3. Qualitative risk characterization in risk assessment

3.1 Introduction

The risk characterization generated by a qualitative risk assessment, while ideally based in numerical data for exposure assessment and hazard characterization, will generally be of a descriptive or categorical nature that is not directly tied to a more precisely quantified measure of risk. Qualitative risk assessments are commonly used for screening risks to determine whether they merit further investigation, and can be useful in the 'preliminary risk management activities' described in FAO/WHO (2002), but may also provide the needed information and analysis to answer specific risk management questions. Examples of published qualitative risk assessments include Stephens (2002), EU-HCPDG (2003), Lake, Hudson and Cressey (2002a, b).

It should be emphasized that the attributes of good risk assessment, as described in Section 2.1, apply equally to qualitative risk assessment. Appropriate data must be collected, documented and fully referenced and synthesized in a logical and transparent manner whichever method is employed. The major difference between qualitative and quantitative risk characterization approaches is in the manner in which the information is synthesized and the communication of the conclusions.

Despite a number of large and well-publicized quantitative microbiological food safety risk assessment projects recently completed, it is probable that the majority of risk assessments utilized by risk managers and policy-makers in the fields of food safety, health and microbiology are not fully quantitative in the sense described in Chapter 5.

There may be a variety of reasons for this. Quantitative microbiological risk assessment is a new and specialized field and methods are still being developed, and the expertise and resources to complete them are not widely available. Equally, as noted in Chapter 2, the results of such assessments are not always 'accessible' to risk managers and other stakeholders. Thus, where a formal risk assessment (i.e. a body of work presented in a way that conforms to a set of risk assessment guidelines and specifically designed to estimate the magnitude of a risk) is commissioned from a risk assessor, a qualitative risk assessment may be specified for reasons including:

- a perception that a qualitative risk assessment is much quicker and much simpler to complete;
- a perception that a qualitative risk assessment will be more accessible and easier for the risk manager or policy-maker to understand and to explain to third parties;
- an actual or perceived lack of data, to the extent that the risk manager believes that a quantitative assessment will be impossible; or
- a lack of mathematical or computational skills and facilities for risk assessment, coupled with a lack of resources or desire to involve an alternative or additional source of expertise.

Whatever the reasons, many of them involve perceptions about the process of defensible qualitative risk assessment that, for reasons also mentioned above, are frequently not valid. Data

are required for any type of risk assessment, irrespective of whether qualitative, semi-quantitative or quantitative approaches are used. Numerical data are preferred, and a lack of appropriate crucial data will affect all approaches adversely. As data collection and documentation is usually the most time-consuming part of the any risk assessment, and defensible logic is required to synthesize the data into an estimate or conclusion concerning the risk, a qualitative risk assessment will not necessarily be quicker or simpler to complete. In many cases, qualitative and semi-quantitative risk assessments are quicker to complete, and, whilst they require an equal degree of logic and considerable numeracy, they require fewer specialized mathematical and computational resources. A qualitative risk assessment has descriptions of the probability of an unwanted outcome in terms that are by their very nature subjective. It means that it is not necessarily easier either for the risk manager to understand the conclusions obtained from the risk assessment, or to explain them to a third party. Crucial to any formal risk assessment method is transparency, whether to describe how a numerical or a qualitative description of risk was achieved, because this enables users to understand the basis of the assessment, to understand its strengths and limitations, to question or critique the assessment, or provide additional data or knowledge to improve the assessment. Additionally, because all approaches also require specialized medical, microbiological, biological, veterinary, epidemiological and other expertise, the inclusion of information and concepts from such a wide variety of areas of knowledge can make the risk assessment less accessible. Chapter 8 considers ways in which the results of risk assessment can be better communicated to users and stakeholders.

