4. Semi-quantitative risk characterization

4.1 Introduction

Semi-quantitative risk assessment provides an intermediary level between the textual evaluation of qualitative risk assessment and the numerical evaluation of quantitative risk assessment, by evaluating risks with a score. It offers a more consistent and rigorous approach to assessing and comparing risks and risk management strategies than does qualitative risk assessment, and avoids some of the greater ambiguities that a qualitative risk assessment may produce. It does not require the same mathematical skills as quantitative risk assessment, nor does it require the same amount of data, which means it can be applied to risks and strategies where precise data are missing. Nonetheless, all forms of risk assessment require the greatest possible collection and evaluation of data available on the risk issue, and food safety risk assessments require in-depth knowledge in a variety of scientific disciplines. Semi-quantitative risk assessment requires all of the data collection and analysis activities for qualitative risk assessment as described in the previous chapter.

Semi-quantitative risk assessment is a relatively new idea in food safety. Codex Alimentarius Commission (CAC) and others generally consider just two categories of risk assessment: qualitative and quantitative. Semi-quantitative risk assessment, as described here, has often been grouped together with qualitative risk assessment, but this understates the important differences between them in their structure and their relative levels of objectivity, transparency and repeatability.

4.1.1 Uses of semi-quantitative risk assessment

Semi-quantitative risk assessment is most useful in providing a structured way to rank risks according to their probability, impact or both (severity), and for ranking risk reduction actions for their effectiveness. This is achieved through a predefined scoring system that allows one to map a perceived risk into a category, where there is a logical and explicit hierarchy between categories.

Semi-quantitative risk assessment is generally used where one is attempting to optimize the allocation of available resources to minimize the impact of a group of risks under the control of one organization. It helps achieve this in two ways: first the risks can be placed onto a sort of map so that the most important risks can be separated from the less important; second, by comparing the total score for all risks before and after any proposed risk reduction strategy (or combination of strategies) one can get a feel for how relatively effective the strategies are and whether they merit their costs. Semi-quantitative risk assessment has been used with great success in various arenas of project and military risk for over a decade, and is beginning to find favour in foodborne pathogen-related areas.

Semi-quantitative risk assessment offers the advantage of being able to evaluate a larger number of risk issues than quantitative risk assessment because a full mathematical model is not necessary. The results of fully quantitative risk assessments, where they have been possible, can be included in a semi-quantitative rationale, although usually at the loss of some quantitative precision, as the more precise enumeration of probability and impact from the quantitative risk assessment has to be placed into categories that cover broad ranges of probability and impact.

Being able to review a larger number of risks and possible risk management strategies in one analysis gives the risk manager a better 'aerial view' of the problem, and helps strategize at a more global level.

4.2 Characteristics of a semi-quantitative risk assessment

Categorical labelling is the basis for semi-quantitative risk assessment. It uses non-technical descriptions of a risk's probability, impact, and severity (the combination of probability and impact), for example: 'Very low', 'Low', Medium', 'High', and 'Very High', or some scaling like A-F. In order for this type of labelling to be unambiguous and useful, management must provide a list of the non-overlapping, exhaustive categorical terms that are to be used, together with clear definitions of each term. For example, a 'Low' probability risk might be defined as an individual risk having between 10^{-3} and 10^{-4} probability of occurring in a year, and a 'High' impact might be defined as an individual suffering long-term sequelae that materially affect their quality of life. This step is crucial, as a number of studies have shown that even professionals well-versed in probability ideas who regularly make decision based on risk assessments have no consistent interpretations of probability phrases ('likely', 'almost certain', etc.), which could lead to inconsistency and lack of transparency. Without numerical definitions of probability, subjective descriptions such as 'low' can be affected by the magnitude of the risk impact: for example, a 5% probability of diarrhoeal illness from some exposure might be considered 'low', but a 10% probability of death from that exposure might be considered 'high'. The number of categories used to express probability and impact should be chosen so that one can be sufficiently specific without wasting time arguing about details that will not ultimately affect the risk management decision. A five-point scale has generally proven the most popular in the risk community, sometimes with a sixth category representing zero for probability and impact, and a seventh 'certain' category for probability representing a probability of 1.

