characterization is the risk estimate, which may be qualitative (low, medium, high); semi-quantitative (the risk assessors making a ranking, i.e. a number within a range, e.g. 0–100); or quantitative (the risk assessors predicting the number of people who are likely to become ill from the pathogen-commodity/product combination). Qualitative risk assessment is performed when data are inadequate to make numerical estimates, but when conditioned by prior expert knowledge and identification of attendant uncertainties, data are sufficient to permit risk ranking or separation into descriptive categories of risk. An example of qualitative risk assessment is given 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 of pathogenic bacteria.

Quantitative risk assessments are based on mathematical models incorporating quantifiable data and emphasize the likelihood of an adverse health effect (e.g. illness, hospitalization, death). These can be further subdivided into deterministic and probabilistic risk assessments. For deterministic risk assessment, single input values that best represent the factors in the system are chosen. The values could represent the most likely value or values that capture a worst-case situation. Deterministic risk assessment does not provide information on the uncertainty of the risk estimate.

However, selecting worst-case values and combining worst-case input values across multiple factors affecting food safety performance may be too stringent for most of the industry if risks are associated with extremes of performance. In the case of probabilistic risk assessments, input values are distributions that reflect variability and/or uncertainty. Uncertainty analysis is a method used to estimate the uncertainty associated with models and assumptions used in the risk assessment.

Almost always, risk assessments have 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 it is always important to 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. Risk assessment is an iterative process and may need re-evaluation as new data become available. Wherever possible, risk estimates should be reassessed over time by comparison with independent human illness data.

Risk management

Risk management is the process of weighing policy alternatives in the light of the results of risk assessment and if required, selecting and implementing appropriate control options including regulatory measures. According to Codex (FAO, 1997), risk management should follow a structured approach involving the elements of risk evaluation, risk management option assessment, implementation of management decision, monitoring and review.

Risk evaluation

Risk evaluation involves identification of a food safety problem, establishment of a risk profile, ranking of hazards for risk assessment and risk management priority, establishment of policy for conduct of risk assessment, commissioning of the risk assessment and consideration of the risk assessment results. Identification of the food safety issue is the entry point for preliminary risk management activities and may come to the attention of the risk manager through disease surveillance data, inquiry from a trading partner or consumer concern. A risk profile comprises a systematic collection of information needed to make a decision. This can include description of the food safety issue, information about the hazard, any unique characteristics of the pathogen/human relationship, information about the exposure to the hazard, possible control measures, feasibility and practicality, information on adverse health effect (type and severity of illness, subset of population at risk) and other information for making risk management decisions. Based on the information generated in the risk profile, the risk manager may be able to make a range of decisions. Where possible and necessary, the risk manager may commission a risk assessment. This would involve defining the scope and purpose of the risk assessment, defining risk assessment policy, interactions during the conduct of the risk assessment and consideration of the outputs of risk assessment.

Risk option assessment

This step consists of identification of available management options, selection of the preferred management option, including consideration of appropriate safety standard, and making the final management decision. Optimization of food control measures in terms of their efficiency, effectiveness, technological feasibility and practicality at different points in the food chain is an important goal. A cost-benefit analysis could be performed at this stage.

Implementation of the risk management decision

This will usually involve regulatory food safety measures such as the Hazard Analysis and Critical Control Points (HACCP). There could be flexibility in the measure applied by the industry as long as it can be objectively demonstrated that the programme is able to achieve the stated goals. On-going verification of the food safety measure is essential.

Monitoring and review

This is the gathering and analysing of data that gives an overview of food safety and consumer health. Foodborne disease surveillance identifies new food safety problems as they emerge. If the monitoring indicates that the required food safety levels are not being reached, redesign of the measures will be needed (FAO/WHO, 2002).