3.1.1 The value and uses of qualitative risk assessment

Risk assessment, at its simplest, is any method that assesses, or attempts to assess, a risk. Qualitative risk assessment is not, however, simply a literature review or description of all of the available information about a risk issue: it must also arrive at some conclusion about the probabilities of outcomes for a baseline risk and/or any reduction strategies that have been proposed. Both CAC (1999) and OIE (1999) state that qualitative and quantitative risk assessments have equal validity, but they have not considered semi-quantitative risk assessment (see Chapter 4). However, neither organization explains the conditions under which qualitative and quantitative risk assessments are equally valid, and there is debate among risk experts about methods and approaches to be applied for qualitative risk assessment, and criteria for their validity. The World Trade Organization Committee on Sanitary and Phytosanitary Measures notes some advantages of quantitative expressions of risk:

> "... quantitative terms, where feasible, to describe the appropriate level of protection can facilitate the identification of arbitrary or unjustified distinctions in levels deemed appropriate in different situations ... use of quantitative terms and/or common units can facilitate comparisons."

However, in the development of risk assessment, assessors have recognized the need to place numeric results in context with a narrative discussion of the limitations of the data and analysis, the important assumptions or variables, and the qualitative aspects of the risk not illuminated by quantitative analysis. The same underlying logic applies whether the assessment is quantitative or qualitative.

It is sometimes the case that a qualitative risk assessment is undertaken initially, with the intention of following up with a quantitative risk assessment if it is subsequently thought to be necessary or useful.

It may be the case that a qualitative assessment provides the risk manager or policy-maker with all the information they require. For example, perhaps the information gathered includes

some piece of evidence that shows that the risk is effectively indistinguishable from zero, and no more need currently be done. Or, conversely, perhaps evidence shows that it is obviously unacceptably large, or that one or more consequences are so unacceptable that safeguards are needed whatever the magnitude. Analogously, qualitative assessments can be used as a first step to quickly explore or implement protective measures where there is expert consensus that such measures would be immediately effective and useful. As such, if there are obvious sources of risk that can be eliminated, one does not need to wait for the results of a full quantitative risk assessment to implement risk management actions. A qualitative risk assessment may also provide the necessary insights into the pathway(s) associated with the risk of concern, but not previously identified, which also allows the risk manager to make decisions or apply safeguards without further quantification.

FAO/WHO (2004) noted:

> "Qualitative risk assessments may be undertaken, for example, using the process of 'expert elicitation'. Synthesizing the knowledge of experts and describing some uncertainties permits at least a ranking of relative risks, or separation into risk categories. … As assessors understand how qualitative risk assessments are done, they may become effective tools for risk managers."

Noting that, in some circumstances, such as those indicated above, they can be conducted quickly and used to address specific questions and may reveal that an extensive, fully quantitative exposure, and risk assessment is not required to provide relevant advice to the risk manager.

3.1.2 Qualitative risk assessment in food safety

Qualitative risk assessments have been extensively used in import-risk assessments of animals and their products. Many animal products are also food intended for human consumption; therefore many of these import-risk assessments have also involved food products intended for human consumption. However, the focus of such import-risk assessments has historically been to assess the risk of a particular exotic pathogen entering a potential importing country or region, carried within the food in question. The intention is generally to assess whether the risk of importing the pathogen in the product is too high to be acceptable to the importing country, and whether safeguards should therefore be applied (such as cooking, freezing, testing or total ban). Frequently, further consequences, in particular any potential consequences to human health, have not been the focus of the risk assessment, even when the pathogen might be a zoonotic organism.

Food product import-risk assessments, in general, assess the probable presence of a pathogen in that product, so that if this probability is unacceptable, then import safeguards can be applied. Human health and safety risk assessments of food products, in general, not only set out to assess the probability of the presence of a pathogen, but also the amount of pathogen present, in order that the human response to the probable dose can be assessed. The latter aspect is sometimes perceived to make qualitative risk assessments less useful in food safety applications, despite the fact that many quantitative dose-response data are very subjective in their estimation methods. As described in Chapter 2, however, not all steps in the risk assessment process (i.e. Hazard Identification, Hazard Characterization, Exposure Assessment, Risk Characterization) are necessary in all cases to assist food safety risk managers to deduce appropriate risk management actions. Actions to reduce exposure, even in the absence of dose-response data, would in many cases be appropriate risk management steps and could be determined from an 'incomplete' risk assessment (i.e. no Hazard Characterization), whether qualitative or

quantitative. An epidemiologically based risk assessment may also not require dose-response data.

