# 3. How to use risk assessments

## 3.1 INTRODUCTION

There are many reasons for doing risk assessments but they all fall into three main categories:

- identifying high risk products and pathogens in your industry;
- managing risks in your industry;
- identifying where in the food chain control steps can best be applied.

In this Section we focus on each of these categories by:

- risk profiling to focus on priorities;
- integrating risk managers with risk assessors;
- linking risk assessment with HACCP.

## 3.2 USE 1: RISK PROFILING AN ENTIRE INDUSTRY

There is sometimes an impression that a particular food category is high risk and people tend to jump to conclusions if there is an outbreak of food poisoning. "*Must be the prawns*" they say, even though consumers ate a range of foods and there is no evidence linking the problem with any one food item. So risk profiling has great use in helping you focus on particular pathogens and products that are more likely than others to cause serious problems. Risk profiling is defined as "*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*".

An example of a risk profile of an entire industry is provided by the Australian industry. In 2000, the Australian seafood industry began to build an Australia Seafood Standard and decided to do a risk profile as a first step. A number of hazard:product pairings were identified and a risk ranking made of each pairing (Table 9). A spreadsheet

TABLE 9
**Risk rankings of hazard:product pairings of significance for the Australian seafood industry**

| Hazard:product pairing | Selected population | Risk ranking * |
|---|---|---|
| Ciguatera in reef fish | General Australian population | 45 |
| Ciguatera in reef fish | Recreational fishers, Queensland | 60 |
| Histamine in tunas and other fish | General Australian population | 40 |
| Algal biotoxin in shellfish-controlled waters | General Australian population | 31 |
| Algal biotoxin – during an algal bloom | Recreational gatherers | 72 |
| Mercury in predaceous fish | General Australian population | 24 |
| Viruses in oysters – contaminated waters | General Australian population | 67 |
| Viruses in oysters – uncontaminated waters | General Australian population | 31 |
| *V. parahaemolyticus* in cooked prawns | General Australian population | 37 |
| *V. cholerae* in cooked prawns | General Australian population | 37 |
| *V. vulnificus* in oysters | General Australian population | 41 |
| *L. monocytogenes* in cold smoked seafoods | General Australian population | 39 |
| *L. monocytogenes* in cold smoked seafoods | Susceptible (aged, pregnant, etc) | 45 |
| *L. monocytogenes* in cold smoked seafoods | Extremely susceptible (AIDS, cancer) | 47 |
| *C. botulinum* in canned fish | General Australian population | 25 |
| *C. botulinum* in vacuum packed smoked fish | General Australian population | 28 |
| Parasites in sushi/sashimi | General Australian population | 31 |
| Enteric bacteria in imported cooked shrimp | General Australian population | 31 |
| Enteric bacteria in imported cooked shrimp | Susceptible (aged, pregnant etc) | 48 |

* Note: a change in risk ranking of six units is equivalent to a tenfold change in risk

tool called Risk Ranger was used (see Section 4), and data to complete the questions were obtained from the literature or were based on expert opinion of the risk assessors. Full details of the profile are presented in Sumner and Ross (2002), which is included in the Resource Bank.

As a result of the profiling exercise, seafoods in Australia were grouped into three risk categories:

**"Low" risk category (risk ranking <32)**

This category includes mercury poisoning (relative risk (RR) = 24), *Clostridium botulinum* in canned fish (RR = 25), or in vacuum-packed cold smoked fish (RR = 28), parasites in sushi/sashimi (RR = 31), viruses in shellfish from uncontaminated waters (RR=31), enteric bacteria in imported cooked shrimp (RR = 31) and algal biotoxins from controlled waters (RR = 31). There have been no documented cases of food-borne illness from any of the above hazard:product pairings in Australia.

**"Medium" risk category (risk ranking 32–48)**

This category includes *V. parahaemolyticus* in cooked prawns (RR = 37), *V. cholerae* in cooked prawns (RR = 37), *L. monocytogenes* in cold smoked seafoods (RR = 39), histamine fish poisoning (HFP) (RR = 40), *V. vulnificus* in oysters (RR = 41), ciguatera in the general Australian population (RR = 45), *L. monocytogenes* in susceptible (RR = 5) and extremely susceptible populations (RR = 47) and enteric bacteria in imported cooked shrimp eaten by vulnerable consumers (RR = 48).

With the exception of *V. cholerae* or enteric bacteria in imported prawns, all of these hazards have caused several outbreaks of food poisoning in Australasia.

**"High" risk category (risk ranking >48)**

This category includes ciguatera from recreational fishing in susceptible areas (RR=60), viruses in shellfish from contaminated waters (RR=67) and algal biotoxins from uncontrolled waters in an algal event (RR=72). All of these hazard:product combinations have caused large-scale food poisoning incidents.

**Directions from the risk profile**

At the end of the risk profiling exercise you will know much about your industry and will be able to make a priority listing of hazards and products that require more complete risk assessment.

The profiles also provide a focus for seafood risk managers, showing them the pathogens and products on which they should concentrate. The ways managers can approach their task is illustrated in the next section.

## 3.3 USE 2: RISK MANAGEMENT

When the risk assessors complete their work and present their estimates, the risk managers use the estimates to regulate (manage) the hazard. Continuing the Australian approach as an example, there are no fewer than eight risk managers who represent the various states and territories in the country. For some states and territories, the profiles alerted risk managers to hazards and products that needed urgent attention. For example:

- Exports of live reef fish to Asia and the risk of ciguatera is managed by the Australian Quarantine and Inspection Service (AQIS).
- A huge recreational fishery for which ciguatera is a risk managed by SafeFood Queensland.
- The risk of enteric pathogens in oysters is managed by several state authorities.
- The risk of uncontrolled gathering of clams on remote beaches during an algal event is managed by various state authorities.