It is the role of risk characterization to provide to management an unbiased estimate of the level of the risk being considered. A risk assessment that concludes the level of the risk under consideration to be 'Low', for example, may be perceived to be making a management evaluation of the risk, and therefore confusing the roles of assessor and manager, which is potentially a key weakness of qualitative risk assessment. Semi-quantitative risk assessment avoids this problem by attaching a specific, quantitative meaning (rather than a judgemental meaning) to terms like 'Low probability'. Tables 4.1 and 4.2 provide some example definitions for probability, exposure rate and impact categories.

Table 4.1 Example definitions of probability and exposure frequency categorical labels.

Category	Probability range (Probability of event per year)
Negligible	Indistinguishable from 0
Very low	$< 10^{-4}$, except 0
Low	10^{-3} to 10^{-4}
Medium	10^{-2} to 10^{-3}
High	10^{-1} to 10^{-2}
Very high	$> 10^{-1}$, not 1
Certain	1

Category	Exposures per year
Negligible	Indistinguishable from 0
Very low	1–2
Low	3–10
Medium	10–20
High	20–50
Very High	>50

Table 4.2 Example definitions of health impact category labels

Category	Impact description
None	No effect
Very low	Feel ill for few days without diarrhoea
Low	Diarrhoeal illness
Medium	Hospitalization
High	Chronic sequelae
Very high	Death

Table 4.3 Example of combining category labels.

Component	Category	Numerical range
Probability that serving is contaminated	Very High	$10^{-1} – 1$
Number of servings in a year	Medium	10 – 20
Probability of illness from a contaminated serving	Low	$10^{-4} – 10^{-3}$
Probability of illness in a year	Low to Medium	$10^{-4} – 2.10^{-2}$

Often, in the course of carrying out a qualitative risk assessment, one can roughly estimate the probability of exposure, etc., from comparison with other, previously quantified risks or from good data pertaining to the problem in hand. If time or the available data are insufficient to carry out a complete quantitative risk assessment, one can use these categorical labels to express the risk level in a more structured way than a simple description of the evidence one has acquired. For example, if the qualitative risk assessment has determined the probability a serving could be contaminated is 'Very High', the number of servings a random person consumes is 'Medium' and the probability of illness given consumption of the contaminated product is 'Low', one can conclude the composite probability to be between 'Low' and 'Medium' by tracking through the corresponding ranges, as shown in Table 4.3, using the example definitions from Tables 4.1 and 4.2.

This approach enables people to make more consistent, logical conclusions: a 'Low' exposure probability per serving and a 'High' probability of illness given exposure cannot, for example, be categorized as a 'Very High' probability of illness per serving.

It is possible to use categorical labels to perform some rudimentary type of probability manipulation. For example, by carefully defining the ranges assigned to each term, it is possible to combine a 'Low' exposure with a 'High' probability of subsequent health effect (the hazard characterization, or dose-response component) to determine the appropriate categorization for the total risk. It is only possible to maintain consistency and transparency in combining categorical labelling of elements of a risk assessment if numerical ranges have been defined for each label, and combining categorical labelling nonetheless should still be approached with some considerable caution (see Section 4.3.3).

4.3 Performing a semi-quantitative risk assessment

A P-I (probability-impact) table offers a quick way to visualize the relative riskiness or severity (a common term in risk analysis for the combination of probability and impact) of all identified risks within the domain of analysis. Table 4.4 illustrates an example. All risks (e.g. the list of pathogens that might appear in a particular food type) are plotted in the one table, allowing for the easy identification of the most threatening risks as well as providing a general picture of the overall risk associated with the food type. The numbers in the table are indices for identified risks. Risks 2 and 13, for example, have high severity; risks 3, 5 and 7 have very low severity. Risks with zero events per year (i.e. zero probability, e.g. risks 11 and 14) or zero impact (e.g. risks 8, 9 and 10) are not strictly risks, but may be useful to document in a P-I table as having been identified and subsequently determined to be negligible.

Table 4.4 Example of a P-I table for individual risk per year.