3.2 Characteristics of a qualitative risk assessment

3.2.1 The complementary nature of qualitative and quantitative risk assessments

The main principles of a risk assessment apply equally anywhere along the qualitative to quantitative risk assessment continuum. These include identification of the hazard, defining the risk question, outlining the steps of the risk pathway, gathering data and information, including information on uncertainty and variability, combining the information in a logical manner, and ensuring all is fully referenced and transparent. It follows from this that many of the activities are the same, up to and including the gathering of the data. Therefore it is frequently the case that a Risk Profile, or qualitative (or semi-quantitative) risk assessment is undertaken initially, with the intention of following up with a quantitative risk assessment if it is subsequently thought to be necessary or useful, and feasible.

The detailed investigative nature of a qualitative risk assessment may provide the risk manager or policy-maker with all the information they require. For example perhaps the information gathered includes some piece of evidence that shows that the risk is effectively indistinguishable from zero, and no more need currently be done. Or, conversely, perhaps evidence shows that it is obviously unacceptably large, or that one or more consequences are so unacceptable, that safeguards are needed whatever the risk probabilities. A qualitative risk assessment may also provide the necessary insights into previously unidentified pathway(s) associated with the risk of concern, which allows the risk manager to make decisions or apply safeguards without further quantification. In these circumstances additional quantitative assessments will probably be deemed unnecessary by the risk manager or policy-maker.

A Risk Profile or qualitative risk assessment is recommended if a quantitative assessment is being planned. It can be used to identify the data currently available, the uncertainties surrounding that data, and uncertainties about exposure pathways, in order to decide if quantification is both feasible and likely to add anything to the current state of knowledge. It can identify areas of data deficiency for targeting future studies necessary prior to quantification. It can examine the probable magnitude of the risks associated with multiple risk pathways, such as exposure pathways, prioritizing them for the application of quantification.

Whatever the initial intention, when a qualitative risk assessment has already been undertaken, much of the work for a quantitative risk assessment has already been done. For the same risk question, quantification will be able to build on the risk pathway(s) and data already collected, to provide a numerical assessment of the risk.

3.2.2 Subjective nature of textual conclusions in qualitative risk assessments

Assessing the probability of any step in the risk pathway, or the overall risk, in terms of high, medium, low, negligible, etc., is subjective, as the risk assessor(s) will apply their own concepts of the meanings of these terms. These meanings may (and probably will) differ from person to person. This is one of the major criticisms levelled at qualitative risk assessments. However, these final risk assessors' estimates should never be viewed in isolation, just as numerical outputs from quantitative risk assessments should not, and reinforces the need for transparent documentation of the data and logic that lead to the assessor's estimate of the risk.

Judgements will be used within any risk assessment. These may be the risk assessor's judgements, or expert opinion, or both, and these will always be subjective. This will apply when defining the scope of the problem, selecting (and rejecting) data, delineating the risk pathways, applying weightings to data or model pathways, selecting the distributions in a stochastic model, etc., as well as selecting a description of high, low, etc., in a qualitative assessment. Therefore any risk manager, policy-maker or other stakeholder who needs to use, or wishes to understand, a given risk assessment should not simply look at the final 'result'. They should have some knowledge of how that result was arrived at.

Many people may not have the knowledge base to directly understand the computations involved within a quantitative risk assessment. They will need to rely on the explanations and opinions of the risk assessor in explaining to them how the result was reached, and what were the underlying assumptions, judgements, uncertainties, etc., in the computation. If the risk assessor is a good teacher as well as a good risk assessor, this can work well. But only under these circumstances is the risk manager likely to be able to decide for their self the significance and meaning of the quantitative result.

As noted in Sections 2.4 and 3.1, the mathematical expression of risk inherent in a quantitative risk assessment may limit accessibility, unless accompanied by narrative explanations. Analogously, with a qualitative assessment, providing it has been written in a transparent and logical way, almost anyone should be able to understand and follow the arguments. Therefore, by examining the complete risk assessment, the risk manager (and others) can see directly whether they agree with the conclusions of the risk assessor.