The above examples are presented to show how risk managers in different parts of a country need to focus on specific, regional risks. Of course, risk managers interface with all stakeholders in risk communication phases, but in the end it is the managers who must make the regulatory decisions to manage specific risks. Risk Ranger is a useful tool for risk managers and following is an example of how they could use the tool.

## 3.4 RISK MANAGEMENT CASE STUDY: ENTERIC VIRUSES IN OYSTERS

Viral contamination of oysters is an enduring cause of illness in many countries. Viruses most commonly associated with outbreaks are Norwalk and noroviruses (also termed small round structured viruses [SRSVs]) and HAV. Illnesses result from contamination of oyster leases by human sewage during heavy rainfall events. Most countries have a classification system for oyster growing areas based on the likelihood of their becoming contaminated by human sewage. The classification is linked with activities such as:

- depuration;
- relaying contaminated oysters in "clean" waters;
- stopping of harvest after rainfall events;
- management strategies intended to reduce viral contaminants to an acceptable level.

Interestingly, while HACCP has become the preferred risk management for the food industry, virus control by depuration and relaying are processes that have not been validated as critical control points (Lees, 2000).

As populations increase, traditional oyster leases become encroached by human habitation, and this results in contamination of oyster beds during rainfall events. One obvious course of action open to you, as a risk manager, is to prevent oysters being harvested in areas that are subject to regular contamination with human faeces (so-called "restricted" areas) by ordering their permanent closure. However, if you try to do this you will find that food safety competes with political, social and economic issues. Clearly it would be advantageous if you could use straightforward risk estimates to explain the bases of your risk management decisions.

One approach is to use Risk Ranger to compare the probability of contracting Hepatitis A after consuming oysters from waters that are never subjected to contamination with human faeces, with oysters from waters that often become contaminated after heavy rainfall. Table 10 contains all the inputs to Risk Ranger for the two scenarios.

A number of assumptions are made:

- Prevalence of HAV in oysters from pristine waters is 0.001 percent.
- In oysters harvested from contaminated waters prevalence is 15 percent. This was the prevalence of contamination in oysters one month after a Hepatitis A outbreak in Australia in 1997 (Conaty *et al.*, 2000; Grohmann, 1997).
- At least 1 000 units of HAV are required to cause illness in the average consumer (Rose and Sobsey, 1993).
- This level will already exist in oysters from polluted waters.
- A 100x increase is required to reach an infective level in oysters from "clean" waters.
- Consumption size is a serving of six oysters (about 100 g).
- In considering consumption from uncontaminated waters, some (25 percent) of the population were assumed to consume a monthly serving.
- In the scenario where oysters were contaminated with HAV, most (75 percent) of a localized population of 100 000 were assumed to consume a weekly serving.

If these data are input to Risk Ranger, there is a great difference in risk ranking and predicted illnesses. Oysters from clean waters have a risk ranking of 20 and predicted illnesses of 1 every 20 years. By contrast, oysters from polluted waters have a risk ranking of 70, which is 100 000 000 times increased risk compared with oysters from clean waters. It is predicted that all 100 000 consumers will become ill.

TABLE 10
**Risk ranking of oysters consumed raw from waters that are never polluted and those that are subject to human faecal contamination**

| Risk criteria | "Clean" waters | Waters subject to pollution |
|---|---|---|
| **Dose and severity** | | |
| Hazard severity | Mild – sometimes requires medical attention | Mild – sometimes requires medical attention |
| Susceptibility | General – all population | General – all population |
| **Probability of exposure** | | |
| Frequency of consumption | Weekly | Weekly |
| Proportion consuming | Some (25%) | Some (25%) |
| Size of population | 1 900 0000 | 100 000 |
| **Probability of contamination** | | |
| Probability of raw product contaminated | 0.001% | 15% |
| Effect of processing | No effect | No effect |
| Possibility of recontamination | None | None |
| Post-process control | Not relevant | Not relevant |
| Increase to infective dose | 100 times | None |
| Further cooking before eating | Not effective in reducing hazard | Not effective in reducing hazard |
| Estimated annual illnesses | 1 every 20 years | 100 000 |
| Risk ranking (0–100)* | 20 | 70 |

* Note: a change in risk ranking of six units is equivalent to a tenfold change in risk

Clearly, your task as risk manager is made more straightforward by Risk Ranger predictions. Now, the responsibility is moved from resting solely on your shoulders, to being shared with stakeholders who must choose whether to continue with increased risk predicted illnesses.

In summary, the risk characterization model allows a rapid "broad brush" estimation of risk, which will assist risk managers to prioritize hazard:product pairings for more intensive risk assessment studies. It also allows timely response to "what if" scenarios, which will benefit risk managers and communicators, alike.

## 3.5 USE 3: RISK ASSESSMENT AND HACCP

Since the 1980s, HACCP has become an important part of the food business as a hazard management system. The first HACCP principle requires assessment of whether the hazard is "significant", which implies some assessment of risk (severity + likelihood), which raises the question *"are HACCP and risk assessment linked?"* Most people would answer *"Yes, they are linked but I cannot quite work out how"*. Here is an example of how HACCP and risk assessment can go together. Note that the example is entirely hypothetical and the photographs (below) do not refer to any problem with transshipping tuna.