Further risk management considerations

Protection of human health should be the primary consideration in arriving at any risk management decision. Other considerations (e.g. economic costs, benefits, technical feasibility and societal preferences) may be important in some contexts, particularly in deciding on the measures to be taken. However, these considerations should not be arbitrary and should be made explicit. Risk management should:

- include the identification and systematic documentation of all elements of the risk management process including decision-making, so that the rationale is transparent to all interested parties (e.g. consumer organizations, food industry and trade representatives, educational and research institutions, and regulatory bodies);
- include determination of risk assessment policy as a specific component. (Risk assessment policy sets the guidelines for value judgments and policy choices that may need to be applied at specific decision points in the risk assessment process, and preferably should be determined in advance of risk assessment, in collaboration with risk assessors.);
- ensure the scientific integrity of the risk assessment process by maintaining the functional separation of risk management and risk assessment. (However, as risk analysis is an iterative process, interactions between risk managers and risk assessors are essential for practical application.);
- lead to decisions that take into account the uncertainty in the output of the risk assessment. (The risk assessment should include numerical expression of uncertainty, and this must be conveyed to risk managers in an understandable form so that the full implications of the range of uncertainty are included in risk management decisions.);
- include clear, interactive communication with consumers and other interested parties in all aspects of the process;
- be a continuing process that takes into account all newly generated data in the evaluation and review of risk management decisions.

Governments in a number of countries are undertaking quantitative risk assessments for specific microbiological hazards in foods with the intention that the output can be used to develop national food safety measures. This is also a requirement in international trade in foods because the SPS Agreement under the World Trade Organization (WTO) permits countries to take legitimate steps to protect the life and health of their consumers, while prohibiting them from using these measures in ways that unjustifiably restrict trade. The standards, guidelines and recommendations of Codex are considered by WTO to reflect international consensus regarding requirements for protecting human health and safety. A member country's food safety measures are considered justified and in accordance with the provisions of the SPS Agreement if they are based on Codex standards or guidelines. Failure to apply Codex standards could create potential for dispute if a member applies a standard that is more restrictive for trade than necessary to achieve the required level of protection. Members are required to justify levels of protection higher than those in Codex by using risk assessment techniques.

In the context of food safety, an appropriate level of protection (ALOP) is a statement of public health protection that is to be achieved by the food safety systems implemented in that country. Most commonly, ALOP is articulated as a statement of disease burden associated with a hazard/food combination and its consumption within the country. ALOP is often framed in the context for continual improvement in relation to disease reduction. For example, if a country has 100 cases of *Vibrio parahaemolyticus* due to consumption of raw oysters per 100 000 population and wants to implement a programme that reduces the incidence, there are two possible approaches in converting this goal into a risk management programme. The first is the articulation of a specific public health goal, i.e. to reduce the number of cases to 10 per 100 000 population. This is based on the assumption that there are practical means of achieving this. The alternate approach is to evaluate the performance of risk management options currently available and select an ALOP based on one or more of these options. This is often referred to as the as low as reasonably achieved (ALARA) approach.

Implementation of a food safety control programme greatly benefits by expression of ALOP in terms of the required level of control of hazard in foods. The concept of food safety objective (FSO) provides a measurable target for producers, consumers and regulatory authorities. FSO has been defined as "the maximum frequency and/or concentration of a microbiological hazard in a food at the time of consumption that provides the appropriate level of protection" (FAO/WHO, 2002). FSOs are usually used in conjunction with performance criteria and/or performance standards that establish the required level of control of hazard at other stages in the food chain. A performance criterion is the required outcome of a step or a combination of steps that contribute to assuring that the FSO is met. Performance criteria are established considering the initial level of hazard and changes during production, distribution, storage, preparation and use of the food. The control of *Listeria monocytogenes* in foods provides an example of the need to consider a structured risk management approach (Box 2).