I	VHI			6			13,2
M	HI	14				15	12
P	MED		5		4	1	
A	LO						
C	VLO	11	7	3			
T	NIL			8,9		10	
		NIL	VLO	LO	MED	HI	VHI
		EVENTS PER YEAR					

Severity scores (sometimes called P-I scores) can be used to rank the identified risks. A scaling factor, or score, is assigned to each label used to describe each type of impact. If a log scale is used to define each categorical scale, as in the examples provided in Table 4.1 for probability and Table 4.2 for impact (one could debate whether there was a log of difference between each impact category and adjust if necessary), the probability and impact scores can be designed such that the severity score of a risk is then the sum of the probability and impact scores, or some other simple mathematical equation. Table 4.5 provides an example of the type of scaling factors that could be associated with each term and impact type combination.

In this example (Table 4.5), an impact of 6 has been given for 'Very High' as this refers to death, which is a much greater leap from chronic sequelae than chronic sequelae is from hospitalization, or any of the other impact increments. The risks of Table 4.4 can now be assigned a severity score, such as that shown in Table 4.6 (where probability and rate as considered equivalent).

Severity scores enable the risks to be categorized and ranked according to severity. In the scoring regime of Table 4.5, for example, a 'High' severity risk could be defined as having a score greater than 7, a 'Medium' severity risk as having a score between 4 and 6 and a 'Low' severity risk as having a score less than 4. A key drawback to this approach of ranking risks is that the process is very sensitive to the scaling factors that are assigned to each term describing the risk impacts.

Table 4.5 Example of the type of scaling factors that can be applied to determine a severity score.

Rating	Probability score	Impact score
None	NA	NA
VLO	1	1
LO	2	2
MED	3	3
HI	4	4
VHI	5	6

Table 4.6 Example severity score calculations for risks from Table 4.4.

Risk index	Probability	Probability score	Impact	Impact score	Severity score
13	VHI	5	VHI	6	5+6 = 11
1	HI	4	MED	3	4+3 = 7
5	VLO	1	MED	3	1+3 = 4

4.3.1 Risks with several impact dimensions

The usual endpoint of a microbiological food safety risk assessment is some measure of human health risk. However, an analysis may consider other types of impact, like economic loss or erosion of quality of life (e.g. reduction in choice of 'safe' food products), some of which have less numerically definable impacts.

P-I tables can be constructed in a number of ways: for example, displaying the various types of impact of each individual risk (such as for a particular bacterium, or a particular food product). Table 4.7 is an example where the human health impact (H), cost (£) and social (S) impact are shown for a specific risk. The probability of each impact may not be the same. In this example, the probability of the risk event occurring is 'high' and if it occurs is certain to result in a cost impact. There is a smaller probability of a health impact, and it is considered that there is a 'low' probability of the event occurring and producing a social impact. Implicit in assigning categories for more than one type of impact is that one has assigned broad correspondence in value between, for example, human health impact and economic loss.

Table 4.7 P-I table for a specific risk.

Impacts for Risk Number 15							
I	VHI						
M	HI				H		
P	MED					£	
A	LO						
C	VLO			S			
T	NIL						
		NIL	VLO	LO	MED	HI	VHI
		EVENTS PER YEAR					

Having several impact dimensions makes it more difficult to produce an overall severity score for the risk, since the impacts are additive, rather than multiplicative. The most common approach is simply to take the maximum of the severity scores for the individual impact dimensions. This works reasonably well if the scaling of probability and impact are logarithmic in nature. So, for example, we can evaluate the risk of Table 4.7 with the scoring system of Table 4.5 as shown in Table 4.8.

Table 4.8 Example of determining an overall severity score, that for 'Risk 15' from Table 4.7.

Impact type	Probability	Probability score	Impact	Impact score	Severity score
Health	MED	3	HI	4	3+4 = 7
Economic	HI	4	MED	3	4+3 = 7
Social	LO	2	VLO	1	1+2 = 3
			Overall severity		MAX(7,7,3) = 7

This example (Table 4.8) illustrates the crudeness of the analysis, since the severity score would be the same if, for example, there were no economic or impact dimension. A slightly more complicated method for getting an overall severity score is to transfer the individual impact severity scores out of logs, add them up, and transfer back into logs. For the risk in Table 4.8 this would give:

$$\text{Overall severity score} = \text{LOG}_{10}(10\text{^}7 + 10\text{^}7 + 10\text{^}3) = 7.3$$

4.3.2 Comparing risks and risk management strategies

Table 4.9 shows how determining a severity score can be used to segregate the risks shown in a P-I table into three regions. This is sometimes known as a 'traffic light' system: risks lying in the green area are well within a comfortably acceptable level (low severity); risks lying in the red region are not acceptable (high severity); and the remaining risks lie in the amber—medium severity—middle ground. The crudeness of the scaling of this semi-quantitative risk assessment approach means that it will often be appropriate to study 'Amber risks' further, perhaps using more quantitative methods, to determine whether they actually lie close to or within the red or green regions.