Your Fisheries Department receives the following photographs by electronic mail from the regulatory authorities in the importing country. One of their inspectors spent all day in transit, and observed several pallets of chilled tuna in cartons that sat on the tarmac for eight hours. The inspector was able to identify the company, which is your largest exporter of tuna. When it arrived in the importing country, the entire consignment was confiscated and an immediate embargo placed on your exports.

### Initial investigation

You are charged with fixing the problem. The importing country stipulates that you must make "risk-based" decisions in solving the problem. Since exports have been banned, your supervisor wants the problem fixed very quickly.

You contact the exporting company and learn that they routinely include a data logger in each consignment. The exporter's agents in the importing country are able to locate the logger and download the data. The temperature:time trace (Figure 1)

*08.00 at the transit airport where product from your country changes flights. The scheduled flight has been cancelled and several tonnes of chilled tuna are left on the tarmac until another flight arrives. The ground temperature is 33 °C*

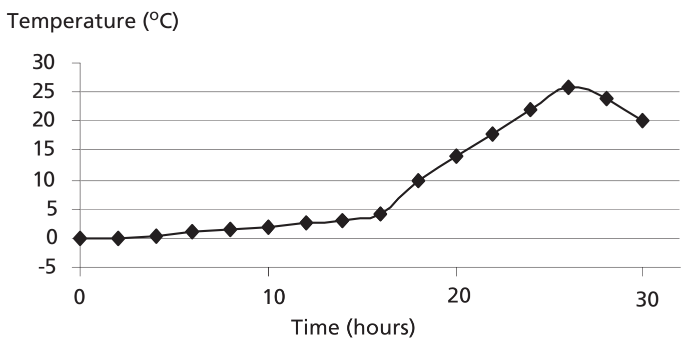
*16.30 at the transit airport. Product is being loaded on a rescheduled flight. During the day, maximum ground temperature reaches 40 °C*

indicates substantial product warming. The agents tell you the carton was on the outside of the stack, which means it measured worst-case product warming of product in the consignment.

### Estimating growth on tuna

By using predictive microbiology you can estimate the growth of histamine-producers on a product in each outer carton. Table 11 contains growth rates at each temperature

FIGURE 1
**Product temperature at site of microbiological concern during transit of chilled tuna**



(from the literature), and by multiplying by the length of time the product was in that temperature zone you can calculate potential growth. You can do this by using data from Figure 1.

TABLE 11
**Potential growth of histamine-producers on tuna abused at high temperatures**

| Temperature zone | Generation time (hours) | Time in zone (hours) | Potential growth (generations) |
|---|---|---|---|
| 10–15 | 3 | 3 | 1 |
| 15–20 | 1.5 | 3 | 2 |
| 20–25 | 1.0 | 5 | 5 |
| 25–30 | 0.75 | 3 | 4 |

## Increased risk at warm temperatures

The steep rise in temperature while product is exposed to direct sunlight sees the surfaces of microbiological concern rise to 26 °C before loading into the air-conditioned hold of the airliner stabilizes temperature. Around 12 generations (3–4 log growth) occurred during the storage on tarmac and this can be inputed to Risk Ranger to assess the increased risk (Table 12).

The total consignment was more than 3 tonnes, of which 1 tonne was severely temperature-abused, and you concentrate on this portion of the consignment. There are around 10 000 servings of 100 g each serving that have been temperature-abused. Calculations indicate that histamine-producers will have grown to around 10 000/g of product. If someone consumed 100 g of this product they would ingest the equivalent of the histamine produced by one million bacteria/g. It is assumed that if histamine-producers reach 100 000 000/g they will produce sufficient histamine to cause illness. Thus a further increase of 100x is needed for a toxic level.

All the above data are input to Risk Ranger. The risk ranking as shown in Table 12 is 67, and around 5 000 illnesses are predicted from the 10 000 servings, which will be eaten over a period of about one week.

TABLE 12
**Semi-quantitative risk characterization of HFP following consumption of tuna that has been temperature-abused**

| Risk criteria | Product that has undergone temperature abuse |
|---|---|
| Dose and severity | |
| Hazard severity | Mild – sometimes requires medical attention |
| Susceptibility | General – all population |
| **Probability of exposure** | |
| Frequency of consumption | Weekly |
| Proportion consuming | All (100%) |
| Size of population | 10 000 |
| **Probability of contamination** | |
| Probability of raw product contaminated | 0.1% |
| Effect of processing | Chilled storage prevents growth of histamine producing bacteria |
| Possibility of recontamination | None |
| Post-process control | Poor (>3 log increase) |
| Increase to infective dose | 100x |
| Further cooking before eating | Not effective in reducing hazard |
| Predicted illnesses | 5 200 |
| Risk ranking (0–100) | 67 |

## Integrating risk assessment with HACCP

You examine the HACCP plans of each company exporting tuna. A typical plan is shown in Table 13 and does not take into account the possibility that product will be held up if flights are delayed. Your supervisor informs you that a high-level delegation is coming from the importing country to review your risk assessments and integration with HACCP. He indicates that they will need to see a great deal of rigour surrounding

TABLE 13
**Current HACCP plan form for control of histamine formation during the air journey**

| Critical Control Point (CCP) | Significant Hazards | Critical Limits for each Preventive Measure | Monitoring | | | | Corrective Action | Records | Verification |
|---|---|---|---|---|---|---|---|---|---|
| | | | What | How | Frequency | Who | | | |
| CCP 6: Air freight | Histamine formation | Fish no warmer than 5 ºC on arrival | Product temperature | Temperature logger | One logger per lot | Importer | Accept/reject fish. Re-ice | Data logger | Check on return of logger |