Despite the subjective differences in the meanings of words, there is usually some correlation in the way people use these terms, and an idea of the magnitude of a risk thus given by them. For example, if 99% of the population were likely to become infected with potential pathogen P, this would be considered by most people as a very high (or higher) risk. Conversely, if potential pathogen P had never been demonstrated to infect humans, despite a high level of environmental contamination in all regions of the world, and highly sensitive tests applied to the population, then most people would be likely to describe this risk as exceedingly low (or lower). If, in addition, P was shown to be a very stable organism that was very unlikely to mutate, then the risk might even be described by many people as negligible. It is the risks in the middle ground for which there will be the least consensus on qualitative statements. This topic is considered further in Section 3.2.4.

A definition of 'negligible' used in qualitative risk assessment is that, for all practical purposes, the magnitude of a negligible risk cannot, qualitatively, be differentiated from zero (for example, see the use of the term in Murray et al., 2004). The term 'zero' is not used because in microbiological food safety there is generally no such thing as absolutely no risk. Note that, since 'negligible' may be understood as 'may be neglected', it can be argued to be a 'risk management' term because it involves a judgement. In some situations a risk will be considered by a risk manager as negligible not because it cannot be differentiated from zero, but because it is considered that measures to further reduce the risk are not warranted, perhaps on economic grounds or technical feasibility. In this sense, 'negligible' might also be interpreted to mean: 'as low as reasonably achievable' (ALARA).

3.2.3 Limitations of qualitative risk characterization

Intuitively, it is difficult to conceive of a fully qualitative risk assessment that will provide useful advice to risk managers, except in a few special cases where the number of factors that could affect the risk being assessed is very low (e.g. less than four) or where every factor that

affects the risk changes the risk in the same 'direction', i.e. each step in the process increases the risk at the highest level or category for that step, or each step in the process decreases the risk by the maximum level or changes it by the minimum amount, or category, for that step. In all other cases, it is virtually impossible to assess the combined affect of multiple stages because the relative contributions of factors, expressed in qualitative terms, cannot be logically combined to determine their overall affect. Thus, while a fully qualitative risk assessment can identify pathways or scenarios that lead to extremes of risk, the relative risk from all other scenarios cannot be logically differentiated. Logical qualitative reasoning can provide conclusions like 'the risk is logically less than that of X' where X is another, more precisely quantified, risk that has previously been deemed acceptable, or 'the risk is logically greater than that of Y' where Y is another, more precisely quantified, risk that has previously been deemed unacceptable, though one can argue that these are a form of worst- and best-case quantitative risk assessment respectively. Cox, Babayev and Huber (2005) discuss these limitations in greater detail and provide examples.

This chapter is concerned with qualitative risk characterization, however, and considers means by which data describing exposure and dose response can be combined qualitatively to generate a risk estimate. Potential problems and limitations relate mainly to appropriate presentation of evidence and transparency in its logical synthesis.

For a qualitative description of a risk to be useful to a risk manager, the assessor and manager must have similar perceptions of the meaning of subjective terms such as 'low', negligible', etc., or other descriptors (see also Section 3.2.2). A final risk characterization label, e.g. 'low', is largely meaningless to a risk manager without some sort of indication of what constitutes 'low' in the eyes of the author of the report. Also, it gives little indication of what particular pieces of evidence would change the assigned label to something other than 'low'. Thus, if evidence were to be presented that 25% of the product was not stored frozen, would the risk increase to moderate?

Qualitative analyses often suffer from the inability to determine what pieces of evidence were influential, how they were combined, and ambiguity concerning the meaning of any assigned risk characterization labels. Without explicit criteria identifying what is meant by descriptions such as high, moderate, and low risk, there is little to distinguish the conclusions from arbitrary and possibly value-laden judgements about the level of risk. These shortcomings tend to make qualitative risk characterization unacceptable in many decision-support situations.

It is possible to present an unstructured analysis as a more structured analysis by including standard documentation headings such as exposure assessment, hazard characterization and risk characterization; however, it is questionable whether such a document should be considered to be a risk characterization. Examples that illustrate qualitative approaches that do link evidence and conclusion are presented in Section 3.4.

If the risk assessment will be read by a broader audience, assessors should be mindful that interpretation of words or terms used as descriptors might vary between languages or regions. Even when there is a consensus between assessors and managers over the interpretation of the terms used, some limitations of qualitative risk assessment can be identified.