Table 4.9 Segregation of risks into Low ['green'], Medium ['amber'] and High ['red'] severities by severity scores.

One dimension severity scores									
I	VHI	NA	7	8	9	10	11		
M	HI	NA	5	6	7	8	9		High severity
P	MED	NA	4	5	6	7	8		
A	LO	NA	3	4	5	6	7		Medium severity
C	VLO	NA	2	3	4	5	6		
T	NIL	NA	NA	NA	NA	NA	NA		Low severity
		NIL	VLO	LO	MED	HI	VHI		
		EVENTS PER YEAR							

Severity scores can help to provide a consistent measure of risk that can be used to define metrics and perform trend analyses. For example, the maximum severity score across all risks associated with a food type gives an indication of the overall 'amount' of risk exposure from that food type. Both of these metrics can be measured for the different impact dimensions (health, cost, etc.), or for different risk types or areas of effect, to determine how risk exposure is distributed. More complex metrics can be derived using severity scores, allowing risk exposure to be normalized and compared with a baseline risk. These permit trends in risk exposure to be identified and monitored, giving valuable information to risk managers on the global improvement of food safety, the emerging prominence of any risk, etc.

4.3.3 Limitations of semi-quantitative risk assessment

Semi-quantitative risk assessment has its limitations. The risks are placed into usually quite broad sets of categories: it is common to use five or so for probability and for impact, not including zero, which gives 25 possible combinations. It is therefore imperative that the categories are carefully constructed. For example, one could break up the probability range into five categories, as in Table 4.10.

Table 4.10 A linear scoring system for probability.

Score	Probability range
1	0 – 0.2
2	0.2 – 0.4
3	0.4 – 0.6
4	0.6 – 0.8
5	0.8 – 1

However, under this scheme, a risk with a probability of 0.1 would sit in the same category as a risk with probability 0.000 001, despite being 100 000 times more likely. This is one reason why a log scale is often chosen for probabilities. The nature of food safety risk means that we are often dealing with probabilities that span over several orders of magnitude, which also make the use of a log scale more appealing.

We cannot easily combine probability scores for components of a risk pathway to get a probability score for the risks as a whole. For example, food safety risk estimation is often split into two parts: the probability of exposure; and the probability of illness given exposure. Using the scheme above, if we felt that the exposure had a 0.3 probability (score = 2) of occurring within a certain period for a random individual, and the probability of illness from that exposure was 0.7 (score = 4), the combined probability is 0.21 (score 2). We can't easily create a rule with scores that replicates the probability rules. Taking the minimum of the two scores is one partial solution (in Excel®, the syntax would be MIN(2,4) = 2) but this generally over-estimates

the risk. For example, changing the probability of illness given exposure to anything from 0.2 to 1.0 would give the same combined probability score of 2 using this formula.

The use of a log scale for probability relieves the problem to some extent if we reverse the probability score order described so far to assign the highest probability with the lowest score, as shown in Table 4.11.

Table 4.11 A logarithmic scoring system for probability.

Category	Probability range	Score
Impossible	0	NA
Very low	$< 10^{-4}$, except 0	5
Low	10^{-3} to 10^{-4}	4
Medium	10^{-2} to 10^{-3}	3
High	10^{-1} to 10^{-2}	2
Very high	$> 10^{-1}$, not 1	1
Certain	Almost 1	0

Using this scheme, the scoring system equivalent of multiplying probabilities is to add scores. For example, if we felt that the exposure had a 0.2 probability (score = 1) of occurring within a certain period for a random individual, and the probability of illness from that exposure was 0.004 (score = 3), the combined probability is 0.0008 (score 4). It does not always work out so neatly, however. An exposure with probability 0.5 (score = 1) and a probability of illness from that exposure of 0.003 (score = 3) gives a combined probability of 0.0015 (score = 3), yet the individual scores sum to 4. Adding scores in a log system like the one in Table 4.11 will often over-estimate the probability by one category. This is one reason for having an amber region in the traffic light system, because risks may be over-estimated, and risks falling into an amber region may in fact turn out to be acceptable.