TABLE 14
**Revised HACCP plan form for temperature control of product at the transit airport**

| Critical Control Point (CCP) | Significant Hazards | Critical Limits for each Preventive Measure | Monitoring | | | | Corrective Action | Records | Verification |
|---|---|---|---|---|---|---|---|---|---|
| | | | What | How | Frequency | Who | | | |
| CCP 6: Transit | Histamine formation | Store in air-conditioned hanger for <3 hours ("normal" transit) | Location | Visual, and record times on Consignment Sheet | Every consignment | Airport agent | Agent arranges immediate transfer to air-conditioned hanger | Consignment sheet | Consignment sheet faxed to company |
| | | Store in air-conditioned hanger for >3 hours ("delayed" transit) | Air temperature | Data logger | Every storage when there is a delay | Airport agent | Agent logs ambient temperature and storage time | Consignment sheet<br>Data logger | Consignment sheet faxed to company<br>Data logger downloaded and information emailed to company |
| CCP 7: Arrival | Histamine formation | Fish no warmer than 5 ºC | Product temperature | Temperature logger in marked carton | One logger per lot | Importer | Accept/reject fish. Re-ice | Data logger | Check on return of logger |

the transit airport. It seems flight delays are not uncommon, which turns out to be the only reason your exporters include a data logger, so they have evidence against the airlines in an insurance claim.

Clearly there is the need for cold storage at the transit airport so that product can be quickly taken from the furnace-heat of the tarmac. Enquiries indicate that there is not much cold storage space, but there is a large air-conditioned hanger at 10–15 °C, which is used for holding flowers, fruits and vegetables. Pallets can be quickly driven there until the transit flight arrives. You simulate these storage conditions in your country by using data loggers and find that product does not rise above 5 °C even after 12 hours storage at 10–15 °C. You use this study as part of the HACCP validation for the visiting delegation.

Your next task is to set up a system at the airport that ensures product is moved to cool storage if there is a flight delay. This involves:

- employing an agent at the transit airport to handle all consignments from your country;
- setting up a record of arrival time and departure time of each consignment;
- placing all consignments in air conditioned hanger until the connecting flight begins loading;
- fixing a single-use data logger to the outside of a pallet stack to monitor ambient temperature and time of delay;
- downloading data to the exporting company for verification of control of air temperature.

The systems you set up are fixed in the new HACCP plan for air transit control (Table 14).

By using Risk Ranger you can quickly estimate changes in risk of becoming ill from HFP with changes to the HACCP plan. The plan as set out in Table 12 has a risk ranking of 67, because flight delays lead to a loss of temperature control. The HACCP plan as set out in Table 14 reduced risk ranking to 12. The reduction in risk is on the order of 100 million times.

This gives you considerable documentation to set before the delegation and, if they request different scenarios, you can quickly simulate them using Risk Ranger.

Your risk assessment work has generated a good deal of information on how your export tuna fishery operates, and you are now able to bring HACCP plans onto a true risk basis.

# 4. Risk Ranger

## 4.1 BACKGROUND TO DEVELOPING RISK RANGER

If you are a risk manager you need to be able to compare and prioritize risks. There are a number of decision support tools that will guide you on whether a pathogen might be an important hazard in a given food or food process combination. These include various semi-quantitative scoring systems such as those by Corlett and Pierson (1992), shown in Table 15 and by Huss, Reilly and Ben Embarek (2000), which is illustrated in Table 16.

While the above approaches are able to categorize risk and direct broad mitigation strategies, neither can be used to assess an as yet undocumented risk, or to measure the effect of contributions to risk of individual factors. These schemes do not focus on the steps or variables where control could most effectively be applied.

Risk Ranger is a simple and accessible food safety risk calculation tool intended to help determine relative risks from various product/pathogen/processing combinations and is presented in Microsoft® Excel spreadsheet software. In particular, it is intended to make the techniques of food safety risk assessment more accessible to non-expert users, and to users with limited resources, both as a decision-aid and an educational tool.

Risk Ranger incorporates all factors that affect the risk from a hazard in a particular commodity including:

- severity of the hazard and susceptibility of the population of interest;
- likelihood of a disease-causing dose of the hazard being present in a meal;
- number of meals consumed by a population of interest in a given period of time.

A number of factors affect each of the above.

Disease severity is affected by:

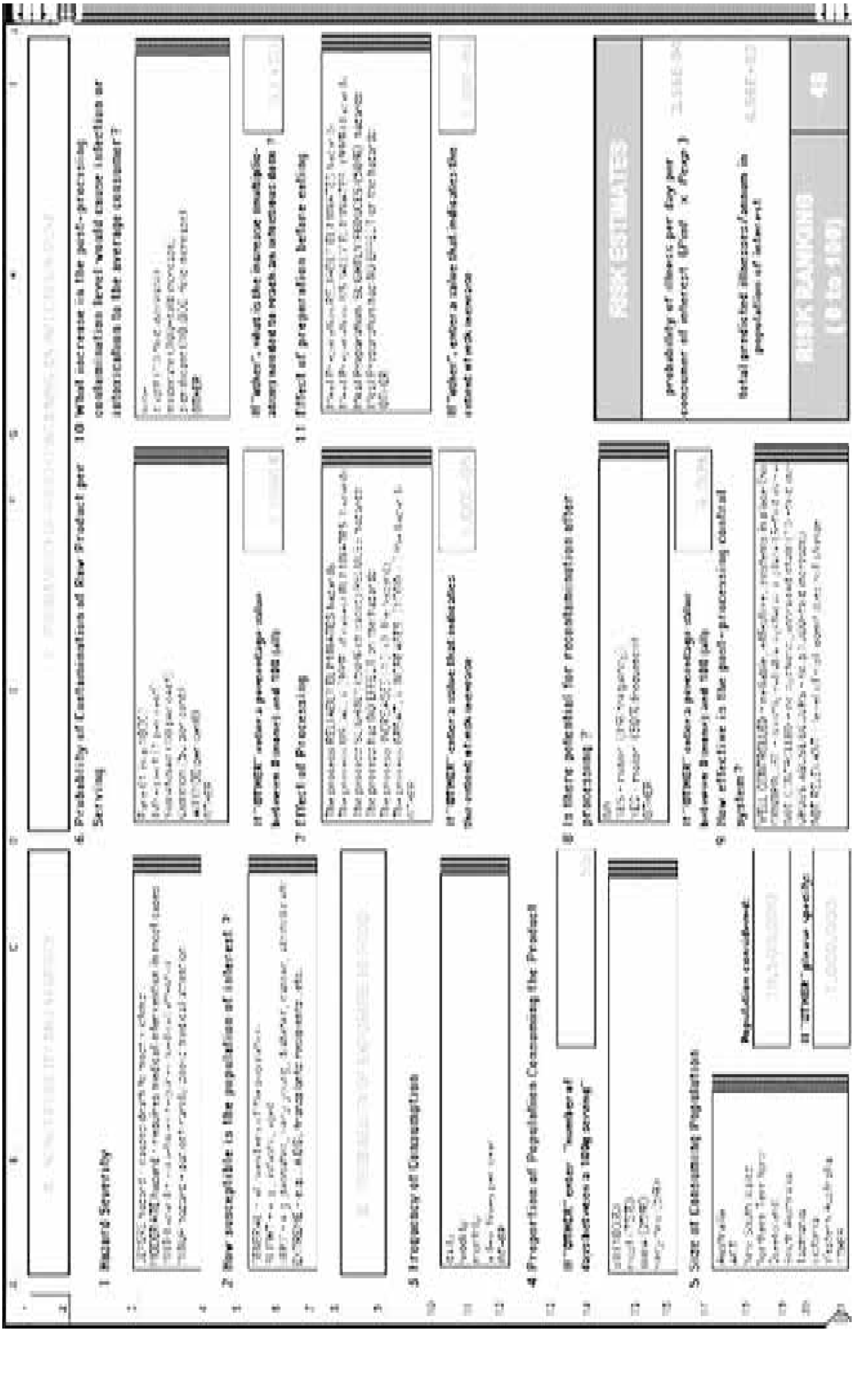
- intrinsic features of the pathogen/toxin;
- susceptibility of the consumer.

TABLE 15
**Hazard classification of Corlett and Pierson (1992)**

| Hazard | Risk characteristics |
|---|---|
| A | Special class restricted for at-risk populations, e.g. the aged, immunocompromised, infants |
| B | Product contains sensitive ingredients |
| C | Process has no step which destroys sensitive organisms |
| D | Product is subject to recontamination between processing and packaging |
| E | Potential for abuse by distributor or consumer, which could render the product hazardous |
| F | Product is consumed without further process to kill micro-organisms |

TABLE 16
**Qualitative risk assessment based on the process of Huss, Reilly and Ben Embarek (2000)**

| Risk criteria | Raw molluscan shellfish | Canned fish | Dried fish |
|---|---|---|---|
| Bad safety record | + | + | - |
| No critical control point 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 |




The Risk Ranger shop front

Exposure to the food will depend on how much is consumed by the population of interest, how frequently they consume the food and the size of the population exposed.

Probability of exposure to an infectious dose will depend on:

- serving size;
- probability of contamination in the raw product;
- initial level of contamination;
- probability of contamination at subsequent stages in the farm-to-fork chain;
- changes in the level of the hazard during the journey from farm to fork, including simple concentration and dilution, growth or inactivation of pathogens.

## 4.2 USER INTERFACE – THE RISK RANGER SHOP FRONT

Risk Ranger has a "shop front" with a series of list boxes into which you enter information using your computer's mouse. In total, you need to answer 11 questions, and a mathematical model then converts each answer to a numerical value or 'weighting'. The weightings are detailed in the paper by Ross and Sumner (2002). Some of the weightings are arbitrary, while others are based on known mathematical relationships, e.g. from days to weeks, or years. To help you make your responses as objective as possible, and to maintain transparency of the model, descriptions are provided and many of the weighting factors are specified. As well, in some cases, if the options provided do not accurately reflect the situation being modelled, you can enter a numerical value by using the "Other".

Behind the shop front is the model, developed in Microsoft® Excel software, using standard mathematical and logical functions. The list box macro tool is used to automate much of the conversion from qualitative inputs to quantities for calculations. For each selection you make from the range of options, the software converts that selection into a numerical value.

## 4.3 HOW TO USE RISK RANGER

To help you understand how Risk Ranger works, let us cover each of the 11 questions in turn and explain the scientific background behind each of them.

### Question 1: Hazard severity

You are offered four choices, based on the severity of the symptoms caused by the hazard. In the Table 17 are our ideas on how seafood hazards fit into the descriptions.

If you click on the coding tab at the bottom left side of Risk Ranger you will switch to the codings for each question. You will see there is a ten-times difference in severity between each category of hazard. This is an arbitrary difference.