3.3 Performing a qualitative risk characterization

3.3.1 Describing the risk pathway

The risk pathway(s) are the potential pathway(s) from the hazard(s) of interest to the outcome(s) of interest. The elucidation and description of such pathways is essential for a risk assessment. Appropriate data for collection and incorporation are identified, based upon the defined steps in the risk pathway. The order in which the data are presented, and the identification of the required probabilities and conclusions, rely on knowledge of the underpinning steps in the risk pathway.

3.3.2 Data requirements

Data used within qualitative, semi-quantitative and quantitative risk assessments will include both numerical and textual information. General issues concerning the quality and relevance of data to risk assessments are addressed in other FAO/WHO risk assessment guidelines (FAO/WHO, 2003, 2008). There are two basic types of data required for a risk assessment, whether qualitative or quantitative, namely:

- the data used to describe the risk pathway, and thus construct the model framework; and
- the data used to estimate the model input parameters.

For some risk management questions, it may be necessary for the assessment to identify all routes that provide exposure to the same pathogen, so as to be able to attribute the health impact to the source(s) of interest. This may be textual, but a risk assessment will be far more robust if quantitative information is available, such as through statistical epidemiological analyses. The description of the pathways that relate a food or animal to human exposure to the pathogen is textual information for both qualitative and quantitative risk assessments. Discussions with producers or processors, or both, and observations on farms or in food processing plants, for example, will enable a description of the steps in the risk pathway to be elucidated. This is then usually converted to a diagram, for clarity, and forms the basis of the steps in the model framework. For this, there is no difference between what is required for qualitative or quantitative risk assessments.

The second type of data— that used to estimate the model input parameters—must all be numerical for a quantitative risk assessment. In the absence of numerical data, quantified expert opinion or surrogate data are needed to fill the gaps. In addition, where uncertainty or variability exist, these must be incorporated mathematically, generally as distributions. Where there are several sources of data for a given input parameter, they must be weighted or combined, or both, in appropriate mathematical ways reflecting their importance in estimating the parameter in question. Despite its name, a qualitative risk assessment still relies on as much numerical data as possible to provide model inputs. The search for information, and thus for numerical data, should be equally as thorough as for a quantitative risk assessment. Also, where there are crucial numerical data deficiencies, expert opinion must again be utilized. The major difference between qualitative and quantitative risk assessment approaches lies in how the data and expert opinion is treated once obtained

3.3.3 Dealing with uncertainty and variability

A qualitative risk assessment should take uncertainty and variability into account. For example, where data giving a range or a specific distribution are available, this should be described in the risk assessment. However, there is no specific way in which uncertainty and variability in any

one input parameter is retained and reflected precisely in the final risk estimate, even when numerical data are available. As with the assessment of risk, the overall assessment of uncertainty and variability from this source will be evaluated in narrative terms such as 'much', 'little', etc.

One option for the inclusion of variability is to include a number of scenarios (e.g. near-optimal conditions, normal situations and a set of adverse conditions) that reflect the variability, evaluate each as a separately measured risk scenario, and compare the results. This approach will make transparent the variability if there is a wide range of scenarios presenting highly variable risks. However, if the scenarios vary very greatly in outcome, such an analysis may provide insufficient support for decision-making in the absence of any description of the relative likelihood of each scenario. It should be noted that population risks can be dominated by, or at least strongly influenced by, the more extreme scenarios (e.g. conditions leading to relatively high risk-per-serving) despite their lower probability. It is important that the risk assessor identifies in the assessment whether this is likely to be the case for the risks being assessed.

In general, the influence of key factors should be discussed in considerable detail where the uncertainty in the factor (e.g. prevalence, treatment effectiveness) is sufficient to change the risk characterization measure. This is particularly important where, within the range of uncertainty, the risk characterization measure could potentially surpass a key decision-making threshold.

However, there are other types of uncertainty. One is model uncertainty. In this case there is uncertainty as to what are the real pathways by which the unwanted outcome can occur. In a qualitative risk assessment the different pathways will be described, ideally with diagrams, and the model uncertainty reported and alternatives discussed.