The calculation of severity scores would need to be changed with this reversed probability scoring. For example, keeping the impact scoring of Table 4.2 we could calculate a severity score as (Impact score minus Probability score). It changes the range of the severity scores but maintains the same order as in Table 4.9. Table 4.12 shows the severity score categories using impact scores of Table 4.5 with the probability scores of Table 4.11 and using the formula: (Severity score) = (Impact score) - (Probability score).

Table 4.12 Segregation of risks into Low ['green'], Medium ['amber'] and High ['red'] severities by severity scores (using reversed probability scoring).

One dimension severity scores										
I	VHI	NA	1	2	3	4	5			
M	HI	NA	-1	0	1	2	3			High severity
P	MED	NA	-2	-1	0	1	2			
A	LO	NA	-3	-2	-1	0	1			Medium severity
C	VLO	NA	-4	-3	-2	-1	0			
T	NIL	NA	NA	NA	NA	NA	NA			Low severity
		NIL	VLO	LO	MED	HI	VHI			
		EVENTS PER YEAR								

There is also a problem of the granularity of the scale. For example, for a risk whose probability of occurrence falls just above the boundary between two categories, and for which we have found a risk management strategy that reduces that probability by a small amount, it could be dropped down one probability category, which is now indistinguishable from reducing the probability by a factor of 10. However, there is nothing to stop the risk assessor from using

score fractions if it seems appropriate. The integer system is designed for convenience and simplicity, and should be changed to include fractions if this better represents the available knowledge.

Using the semi-quantitative risk assessment scoring system as a surrogate for probability calculations is also likely to cause more severe inaccuracies when one assesses a longer sequence of events.

4.3.4 Dealing with uncertainty and variability

In one sense the broad category ranges assigned to probability and impact scales make it less essential to consider anything but large-scale uncertainty. The overview nature of semi-quantitative risk assessment also helps one think about more global issues of model uncertainty. That said, quantitative food safety risk assessment results that are not anchored to correspond to observed illness rates frequently span several orders of magnitude of uncertainty. The level of available information may also make it difficult to assign probability and impact categories to a particular risk. It would be useful and more objective to be able to express this uncertainty. One method is to describe the uncertainty by showing a risk as lying within an area of the P-I table, as in Table 4.13.

Table 4.13 Graphically expressing uncertainty about a risk category.

I	VHI						
M	HI						
P	MED				4		
A	LO						
C	VLO						
T	NIL						
		NIL	VLO	LO	MED	HI	VHI
		EVENTS PER YEAR					

Here, the (optional) darker shading represents where the risk assessment team feel the risk most likely lies, and the lighter shading represents the range of uncertainty about that evaluation. Graphical shapes, like circles, drawn on the table to represent uncertainty make it easier to plot several risks together.

One can also employ standard Monte Carlo simulation to express uncertainty in scores where they are being manipulated in more mathematical analyses discussed above.

Variability, such as variability in susceptibility between subpopulations, can easily be incorporated in semi-quantitative risk assessment (where the necessary data are available) by estimating the risk for subpopulations and plotting them separately on the same chart. This provides an excellent overview of how different subpopulations share the food safety risk.

4.3.5 Data requirements

The basic principle of risk assessment is to collect as much data as you can, providing that the inclusion of more data may affect the decision being made. The data collected for a qualitative risk assessment are often sufficient for semi-quantitative risk assessment needs. The difference

between the two is that semi-quantitative risk assessment has a greater focus on attempting to evaluate the components of the risk to within defined quantitative bounds. Thus, at times, one may do a statistical analysis on a data set to attempt to more precisely estimate a probability, or the expected impact, providing it will give the assessor more confidence about how to categorize the risk.

Semi-quantitative risk assessment is usually used as a means to compare several risks or risk management strategies. At times we may have sufficient data to be able to perform a full quantitative risk assessment for a select number of risks (e.g. food–pathogen combinations). A quantitative model can give us more information about specific strategies to apply to that particular risk issue, but we can also use the quantitative results to place these more precisely evaluated risks into context with others of concern in a semi-quantitative environment.