BOX 2

The control of *Listeria monocytogenes* in foods

The FAO/WHO (2004) risk assessment for *L. monocytogenes* in ready-to-eat foods indicates that *Listeria* is frequently consumed in small amounts by the general population without apparent ill effects. Dose response data indicate that only higher levels of *Listeria* have caused severe disease problems. It is also evident that *Listeria* is a bacterium that will always be present in the environment. Therefore, the critical issue may not be how to prevent *Listeria* in foods, but how to control its survival and growth in order to minimize the potential risk. Complete absence of *Listeria* is unrealistic and unattainable for many foods, and trying to achieve this goal can limit trade without having any appreciable benefit to public health. A relevant risk management option, therefore, is to focus on foods that support growth of *Listeria* to high levels, rather than those that do not. Thus, establishment of tolerable low levels of *Listeria* in specific foods may be one food safety objective established by risk managers after a rigorous and transparent risk analysis. However, there is no internationally accepted FSO for *L. monocytogenes*, and the Codex Committee on Food Hygiene (CCFH) has come up with questions to the risk assessment team including an estimation of the difference in risk resulting from FSOs varying between "absence" (0 cells/25 g) and 1 000 cells/g.

Risk communication

Risk communication is an interactive process of exchange of information and opinion on risk among risk assessors, risk managers and other interested parties (e.g. government agencies, industry representatives, the media, scientists, professional societies, consumer organizations, other public interest groups and concerned individuals). The practical application of risk communication in relation to food safety involves all aspects of communication among risk assessors, risk managers and the public. Risk communication may originate from official sources at the international, national or local levels. It may also be from other sources such as industry, trade, consumers and other interested parties. In some cases, risk communication may be carried out in conjunction with public health and food safety education programmes. The goals of risk communication are to:

- promote awareness and understanding of the specific issues under consideration during the risk analysis process by all participants;
- promote consistency and transparency in arriving at and implementing risk management decisions;
- provide a sound basis for understanding the risk management decisions proposed or implemented;
- improve the overall effectiveness and efficiency of the risk analysis process;
- contribute to the development and delivery of effective information and educational programmes, when they are selected as risk management options;
- foster public trust and confidence in the safety of the food supply;
- strengthen the working relationships and mutual respect among all participants;
- promote the appropriate involvement of all interested parties in the risk communication process; and
- exchange information on the knowledge, attitudes, values, practices and perceptions of interested parties concerning risks associated with food and related topics.

At an international level, organizations like the Codex Alimentarius Committee (CAC), FAO, World Health Organization (WHO) and WTO are involved in risk communication. The general subject Codex Committees are involved in risk management such as development of standards, guidelines and other recommendations. Risk assessment information is often provided by the Joint FAO/WHO Expert Committee on Microbiological Risk Assessments. The FAO/WHO Codex Secretariat carries out risk communication through publication of various documents and Internet-based communications. The WTO SPS Committee manages the implementation of the SPS Agreement for WTO member countries; and, through the notification procedure required by the SPS Agreement, it communicates risk management decisions among those member countries.

National governments have the fundamental responsibility of risk communication while managing public health risks, regardless of the management method used. Governments that are members of CAC need to take an active role in the Codex process and ensure that all interested parties in their countries contribute to the national position on Codex matters to the extent practicable and reasonable. Since industry is responsible for the safety of the food it produces, it has corporate responsibility to communicate information on the risks to the consumers. Food labeling is used as a means of communicating instructions on the safe handling of food as a risk management measure. Consumer organizations can work with government and industry to ensure that risk messages to consumers are appropriately formulated and delivered.

FAO/WHO RISK ASSESSMENT FOR CHOLERAGENIC *VIBRIO CHOLERAE* IN WARMWATER SHRIMP IN INTERNATIONAL TRADE: EXAMPLE OF A RISK ASSESSMENT

Seafood exports are a major source of foreign exchange for many Asian countries. Incidentally cholera is endemic in some Asian countries; and exports are often affected whenever there are reports of cholera in seafood-producing countries. Shrimp constitute the major seafood commodity that is affected. In 2003, there were 4.3 million tonnes of shrimp in international trade, of which 70 percent was warmwater shrimp. Considering the importance of shrimp from warm waters in international trade, FAO/WHO set up an expert committee to perform a risk assessment for *Vibrio cholerae* in warmwater shrimp processed for export. This section summarizes the findings of the FAO/WHO Drafting Group; the complete risk assessment is given in FAO/WHO (2005).