A further type of uncertainty is where data are available, but they lack specificity in their description. Suppose, for example, a risk assessment is being undertaken where the hazard is microbe species M, subspecies S. Suppose that, universally, data on this microbe is sparse, but there are some data available on microbe M, subspecies unspecified. In a quantitative risk assessment, a decision would have to be made as to whether the range of known subspecies of M was similar enough to S to utilize this unspecified data. Using it might lead to precision but inaccuracy (if the subspecies were in fact very different); whereas not using it might lead unnecessarily to a lack of data (if in fact it was subspecies S). The decision would be subjective, based on the risk assessor's or expert opinions. However, with a qualitative assessment, the data can be described as reported, and the lack of precision in subspecies identification will then be obvious. In addition, information can be given regarding the probable similarity or otherwise of behaviour, properties, etc., of known subspecies of M. Thus, all available data can be utilized and its relevance assessed by any reader, rather than the extremes of either discarding, or giving too much weight, to data lacking specificity in its description. This should also enhance transparency. The need for transparency in evaluating the relevance and reliability of the use of data of M, subspecies unspecified, applies equally to quantitative assessments.

3.3.4 Transparency in reaching conclusions

A qualitative risk assessment should show clearly how each of the risk estimates is reached. The precise way of doing this will vary depending in part upon the complexity of the risk assessment, and in part upon the risk assessor(s) preferences. Methods used include:

- a tabular format, with data presented in the left hand column, and the conclusions on risk in the right column; or
- a format with a summary or conclusions section at the end of each data section.

Examples of these formats that illustrate 'good practice' (i.e. documentation of evidence and logic) are presented in Tables 3.1 and 3.2. The examples are based on particular steps in an overall risk assessment for which the risk question is: What is the probability of human illness due to microbe 'M', in country 'C', due to the consumption of meat from livestock species 'S' infected with microbe M?

Table 3.1 Example of a possible tabular format for presenting data linked to risk estimates and conclusions**.**

Step being estimated: **'What is the probability of a randomly selected example of species S in country C being infected with microbe M?**	
Data available	**Risk estimate and conclusions**
The prevalence of microbe M in species S in Country C was reported as 35% (Smith & Jones, 1999*). The prevalence of microbe M in region R, a district within country C, was reported as 86% (Brown, 2001*). There are no particular geographical or demographic (with respect to S) differences in region R, compared with the rest of C (Atlas of World Geography, 1995*). The diagnostic test for microbe M, used in the livestock surveillance programme in country C is reported to have a sensitivity of 92% and a specificity of 99% (Potter & Porter, 1982*). **Fictional references for illustrative purposes only*	The studies suggest that the probability of a randomly selected example of species S in country Y being infected with microbe M is medium to high. However, the two studies indicate that considerable variability by region is likely. With only two studies available, there is also considerable uncertainty of the actual range of prevalence by region, as well as the probability of infection in a randomly selected example of S. In addition, the timing of these surveys may suggest an increasing prevalence of M in C. The reported parameters for the diagnostic test used do not alter these conclusions.

Table 3.2 Example of a possible sectional format for presenting data linked to risk estimates and conclusions.

SECTION X. What is the probability of human ill health, given infection with microbe M?
Data available
• No specific dose-response data has been found for microbe M. • Health authorities for country C provide the following data (National Health Reviews, 1999–2002*). • Incidence over the period was reported as 22 cases per million of the population per year (22 per million is 0.000022% of the population per year). • Clinical incidence recording and reporting systems in Country C are considered to be of exceptionally high quality (Bloggs, pers. comm.*). • Expert opinion amongst specialists indicates that once clinical symptoms appear, cases are likely to consult a medical practitioner (Journal of Microbial Medicine, 1992*). • Cases tend to be seen in the very young or the very old (Journal of Microbial Medicine, 1992*). • A surveillance study undertaken by practice-based serological testing indicated that 35% of the population of C had been exposed to microbe M and had sero-converted (Hunt, Hunt and Seek, 2001*). This was a countrywide, statistically representational study. **Fictional references for illustrative purposes only*
Conclusions
Data suggest a high level of exposure to microbe M in country C, but a very low incidence of clinical disease. Expert opinion indicates under-reporting of clinical disease due to lack of medical practitioner involvement is unlikely to account for this. Overall, therefore, the probability of human ill health, given infection with microbe M, is likely to be low. The level of uncertainty in the data specific to country C appears to be low, making this conclusion reasonably certain. However, data also indicate that there are specific groups at higher risk of clinical illness, specifically the very old and very young. From the data currently available it is not possible to indicate how much higher this risk is likely to be.