4.3.6 Transparency in reaching conclusions

Semi-quantitative risk assessment offers a lot of advantages in achieving transparency. No sophisticated mathematical model is necessary, for example, which is appealing to the lay person. However, the use of mathematical models as an obstacle to transparency may be over-emphasized. Most food safety risk assessments require understanding of complex microbiological information and usually a reasonable level of human medicine, and of epidemiological principles which tend to be postgraduate topics, whereas quantitative risk assessment uses mathematics generally covered at undergraduate level. The main obstacle to transparency of quantitative models is that there are only a few people who have specialized in the field.

Semi-quantitative risk assessment encourages the development of decision rules (e.g. the traffic-light system) that can be easily followed and checked. The framework for placing risks within a P-I table makes it much easier to demonstrate a consistency in handling risks because they are all analysed together.

The key transparency issue with semi-quantitative risk assessment arises from the granularity of the scales used in scoring. The usually rather broad categories means that we lose any distinction between risks that can be considerably different in probability and/or impact magnitude. This means, for example, that one food industry could be unfairly penalized because its product lies just above a category, or that industries or regulator only have the incentive to push a risk just over the category boundary.

Semi-quantitative risk assessment is a system for sorting out risks, focusing on the big issues, and managing the entire risk portfolio better. The scoring system is inherently imperfect, but so is any other risk evaluation system. If the scoring system being used can be shown to produce important errors in decision logic, then one can use potentially more precise quantitative risk assessment arguments, or change the scoring system to something more precise.

4.4 Examples of semi-quantitative risk assessment

4.4.1 New Zealand risk profile of *Mycobacterium bovis* in milk

The New Zealand Food Safety Authority commissioned the New Zealand Institute of Environmental Science & Research Ltd (ESR) to provide a ‘Risk profile’ of *Mycobacterium bovis* in milk (Lake, Hudson and Cressey, 2002b).

The analysis took the form of a 'Risk Profile' which is used in the New Zealand food safety system to rank food safety issues for risk management. It forms an early part of their risk evaluation process, which comprises:

- identification of the food safety issue;
- establishment of a risk profile;
- ranking of the food safety issue for risk management;
- establishment of risk assessment policy;
- commissioning of a risk assessment; and
- consideration of the results of risk assessment.

The pathogen was selected for assessment because

> "although it is likely to have minimal public health significance, demonstration of the safety of New Zealand produced food with respect to this pathogen may have trade implications. The food most commonly associated with transmission to humans is cow's milk."

The system for assignment of a category for a food/hazard combination uses two criteria: incidence (rate) and severity assigning categories to the estimate of each. A four-category scoring system was proposed for the rate, based on foodborne disease rates experienced in New Zealand (Table 4.14).

A three-category scoring system was proposed for the severity, based on a comparison of the proportion of New Zealand foodborne cases that result in severe outcomes (long-term illness or death) (Table 4.15).

Table 4.14 The four categories proposed in New Zealand for the incidence (rate).

Rate Category	**Rate range** (per 100 000 per year)	**Examples**
1	>100	Significant contributor to foodborne campylobacteriosis
2	10–100	Major contributor to foodborne salmonellosis Significant contributor to foodborne noroviruses
3	1–10	Major contributor to foodborne yersiniosis, shigellosis
4	<1	Major contributor to foodborne listeriosis

Table 4.15 The three categories proposed in New Zealand for severity.

Severity Category	**Fraction of cases that experience severe outcomes**	**Examples**
1	5%	listeriosis; STEC; hepatitis A; typhoid
2	0.5-5%	salmonellosis; shigellosis
3	<0.5%	campylobacteriosis; yersiniosis; noroviruses; toxins

NOTES: STEC = Shiga-toxin-producing *Escherichia coli.*

Analysis for *Mycobacterium bovis* in milk was hampered by a complete lack of prevalence information, so it was considered impossible to make even qualitative statements of exposure. The only available dose-response data were from animal experiments from 1934 and earlier, making it meaningless to consider a usual food safety risk assessment of exposure and hazard characterization. The risk profile method is based solely on epidemiological data in an attempt to inform decision-makers of how important the issue is among other food safety issues that need to be managed. The analysis discussed the available evidence and gave the following scores:

- **Severity**: 1 (>5% serious outcomes)
- **Incidence**: 4 (<1 per 100 000 people per year)
- **Trade importance**: high

ESR produces a risk profile for *Salmonella* in poultry (whole and pieces) using the same methods, but with considerably more data available (Lake, Hudson and Cressey, 2002a). Note that the risk assessment titles described these as 'qualitative' risk assessments. However, the numerical definitions of the broad category bands would place these risk assessments within the range of semi-quantitative risk assessments as discussed in this document.