You may not agree with the descriptions and the way hazards are linked with them in Table 17. For example, you might say that most cases of *L. monocytogenes*, enterohaemorrhagic *Escherichia coli* (EHEC) and *V. vulnificus* do not require medical intervention, and it is only for susceptible groups that the description is true. Similarly, in some cases, *Salmonella* can be a serious infection with long-lasting consequences

TABLE 17
**Associating hazards with Risk Ranger descriptions at Question 1**

| Description | Consequences of the hazard | Hazard |
|---|---|---|
| Severe | Death in most cases | Tetrodotoxin, Botulinum toxin |
| Moderate | Most cases require medical treatment | *Listeria monocytogenes, Vibrio vulnificus, Vibrio cholerae,* EHEC |
| Mild | Sometimes medical treatment is needed | *Vibrio parahaemolyticus,* Hepatitis A, Norwalk-like viruses, histamine, ciguatera, algal biotoxins, *Salmonella* |
| Minor | Medical treatment rarely required | *Staphylococcus aureus, Clostridium perfringens* |

such as reactive arthritis. But Mead *et al.* (1999) state that, in the United States, there are probably 38 times more cases of salmonellosis than those that are reported, so for most people *Salmonella* infection obviously resolves itself without entering the medical system. By contrast, at least 50 percent of listeriosis cases are reported. And this ratio is probably higher for EHEC.

This is one limitation of Risk Ranger and, if you believe a description is wrong for the specific country or system you are working on, then by all means move the hazard to the category of your choice.

**Question 2: Susceptibility of the population in which you are interested**

Risk Ranger allows you to select one of four populations that vary in their level of susceptibility. Groups that are slightly (five times) more susceptible than the general population to food-borne hazards are small children (1–5 years old) and people over 65 years old. In the "very susceptible" category are newborn babies, children under one year and people with conditions such as diabetes, cancer and liver damage, which predispose them to infectious diseases. They are rated 30 times more susceptible than the general population. People with AIDS or who are recovering from transplant surgery have very impaired immune systems, which place them in the "extremely susceptible" category, 200 times more likely to succumb to hazards than the general population. The various weightings, 5x, 30x and 200x, are loosely based on the relative susceptibility of each population subgroup to *Listeria monocytogenes*. Consequently, they may give unexpected results if applied to hazards that all people are more or less equally susceptible to, for example, *S. aureus* enterotoxin. If you want more details of the reasons for these weightings, see Ross and Sumner (2002).

When you select this subpopulation, Risk Ranger automatically makes changes in two other questions:

- In Question 5, the size of the subpopulation is modified to the correct proportion of the total population.
- In Question 10, the increase to infectious dose is automatically adjusted to take into account the increased vulnerability of subgroups.

Absolute risk is based on the population size, the proportion of the population consuming the food and how frequently people eat the food, and this information is selected in Questions 3–5.

**Question 3: Frequency of consumption**

Obviously, the more often we face a hazard, the more likely we are to be affected by it, and this question reflects the popularity of a seafood product. The selections you can make are set in absolute terms, based on annual consumption, and this is obvious from the coding used.

**Question 4: Proportion of population consuming the product**

The proportion consuming the product is set for all (100 percent), most (75 percent), some (25 percent) and a few (5 percent) of the population.

It is best to link your selections for Questions 3 and 4, such as *"Everyone eats the product daily"*, which might apply to consumption of reef fish by the population living on a Pacific atoll. By contrast you may select *"Some people (25 percent) eat the product weekly"*, which might apply to oyster consumption in a European country.

You can answer Questions 3 and 4 using either of two methods:

- using consumer survey data that gives you a very good idea of consumption pattern;
- calculating the amount consumed from product landing or harvest and then dividing by the population you think eats that product. Obviously you need to make an assumption here and to state what your assumption is.

**Question 5: Size of consuming population**

Risk Ranger has several country populations already programmed into Question 5 and, if you want to select another country just select "Other" in the list box, and type the population of that country in the "Other" box. Alternately, if you want to make the list box specific, click the tab for CODINGS and you will see instructions on how to put in your own populations.

If you select a subpopulation from the general population in Question 2, Risk Ranger automatically estimates the number in that category. Because Risk Ranger was developed in Australia, the proportions refer to that country, and they also fit many other countries with similar lifestyles, particularly in North America and Europe. However, you may need to recalibrate the coding for this question for countries in which certain diseases are rampant, e.g. for countries with a high prevalence of AIDS.

**Question 6: Probability that a serving of raw product is contaminated**

To answer this question you obviously need data. For example, if you were considering viruses in oysters, it is important to know how many servings have sufficient viruses to infect you. Similarly, you may want to know how prevalent is a bacterial pathogen, such as *Salmonella*, in raw shrimp. If you have data from a properly designed survey you can insert the exact level by selecting "Other" in the list box, then typing the percentage in the box below. Alternatively you may not have an accurate idea on proportion contaminated and, in this case, you can select the most appropriate category in the list box.

**Question 7: Effect of processing**

To answer this question you need to know about the process and how it affects the hazard. Here are some examples:

- If you are considering viruses in oysters to be consumed raw, their numbers are not affected by processes such as shucking or storage, so you select "No effect on the hazard". The same selection is made for ciguatera in reef fish, because the level of toxin is not affected by the process.
- If you are considering *Salmonella* in cooked shrimp, the cooking process is sufficient to kill all of the bacteria, so select "Reliably eliminates hazard". The same selection is made for *Listeria monocytogenes* in hot smoking and for *Clostridium botulinum* in canning.
- If you hold tuna from warm waters without ice, the bacteria will produce histamine at a rate that depends on temperature and time. You select either "Increases the hazard" or "Greatly increases the hazard", depending on the extent of temperature abuse.
- If you freeze seafood, a proportion of bacteria are likely to die – perhaps as many as 50 percent – and this option can be selected.