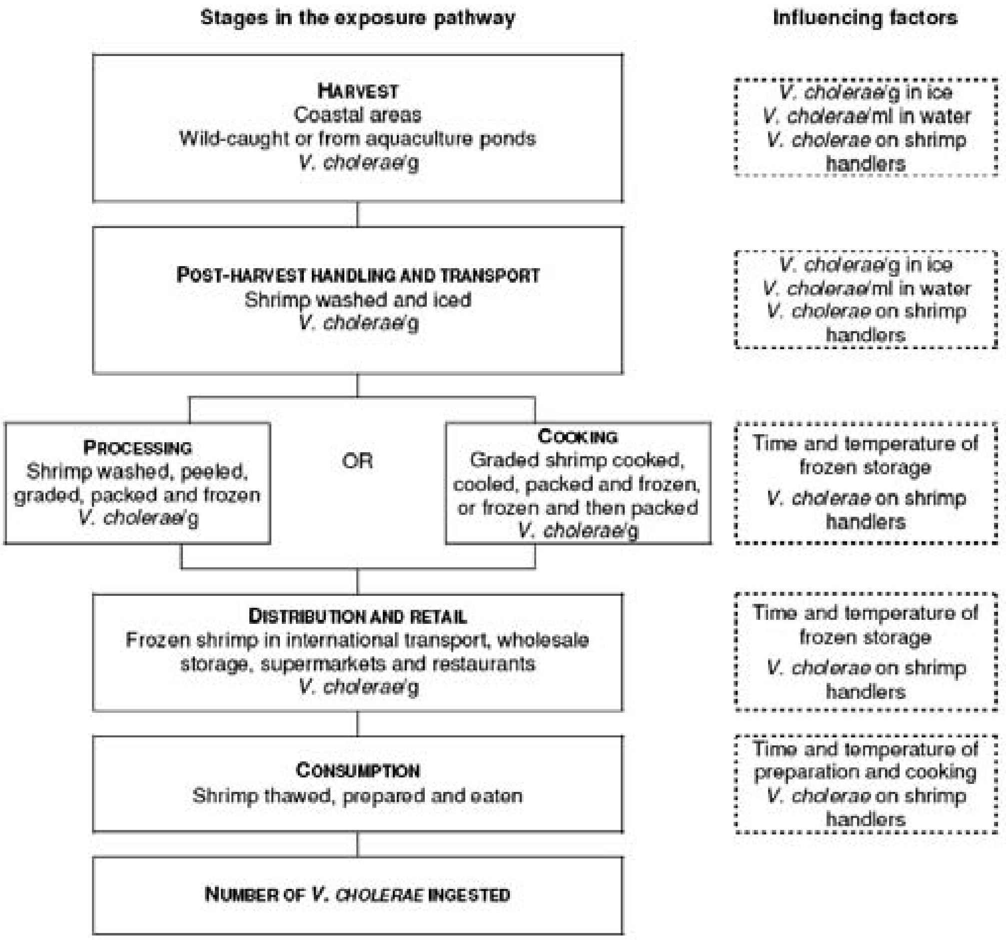
Vibrio cholerae is a heterogeneous species consisting of over 220 serotypes. The disease cholera is caused only by serotypes O1 and O139, which are also referred to as choleragenic *V. cholerae*. Strains belonging to non 01/non-0139 serotypes of *V. cholerae* are widely distributed in the aquatic environment and are mostly nonpathogenic to humans, although they are occasionally associated with sporadic cases of gastroenteritis (Kaper, Morris and Levine, 1995; Desmarchelier, 1997). Choleragenic *V. cholerae* are characterized by their ability to produce cholera toxin, which is a complex protein consisting of A and B subunits. Production of cholera toxin is encoded by *ctx*AB genes. The *ctx* gene is present in a filamentous bacteriophage that infects *V. cholerae* through a pilus called toxin co-regulated pilus (Waldor and Mekalanos, 1996; Faruque, Albert and Mekalanos, 1998). Since the *ctx*AB gene is phage encoded and there may be loss of bacteriophage in some environmental strains, it is possible to isolate non-toxigenic *V. cholerae* O1 from the environment and occasionally from seafoods like shrimp (Colwell, Kaper and Joseph, 1977; Kaper *et al*., 1979; Dalsgaard *et al.,* 1995). Serotyping alone is inadequate to detect choleragenic *V. cholerae* due to serological cross reactions (Shimada, Sakazaki and Oue, 1987; Dalsgaard, Mazur and Dalsgaard, 2002). Thus use of molecular techniques such as polymerase chain reaction (PCR) or DNA probe hybridization has become important in determining the presence of choleragenic *V. cholerae* in seafood (Koch *et al.,* 1993, Karunasagar *et al*., 1995).