3.4 Examples of qualitative risk assessment

A number of existing, published, qualitative risk characterizations are presented below.

3.4.1 WHO faecal pollution and water quality

The 'Annapolis Protocol' (WHO, 1999) was developed in response to concerns regarding the adequacy and effectiveness of approaches to monitoring and management of faecally-polluted recreational waters. One of the most important changes recommended in the Annapolis Protocol was a move away from sole reliance on 'guideline' values of faecal indicator bacteria to the use of a qualitative ranking of faecal loading in recreational-water environments. The protocol was tested in several countries, and an expert consultation was convened by WHO (WHO, 2001) to update the draft 1998 WHO Guidelines for Safe Recreational-water Environments. A revised Chapter 4 in Volume 1 of the guidelines was produced from the expert consultation, which described a suitable approach to risk assessment and risk management (WHO, 2003). Tables were produced for water bodies affected by three different sources of human faecal contamination: sewage outfalls, riverine discharges and bather shedding. The tables were based on qualitative assessment of risk of exposure under 'normal' conditions of sewage operation, water levels, etc, and classified the potential human risk. Table 3.3 reproduces the classification for sewage outfalls.

Table 3.3 Relative risk potential to human health through exposure to sewage through outfalls (reproduced from WHO, 2003).

Treatment	Discharge type		
	Directly on beach	Short outfall[a]	Effective outfall[b]
None[c]	Very High	High	NA[d]
Preliminary	Very High	High	Low
Primary (including septic tank)	Very High	High	Low
Secondary	High	High	Low
Secondary plus disinfection[e]	Moderate	Moderate	Very Low
Tertiary	Moderate	Moderate	Very Low
Tertiary plus disinfection	Very Low	Very Low	Very Low
Lagoons	High	High	Low

Notes: (a) The relative risk is modified by population size. Relative risk is increased for discharges from large populations and decreased for discharges from small populations. (b) This assumes that the design capacity has not been exceeded and that climatic and oceanic extreme conditions are considered in the design objective (i.e. no sewage on the beach zone). (c) Includes combined sewer overflows. (d) NA = not applicable. (e) Additional investigations recommended to account for the likely lack of prediction with faecal index organisms

3.4.2 Australian Drinking Water Guidelines

As part of Australia's National Water Quality Management Strategy the Australian National Health and Medical Research Council produced the Australia Drinking Water Guidelines (NHMRC, 2004) as a framework for good management of drinking water supplies. The guidelines are not mandatory standards, but are designed to provide an authoritative reference document and framework for good management of drinking water supplies to assure safety at point of use by consumers in all parts of Australia. The guidelines consider that the greatest risks to consumers of drinking water are pathogenic microorganisms, and as such covers similar issues for water that microbiological food safety risk assessment covers for food, although it should be noted that the issue of microbiological growth and inactivation (through food processing) are likely to play a much larger role in microbiological food safety risk assessment. The extensive guidelines document includes a qualitative method for assessing human health risks and recommends that risks should be assessed at two levels:

- **Maximum risk** in the absence of preventive measures (equivalent to 'unrestricted risk' as described in Section 2.3.1); and
- **Residual risk** after consideration of existing preventive measures.

The level of risk of each hazard (pathogen, or hazardous event) is qualitatively assessed by combining a qualitative assessment of the likelihood of the hazard occurring, and the severity of the consequences if it were to occur, according to Tables 3.4a–c (Tables 3.1, 3.2 and 3.3 in the original document), which were developed from the Australian/New Zealand risk analysis standard 'AS/NZS 4360:1999: Risk management', which has since been superseded (AS/NZS 4360:2004). The guidelines document also includes what are essentially qualitative hazard identification and hazard characterizations for a wide range of water-borne hazards that can be used to assist in the application of the risk matrices. The stated aim of the methodology is "to distinguish between very high and low risks" (NHMRC, 2004).