4.4.2 Seafood safety using RiskRanger

FAO (2004) discusses the continuum between qualitative and quantitative risk assessment for seafood, and introduces a semi-quantitative risk assessment method that has been coded into a freely-available prototype decision support software tool called RiskRanger (Ross and Sumner, 2002). The tool requires answers to 11 questions, which describe the factors from harvest to consumption that affect the food safety risk of seafood. The questions can be answered in either qualitative (with predetermined categories) or quantitative terms. Qualitative answers are converted to quantitative values according to sets of tables.

The model is intended to be population specific, so key inputs like total and/or region population size are required to be predefined, although user-defined values can also be input. A score is then calculated from the inputs, allowing the ranking of various food–pathogen combinations. The scoring system is designed to have a scale of 0 to 100, where 100 represents the worst imaginable scenario, i.e. that every member of the population consumes a lethal dose every day. A 0 score was arbitrarily set to equate to one mild diarrhoeal case per 100 billion people per hundred years, the logic being that the Earth's population is significantly less than 100 billion, so one would not expect to see an occurrence of the risk anywhere within a person's lifetime. The chosen range extends over 17.6 orders of magnitude, which equates to $100/17.6 \approx 6$ 'risk ranking' units for each factor of 10 between risks.

The method has been designed to screen risks and to screen major categories of risk management options. The spreadsheet interface allows a risk manager to instantaneously consider what-if scenarios that can stimulate discussion of possible risk management strategies. The simplicity and generic nature of the model means that its results remain fairly crude. It also means that the questions that are posed are of a very general nature. The authors go into considerable detail to warn the reader of these limitations. There is, for example, no incorporation of uncertainty and variability in the model, though this could be readily added into the spreadsheet model using Monte Carlo simulation.

The tool was then used to evaluate 10 Australian seafood hazard+product combinations, and considered different consuming subpopulations in Australia, with the results shown in Table 4.16 (from Sumner and Ross, 2002).

The authors compared the ranked risks against observations in Australia. There had been no documented cases in Australia for risks with a score <32. All risks with scores between 32 and 48 (a range of three orders of magnitude) had caused several outbreaks of foodborne illness in Australia, with the exception of *Vibrio cholera*. Risks with scores >48 had all caused outbreaks of large numbers, some in specific regions.

Table 4.16 Result of using RiskRanger to evaluate hazard+product combinations for various sub-populations in Australia.

Hazard+product pairing	Selected population	Risk ranking
Ciguatera in reef fish	General Australian population	45
Ciguatera in reef fish	Recreational fishers, Queensland	60
Scombrotoxicosis	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
Vibrio parahaemolyticus in cooked prawns	General Australian population	37
Vibrio cholerae in cooked prawns	General Australian population	37
Vibrio vulnificus in oysters	General Australian population	41
Listeria monocytogenes in cold-smoked seafoods	General Australian population	39
Listeria monocytogenes in cold-smoked seafoods	Susceptible (aged, pregnant, etc.)	45
Listeria monocytogenes in cold-smoked seafoods	Extremely susceptible (AIDS, cancer)	47
Clostridium botulinum in canned fish	General Australian population	25
Clostridium botulinum in vacuum packed smoked fish	General Australian population	28
Parasites in sushi or 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

Key among the cautions the authors cite are that they have not been able to systematically and objectively evaluate the model's performance because there are few data sets describing exposure and foodborne disease incidence. That caution, however, is also evidence that full quantitative models would also not have been possible.

The authors also found that the model was a powerful tool for teaching the principles of risk analysis.