In the aquatic environment, *V. cholerae* may be associated with copepods (Huq *et al.,* 1983). But copepods are planktonic organisms while shrimp are demersal and therefore, *V. cholerae* is generally not associated with shrimp in their natural environment. Under an FAO-sponsored shrimp microbiology project during the late 1980s, shrimp surface and gut were tested for the presence of *V. cholerae* in a number of countries such as India, Thailand, Sri Lanka, Indonesia, Malaysia and the Philippines. The data from this study indicated absence of choleragenic *V. cholerae* in association with shrimp (Karunasagar *et al.,* 1990, 1992; Fonseka, 1990; Rattagool *et al.,* 1990). Although one study in the mid 1990s detected *V. cholerae* O1 in tropical shrimp, molecular studies indicated that the isolates were non-toxigenic (Dalsgaard *et al.*, 1995).

For risk assessment, it is important to consider the prevalence and concentration of choleragenic *V. cholerae* in shrimp during all stages of the farm to fork chain. The model considered in this risk assessment is shown in Figure 2. Warmwater shrimp intended for export is handled as per HACCP guidelines, which involve the use of adequate ice to cool shrimp immediately after harvest, use of potable water to make ice, hygienic practices in handling and processing etc. Studies conducted in Peru during an epidemic of cholera in 1991 have shown that contamination of seafood with *V. cholerae* can be prevented by adopting HACCP procedures (De Paola *et al*., 1993).

Freshly harvested shrimp have a bacterial count of about 10^3–10^4 cfu/g, and diverse bacterial groups are present (Karunasagar *et al.,* 1992). If contamination with *V. cholerae* occurs in raw shrimp, this organism has to compete with other natural flora

FIGURE 2
Production to consumption pathway for exposure assessment for choleragenic *Vibrio cholerae* in warmwater shrimp



Source: FAO/WHO, 2005.

on the surface of shrimp. Studies indicate that *V. cholerae* is unable to multiply in raw shrimp (Kolvin and Roberts, 1992). Studies conducted in our laboratory show that icing and storage in ice for 48 hr can lead to a 2 log reduction in *V. cholerae* levels, if the organism was present on shrimp before icing (Table 2). Studies conducted in Argentina show that freezing and frozen storage of shrimp can lead to a 3–6 log reduction in levels of *V. cholerae* (Reilly and Hackney, 1985; Nascumento *et al.,* 1998). As shrimp are normally consumed after cooking, and as *V. cholerae* is sensitive to heat with a D value of 2.65 min at 60 °C (ICMSF, 1996), it can thus be expected that there will be about a 6 log reduction in numbers during cooking of shrimp (Table 2).

For risk assessment, dose-response data are important. Data based on human volunteer studies conducted in the United States in connection with cholera vaccine trials (Cash *et al.,* 1974; Black *et al.,* 1987; Levine *et al.,* 1988) indicate that the infective dose would range from 10^6–10^8 for different strains of choleragenic *V. cholerae*. Data on the prevalence of choleragenic *V. cholerae* in warmwater shrimp were based on "port of entry testing for *V. cholerae*" at Japan, the United States of America and Denmark. Of 21 857 samples of warmwater shrimp tested, two were positive (0.01 percent) for choleragenic *V. cholerae.* The risk assessments assumed that 90 percent of warmwater shrimp are eaten cooked and 10 percent are eaten raw (as sashimi, etc.). Qualitative risk assessment indicated that the risk to human health is very low. Since the risk of the organism occurring in shrimp is low, the organisms would need to multiply in the product to attain infectious levels, but during the processing of warmwater shrimp