**Question 8: Potential for recontamination after processing**

Recontamination is particularly important for those products that have received heat treatment during the process. Such products have low bacterial levels and any contaminant will be able to grow with little competition. Examples of where recontamination is important include:

- cooked, peeled shrimp recontaminated with *Staphylococcus aureus* from the hands or noses of food handlers;
- hot smoked salmon recontaminated during slicing and packing with *L. monocytogenes* from the environment;
- canned seafood recontaminated through a leaking seam with *Clostridium botulinum* from seawater used in cooling.

To answer Question 8 you really need data generated from surveys, and this can be typed in the "Other" box. If you do not have data on recontamination you can make an assumption based on observation or on comparison with similar processes that have been surveyed in countries with conditions similar to your own. For example, if you observe operators peeling shrimp with their bare hands you can predict that up to 50 percent of the product will be contaminated, because 30–50 percent of food handlers carry *S. aureus* on their hands and nose.

**Question 9: How effective is post-processing control?**

In this question you need to know how the product is handled during storage, distribution and retailing. Also you need to know something about the hazard and how it responds to those controls. Here are some examples:

- Bacterial pathogens in frozen seafood cannot increase, and may even die, so select "Well controlled" from the list box.
- The population of viruses in oysters will remain static during storage, so select "Not relevant".
- In smoked seafoods stored at 4–5 °C, *L. monocytogenes* will be able to multiply. If the shelf-life is long (4–6 weeks) growth will be considerable, so select "Gross abuse occurs".
- In chilled, ready-to-eat seafoods such as cooked shrimp, stored at 4–5 °C, *L. monocytogenes* will grow, but because the shelf-life is only short, increase in growth will not be great, so select "Controlled".

**Question 10: What level of increase is needed to cause illness?**

To answer this question you need to know something about the amount of the hazard that would be required to cause illness. Table 18 presents some data on the number of organisms it takes to make a healthy person ill. The numbers are given for a 100 g serving, so the count/g of food is 100x lower. It is with great trepidation that these numbers are presented here because not every microbiologist will agree with them. These numbers should be regarded as guidelines, and do not forget that vulnerable consumers require much lower doses to make them ill. And if you believe a number is wrong and have good evidence, please use your own data at Question 10.

TABLE 18
**Levels of pathogenic bacteria that are likely to cause illness in healthy people**

| Organism | Infective dose in a 100 g serving |
|---|---|
| *Salmonella* | 10 000 000 |
| *Listeria* | 10 000 000 000 |
| Viruses (Hepatitis A, Norwalk) | 10–100 |
| Enterohaemorrhagic *E. coli, Shigella* | 1 000 |
| *Staphylococcus aureus* | 100 000 000 |

Knowing the number of micro-organisms surviving after processing, divide this number into the number required to cause illness (from Table 18 or more updated data) and you have the answer to Question 10.

For example, if you are considering Hepatitis A contamination in oysters, then select "None", because the infective dose is already contained in the serving. The same answer is selected for ciguatera, since the toxin is already present at processing.

If you are considering *L. monocytogenes* in smoked seafood, you probably will not know the contamination level after processing and recontamination. The literature tells us that contamination level will probably not exceed 10 g, so if we consume 100 g there are 1 000 cells in our serving just after processing. If we assume that we need around 10 000 000 000 to make us ill, the increase to infective dose is 10 000 000-fold and we can enter that in the "Other" box at Question 10.

### Question 11: Effect of meal preparation

This question considers the form of cooking and preparation for cooking. Here are some examples of how you can answer Question 11:

- for cooked shrimp kept chilled until consumption, select “No effect”;
- for histamine in tuna, staphylococcal toxin in cooked crustaceans, ciguatera in reef fish, or algal biotoxins in bivalves, select “No effect” because the toxins are heat-stable;
- for viruses in oysters eaten raw, select “No effect” but, if cooked lightly in the half-shell, select “Slightly reduces” the hazard;
- for raw seafood contaminated with pathogenic bacteria or viruses that will be thoroughly cooked, select “Reliably eliminates”.

## 4.4 RISK ESTIMATES

Risk Ranger combines the factors in Questions 1–11, including some logical tests to generate three estimates of risk:

- risk ranking – a score between 0–100;
- predicted annual illnesses in the population you selected;
- probability of illness per day in target population;

Full details of the logic and equations leading to the risk estimates are shown in the paper by Ross and Sumner (2002), which is included in the Resources Bank.

### Risk ranking

The risk ranking value is scaled logarithmically between 0 and 100. The former (Risk Ranger = 0) is equated to a probability of food-borne illness of less than, or equal to, one case per 10 billion people (greater than current global population) per 100 years. At the upper limit (risk ranking = 100), every member of the population eats a meal that contains a lethal dose of the hazard every day. A risk ranking change of 6 corresponds to a tenfold difference in the absolute risk. Thus an increase in risk ranking from 36 to 48 means that the risk increases 100-times.

### Predicted annual illness

Risk Ranger estimates the total number of illnesses in the population you select at Question 5. Obviously, the higher the risk ranking, the greater the proportion of the population that will become ill. The absolute numbers of illnesses, however, will depend on the population size.