4.4.3 Australia's animal and animal product import-risk assessment methodology

In 1998, a trade dispute between Canada and Australia over Australia's 24-year ban of uncooked salmon went to the WTO court (WTO, 1998). The Australia Quarantine Inspection Service had produced a qualitative risk assessment analysing the disease threat in 1995, and another in 1996: the former assessed the risk to be acceptably low; the latter reached the opposite conclusion. The difference in conclusion came about through using a different qualitative risk assessment approach, rather than through the emergence of new information. The WTO Appellate Body came down on Canada's side because, *inter alia*, it considered that Australia had not implemented a proper risk assessment of salmon imports. This highlighted to the risk analysis community the potential problems of relying on a purely qualitative risk assessment methodology, especially in an adversarial environment.

Australia's regulatory body assessing import risk was re-structured, and it now falls under the responsibility of Biosecurity Australia. They have developed a semi-quantitative approach to assessing import risk (Biosecurity Australia, 2001). The risk evaluation is based on placing the estimated risk in a table (Table 4.17). The band of cells marked 'very low risk' represents Australia's Appropriate Level of Protection (ALOP), or tolerance of loss, a two-category version of the 'traffic light' concept.

The guidelines describe qualitative (e.g. low, medium, high), semi-quantitative (e.g. $0 \rightarrow 0.0001$; $0.0001 \rightarrow 0.001$; $0.001 \rightarrow 0.01$; $0.01 \rightarrow 1$) and quantitative (exact probability calculation) evaluation of likelihood of entry of an exotic disease into Australia. This has the potential advantage of using one environment to incorporate risk assessments along the qualitative to quantitative continuum. Qualitative evaluations of steps in a sequence that results in exotic disease entry are allowed through a matrix rule for combining such qualitative probabilities.

The consequence assessment component of the risk estimate for an exotic disease import risk is generally considered far more difficult than evaluating the probability of disease entry. This is because imports are regulated and fairly simple to model, and their probabilities are well understood, whereas there are no data on the spread of disease in the naïve country, and disease spread is anyway extremely complex to model.

Biosecurity Australia wished to evaluate the probability and magnitude of a variety of impacts should the disease enter the country. They devised a series of rules that allowed the incorporation of the geographical extent of the consequence (local, district, regional, national), and the level to which the consequence would be felt at that scale. Other rules combined the (necessarily qualitative or semi-quantitative) estimates of likelihood of these consequences (given the disease has entered Australia) to allow a placement of the unrestricted risk estimate in the table (Table 4.17).

If the unrestricted risk (i.e. the risk from a product where no specific controls are in place to protect against the pathogen in question) estimate fell into an acceptable region, the import would be allowed without any restrictions. If not, restrictions (testing, heat treatment,

evisceration, etc.) would be evaluated to determine the least trade-restrictive option that would allow the import product to meet Australia's ALOP.

Whichever approach (or combination of approaches) is chosen, the guidelines state that the approach should provide for the following:

- an assessment based on sound science;
- an assessment that is structured and transparent;
- an assessment that is internally consistent, and that can be repeated (with the same or a similar outcome) by another operator using the same framework and data;
- an outcome that will support the estimation of 'risk' (a combination of likelihood and consequences);
- an outcome that will enable risk to be evaluated against the importing country's ALOP, or 'tolerance for loss'; and
- a framework within which the efficacy of risk management and the acceptability of a mitigated risk can be evaluated.

Table 4.17 Tabulation of risk as a combination of likelihood and impact.

Likelihood of entry and exposure[1]	*Negligible impact*	*Very low impact*	*Low impact*	*Moderate impact*	*High impact*	*Extreme impact*
High likelihood	Negligible risk	Very low risk	Low risk	Moderate risk	High risk	Extreme risk
Moderate likelihood	Negligible risk	Very low risk	Low risk	Moderate risk	High risk	Extreme risk
Low likelihood	Negligible risk	Negligible risk	Very low risk	Low risk	Moderate risk	High risk
Very low likelihood	Negligible risk	Negligible risk	Negligible risk	Very low risk	Low risk	Moderate risk
Extremely low likelihood	Negligible risk	Negligible risk	Negligible risk	Negligible risk	Very low risk	Low risk
Negligible likelihood	Negligible risk	Negligible risk	Negligible risk	Negligible risk	Negligible risk	Very low risk

Consequences of entry and exposure

NOTES: (1) Read '*entry, establishment and spread*' for import-risk analyses for plants or plant products.