TABLE 2
Effect of processing on levels of choleragenic *Vibrio cholerae* in shrimp

Processing step	Temperature distribution (°C)	Time distribution	Effect on population of V. cholerae O1	Source of data
HARVEST				
Handling time before icing				Industry data for time, temperature, Kolvin and Roberts (1982) for multiplication
Cultured shrimp	15–35	0–1 hr	No effect	
Wild-caught shrimp	10–30	0–3 hr	0–1 log increase	
WASHING				
Washing and icing of cultured shrimp	0–7	1–4 hr	1 log reduction	Dinesh (1991)
Washing in seawater of wild-caught shrimp	0–30	1–4 hr		
ICING				
Icing during transport (including on board fishing vessel for wild-caught shrimp) to processor	0–7	2–16 hr (cultured) 2–48 hr (wild-caught)	2–3 log reduction	Karunasagar (unpublished)
WATER USE				
Water use during handling at processing plant	4–10	1–3 hr	No effect	Industry data, Kolvin and Roberts (1982)
TEMPERATURE				
Temperature during processing before freezing	4–10	2–8 hr	No effect	Industry data, Kolvin and Roberts (1982)
COOKING				
Cooking at processing plant	>90	0.5–1.0 min (This is the holding time at >90 °C)	>6 log reduction	Based on industry data on total plate count (Sterling Foods Mangalore, India, pers. comm.) In shrimp homogenate $D_{82.2}$=0.28 (Hinton and Grodner 1985)
FREEZING				
Freezing of cooked and raw products, storage, and shipment time	-12 to -20	15–60 d	2–6 log reduction	INFOFISH (pers. comm.) for shipment time, Reilly and Hackney (1985); Nascumento *et al*. (1998) for survival in frozen shrimp

Source: from FAO/WHO, 2005.

(icing, freezing, cooking), significant reductions in level are expected to occur (Table 3). Also epidemiological evidence shows no link between imported warmwater shrimp and cholera in importing countries. Semiquantitative risk assessment using Risk Ranger (Ross and Sumner, 2002) estimated 1–2 cases per decade for Japan, the United States and Spain. For other shrimp-importing countries, the estimate was 3–4 cases/century. For a quantitative risk assessment, numerical inputs for a full harvest to consumption model were not available; hence a shortened exposure pathway that began at the port of entry of the importing country was taken (Figure 3). The quantitative model estimated that the median risk of acquiring cholera from warmwater shrimp in selected importing countries ranges from 0.009 to 0.9 per year. The prediction of low risk by each of the approaches mentioned above is supported by the absence of epidemiological evidence that warmwater shrimp has ever been incriminated in any cholera outbreak in any developed nation in the world.

CONCLUSIONS

Food safety systems based on a risk analysis approach are essential to protect public health and promote international trade in food products, including products of aquaculture. Risk assessment is a science-based process and requires reliable