3.4.3 EFSA BSE/TSE risk assessment of goat milk and milk-derived products

A research group in France found a suspected case of Bovine Spongiform Encephalopathy (BSE) infection in a slaughtered goat in 2002. As a result, the European Commission (EC) requested advice from the European Food Safety Authority (EFSA) on the safety of milk and meat in relation to Transmissible Spongiform Encephalopathy (TSE) in goats and sheep. EFSA (2004a) published the following preliminary statement:

> "From the limited data available today it is concluded that in the light of current scientific knowledge and irrespective of their geographical origin, milk and milk derivatives (e.g. lactoferrin, lactose) from small ruminants **are unlikely to present any risk** of TSE contamination provided that milk is sourced from clinically healthy animals. Exclusion of animals with mastitis is considered to reduce the potential risk. Further assurance of healthy milk could include milk tests for total somatic cell counts indicative of inflammation." [Emphasis added].

EFSA also commented (EFSA Press release 713):

> "A comprehensive and quantitative assessment of the risks involved in the consumption of goat meat, milk and dairy products will only be possible if more scientific research data on the occurrence of TSE in small ruminants can be obtained. Such a quantitative risk assessment, if feasible, will take considerably more time."

Table 3.4a Qualitative measures of likelihood.

Level	Descriptor	Example description
A	Almost certain	Is expected to occur in most circumstances
B	Likely	Will probably occur in most circumstances
C	Possible	Might occur or should occur at some time
D	Unlikely	Could occur at some time
E	Rare	May occur only in exceptional circumstances

Table 3.4b Qualitative measures of consequence or impact.

Level	Descriptor	Example description
1	Insignificant	Insignificant impact; little disruption to normal operation; low increase in normal operation costs
2	Minor	Minor impact for small population; some manageable operation disruption; some increase in operating costs
3	Moderate	Minor impact for large population; significant modification to normal operation but manageable; operation costs increased; increased monitoring
4	Major	Major impact for small population; systems significantly compromised and abnormal operation, if at all; high level of monitoring required
5	Catastrophic	Major impact for large population; complete failure of systems

Table 3.4c Qualitative risk analysis matrix: level of risk.

Likelihood	Consequences				
	1 Insignificant	2 Minor	3 Moderate	4 Major	5 Catastrophic
A (almost certain)	Moderate	High	Very high	Very high	Very high
B (likely)	Moderate	High	High	Very high	Very high
C (possible)	Low	Moderate	High	Very high	Very high
D (unlikely)	Low	Low	Moderate	High	Very high
E (rare)	Low	Low	Moderate	High	High

It is extremely difficult to assess the risk of BSE-contaminated product because there is no means to measure the number of prions present in a food product, and no human-dose-response relationship for prion levels. EFSA nonetheless needed to provide comment on the level of the above risk, and relied on an expert panel to review the available data.

3.4.4 Geographical BSE cattle risk assessment

In 2003, EFSA was requested by the EC to re-assess geographical BSE risk (GBR) and concluded the following (EFSA 2004b):

> "1. The Geographical BSE-Risk (GBR) is a qualitative indicator of the likelihood of the presence of one or more cattle being infected with BSE, pre-clinically as well as clinically, at a given point in time, in a country. Where its presence is confirmed, the GBR gives an indication of the level of infection.

2. The GBR assessments are based on information submitted by countries concerned in response to a European Commission recommendation in 1998 setting out the information requirements for such an assessment. The information concerns in particular imports of bovines and meat and bone meal (MBM) from the United Kingdom and other BSE-risk countries, rendering standards for animal by-products, use of so called Specified Risk Materials (SRMs), feeding of MBM to ruminants, etcetera.

3. Table 3.5 shows the current GBR levels of the seven countries assessed by EFSA so far, as well as their former classification where available. "

Table 3.5 Geographical BSE Risk (GBR) in 2003 in seven countries as assessed by EFSA (2004b). Earlier assessed levels are also shown.

GBR level	Presence of one or more cattle clinically or pre-clinically infected with the BSE agent in a geographical region or country	GBR of the country or region Current status (status before)
I	Highly unlikely	Australia (I)
II	Unlikely but not excluded	Norway (I), Sweden (II)
III	Likely but not confirmed or confirmed at a lower level	Canada (II), Mexico (N/A), South Africa (N/A), USA (II)
IV	Confirmed at a higher level	none

NOTES: N/A = not applicable, i.e. not assessed before"