### Probability of illness per day in target population

Risk Ranger targets the proportion of the population that you select at Question 2. Risk ranking remains the same, irrespective of whether you are considering the general population, or a highly susceptible subpopulation. But the probability of illness increases in the target population. This output tells you where illness is focused.

## 4.5 EVALUATING RISK RANGER

To evaluate the performance of the tool, the authors modelled several scenarios and compared the results with actual data or with other risk assessments. In the first evaluation, conditions leading to an outbreak of Hepatitis A from consumption of oysters in Australia in 1997 were simulated using the model and compared with the epidemiological data reported by Conaty *et al.* (2000). In the second evaluation, the data and assumptions of the quantitative risk assessment of Cassin *et al.* (1998) for the risk of illness from enterohaemorrhagic *E. coli* due to consumption of hamburgers in North American culture were used to derive answers to the questions of the risk assessment spreadsheet. The results of both assessments were compared and are detailed in Ross and Sumner (2002). In general, Risk Ranger predicted illness of the same order of magnitude as in the actual events.

## 4.6 HOW RISK RANGER CAN BE USED

Risk ranger was originally developed as a means of quickly assessing the performance of various conceptual models for food safety risk assessment. However, it is also a useful tool for risk assessment and risk communication. It can be used by risk managers and others without extensive experience in risk modelling:

- as a training and risk communication aid;
- to develop risk assessments;
- to determine data needs;
- as a simple and quick means to develop a first estimate of relative risk.

Tools such as this can help managers to think about how risks arise and change and to help to decide where interventions might be applied with success.

## 4.7 LET US WORK THROUGH SOME EXAMPLES

Working through some examples together will help you see how Risk Ranger is used.

Let us use consumption of chilled, hot-smoked salmon contaminated with *L. monocytogenes* in the United States. For more than ten years the United States risk management strategy has been to operate zero tolerance for this organism in this product (in a 25/g sample), reflecting the seriousness that the risk manager (Food and Drug Administration) ascribes to this hazard:product pairing.

We can summarize the inputs in Table 19 and you should open Risk Ranger and work through the inputs for the general population. You will see that the Risk Ranking is 41 with predicted illnesses of 400 per annum from the United States population of 270 million. The probability of illness per day per consumer in the general population is $8^{-8}$.

Important questions and assumptions are:

Question 7, where we assume that hot smoking eliminates all *L. monocytogenes*.

Question 8, where we assume first that 1 percent of servings are recontaminated and second that the level of recontamination is 0.1 cell/g (10 cells/serving).

Question 9, where we assume the shelf-life at around 5 °C is long (several weeks in the distribution and retailing chain) and the population increases to 100/g (10 000/serving).

Question 10, where we assume that the infective dose for the general population is 10 000 000/g (10 000 000 000/serving). So for Question 10, you need to select “Other” and insert 1 000 000 for the increase needed for an infective dose.

Now let us consider the effect of contaminated smoked salmon on a more susceptible subpopulation, the very young and very old. When you select this subpopulation, Risk Ranger automatically makes changes in two other questions:

- In Question 5, the size of the subpopulation is selected. In the United States this group comprises around 50 million individuals.
- In Question 10, the increase to infectious dose is automatically adjusted. You do not need to make any change – Risk Ranger does it for you.

The consumption frequency remains the same, as do the contamination levels in raw product and the effect of processing, recontamination and post-process control. Risk Ranking remains the same as for the general population; the number of illnesses falls slightly to around 350 per annum and the probability of illness per day in this vulnerable group is $2^{-6}$. The latter two outputs tell you that the vulnerable subpopulation bears almost all the risk of illness with 75 percent of all listerioses and much higher probability of illness on any one day.

**Reality check**

Let us do a reality check on listeriosis in the United States to see if the annual illnesses we are predicting from Risk Ranger are approximately correct. Statistics indicate around 1 000 cases notified each year (4 cases/million population), which, when we take into account under-reporting, extends to around 2 000 cases. Risk Ranger predicts around 400 annual cases due to the consumption of smoked salmon, a prediction which is in an acceptable range.

**Summary**

The main reason for doing this exercise is to help you understand how Risk Ranger automatically selects subpopulations for you, plus how important it is to understand how to calculate the increase to infectious dose (Question 10). The more you understand a food process and the behaviour of the target pathogen, the better outputs you will get from Risk Ranger.

TABLE 19
**Risk Ranger inputs for *L. monocytogenes* in chilled, hot-smoked salmon in the United States**

| Risk criteria | General population | Very young and old |
|---|---|---|
| **Dose and severity** | | |
| Hazard severity | Moderate – usually requires medical attention | Moderate – usually requires medical attention |
| Susceptibility | General – all population | Very young and very old |
| **Probability of exposure** | | |
| Frequency of consumption | Few times a year | Few times a year |
| Proportion consuming | Few (5%) | Few (5%) |
| Size of population | 270 million | ca 50 million |
| **Probability of contamination** | | |
| Probability of raw product contaminated | 10% | 10% |
| Effect of processing | Hot smoking eliminates all contaminants | Hot smoking eliminates all contaminants |
| Possibility of recontamination | Minor (1%) | Minor (1%) |
| Post-process control | Poor (>3 log increase) | Poor (>3 log increase) |
| Increase to infective dose | 1 000 000x | 1 000 000x |
| Further cooking before eating | Not effective in reducing hazard | Not effective in reducing hazard |
| Predicted annual illness in the population considered | 400 | 365 |
| Probability of illness per day per consumer of interest | $8.22 \times 10^{-8}$ | $2.47 \times 10^{-6}$ |
| Risk ranking (0–100) | 41 | 41 |