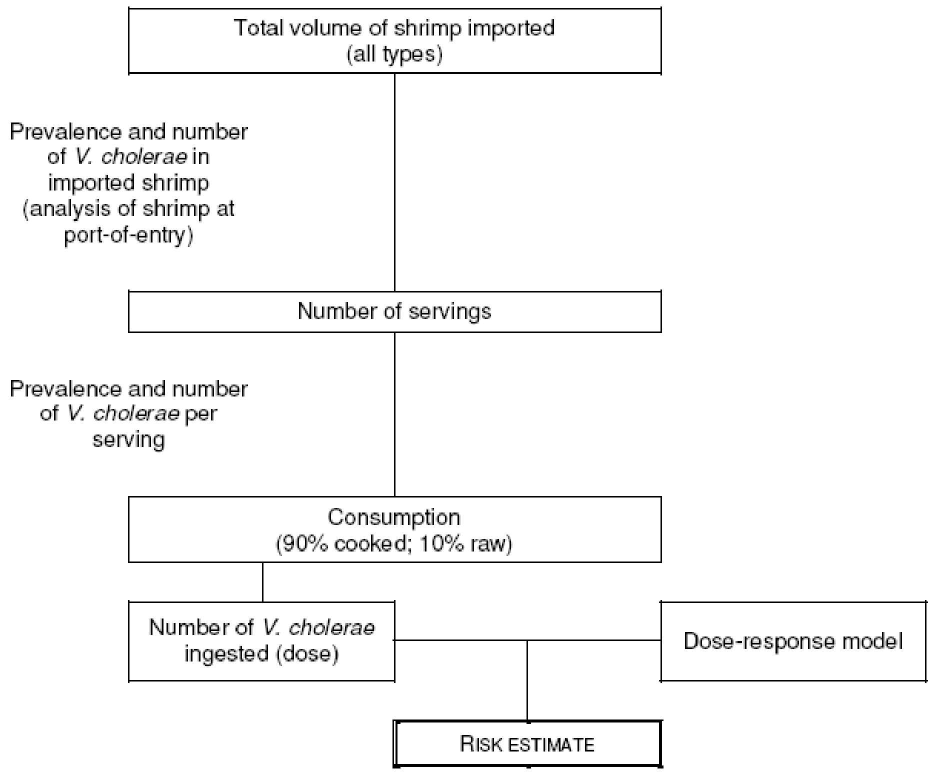
TABLE 3
Qualitative risk assessment for choleragenic *Vibrio cholerae* in warmwater shrimp

Product	Identified hazard	Severity[1]	Occurrence risk[2]	Growth in product required to cause disease	Impact of processing and handling on the hazard	Consumer terminal step[3]	Epidemiological link	Risk rating
Raw shrimp	*V. cholerae*	II	Very low	Yes	Level of hazard reduced during washing (0–1 log), icing (2–3 logs), freezing (2–6 logs)	No	No	Low
Shrimp cooked at the plant & eaten without further heat treatment	*V. cholerae*	II	Very low	Yes	Level of hazard reduced during washing (0–1 log), icing (2–3 logs), cooking (>6 logs), freezing (2–6 logs)	No	No	Low
Shrimp cooked immediately before consumption	*V. cholerae*	II	Very low	Yes	Level of hazard reduced during washing (0–1 log), icing (2–3 logs), freezing (2–6 logs), thawing and cooking (>6 logs)	Yes	No	Low

[1]Severity of the hazard classified according to International Commission of Microbiological Specifications for Foods (ICMSF 2002). Level II = serious hazard; incapacitating but not life threatening; sequale rare; moderate duration.
[2]Very low occurrence of illness – an average of less than one case per ten million population per year based on the data for over a six-year period. This reflects the situation in all countries considered except Japan, which experienced an average of less than one case per million population.
[3]Cooking, which brings about >6 log reduction in the level of V. cholerae.

Source: FAO/WHO, 2005.

FIGURE 3
Import to consumption pathway used in quantitative risk assessment



Source: FAO/WHO, 2005.

data. It involves expertise in different fields such as food production (aquaculture), microbiology, epidemiology, food-processing technology and statistics. Thus, it requires both human and financial resources, and this could be one of the major constraints for developing countries. This has been recognized in WTO agreements. The SPS Agreement encourages the provision of technical assistance to member states, particularly developing countries, through bilateral agreements and via international organizations. SPS accepts Codex standards and guidelines as representing international consensus. Thus Codex standards serve as the benchmark for comparison of national SPS measures. The FAO/WHO Trust Fund for Participation in Codex provides resources to enhance developing-country participation in Codex standard setting. The Standards and Trade Development Facility (STDF) is a joint initiative of the World Bank (WB), FAO, the World Organisation for Animal Health (OIE), WHO and WTO that aims to strengthen donor contribution in standard setting related to food safety. STDF provides small grants for pilot projects that build capacity in standard setting and development in developing countries. STDF also provides assistance to government and the private sector in meeting international standards and promotes interagency coordination and donor collaboration in the delivery of technical assistance. Developing countries can make use of these opportunities to strengthen their capacity in the area of food safety and public health protection.

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