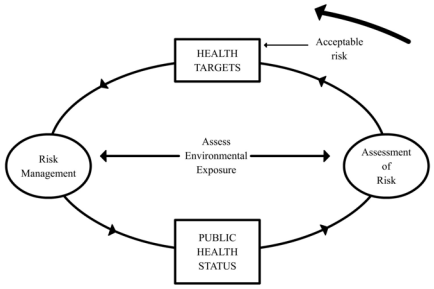

10

Acceptable risk

Paul R. Hunter and Lorna Fewtrell

The notion that there is some level of risk that everyone will find acceptable is a difficult idea to reconcile and yet, without such a baseline, how can it ever be possible to set guideline values and standards, given that life can never be risk-free? Since zero risk is completely unachievable, this chapter outlines some of the problems of achieving a measure of 'acceptable' risk by examining a number of standpoints from which the problem can be approached.

10.1 INTRODUCTION

A number of chapters within this book examine the question of what is risk and how we define it. Risk is generally taken to be the probability of injury, disease, or death under specific circumstances. However, this 'objective' measure of risk does not tell the whole story and, in determining acceptability of any particular risk, perceived risk is likely to play a large role.

 Water Quality: Guidelines, Standards and Health. Edited by Lorna Fewtrell and Jamie Bartram. Published by IWA Publishing, London, UK. ISBN: 1 900222 28 0

The following is a list of standpoints that could be used as a basis for determining when a risk is acceptable or, perhaps, tolerable. These will be explored under broad headings.

A risk is acceptable when:

- it falls below an arbitrary defined probability
- it falls below some level that is already tolerated
- it falls below an arbitrary defined attributable fraction of total disease burden in the community
- the cost of reducing the risk would exceed the costs saved
- the cost of reducing the risk would exceed the costs saved when the 'costs of suffering' are also factored in
- the opportunity costs would be better spent on other, more pressing, public health problems
- public health professionals say it is acceptable
- the general public say it is acceptable (or more likely, do not say it is not)
- politicians say it is acceptable.

10.2 A PREDEFINED PROBABILITY APPROACH

One definition of acceptable risk that has been widely accepted in environmental regulation, although is not relevant to microbiological parameters, is if lifetime exposure to a substance increases a person's chance of developing cancer by one chance in a million or less. This level, which has come to be taken as 'essentially zero', was apparently derived in the US in the 1960s during the development of guidelines for safety testing in animal studies. A figure, for the purposes of discussion, of 1 chance in 100 million of developing cancer was put forward as safe. This figure was adopted by the Food and Drug Administration in 1973, but amended to one in a million in 1977 (Kelly and Cardon 1994). This level of 10^{-6} has been seen as something of a gold standard ever since. The US Environmental Protection Agency (EPA) typically uses a target reference risk range of 10^{-4} to 10^{-6} for carcinogens in drinking water (Cotruvo 1988), which is in line with World Health organization (WHO) guidelines for drinking water quality which, where practical, base guideline values for genotoxic carcinogens on the upper bound estimate of an excess lifetime cancer risk of 10^{-5} (WHO 1993).

Similar approaches have been adopted elsewhere and for other risks. In the UK, for example, the Health and Safety Executive (HSE) adopted the following levels of risk, in terms of the probability of an individual dying in any one year:

- 1 in 1000 as the 'just about tolerable risk' for any substantial category of workers for any large part of a working life.
- 1 in 10,000 as the 'maximum tolerable risk' for members of the public from any single non-nuclear plant.
- 1 in 100,000 as the 'maximum tolerable risk' for members of the public from any new nuclear power station.
- 1 in 1,000,000 as the level of 'acceptable risk' at which no further improvements in safety need to be made.

The HSE set these guidelines after considering risks in other contexts, with a risk of 1 in 1,000,000 being roughly the same as the risk of being electrocuted at home and a hundredth that of dying in a road traffic accident (RCEP 1998). Interestingly, although the final figure of one in a million appears to be the same as that followed in the US, the figure in the UK is an annual rather than lifetime risk.

With regards to microbiological risks from drinking water, the US EPA, using *Giardia* as a reference organism, required that the microbial risk is less than 1 infection per 10,000 people per year (Macler and Regli 1993). The logic behind the choice of *Giardia* was that it was known to be more resistant to disinfection than most other microbial pathogens (although *Cryptosporidium* sp. has since challenged this 'status'). Therefore, protection against *Giardia* infection should provide protection against other organisms, with the intention of minimising all microbial illness.

It is interesting to compare the levels of protection between microbiological and carcinogen risk. If it is assumed that there is a 50–67% frequency of clinical illness following infection with *Giardia* (Gerba *et al*. 1996) then, using the lower bound of 50%, this translates to an annual risk of illness of 1 in 20,000. Gerba and colleagues do not cite a case-fatality rate for *Giardia*, but 0.1% in the general population seems to be a reasonable level based on other pathogens causing gastrointestinal symptoms (Gerba *et al*. 1996; Macler and Regli 1993). This results in an annual risk of death of 1 in 20,000,000. Converting this to a 70-year lifetime risk to be comparable with rates cited for chemical contaminants results in a risk of 1 in 2×10^{-5}, a figure that is similar to that considered acceptable by the WHO for carcinogenic risks.

The outcome of infection, however, will vary according to a number of factors and many groups within society, such as the young, elderly, malnourished and so on are more susceptible to developing illness following infection than the general population. This is a theme that we will return to in a later section but, clearly, the level of protection will not be the same for all people.

Examination of what is currently being achieved versus what is claimed to be an acceptable risk makes for interesting and sobering reading. Haas and Eisenberg, in Chapter 8 of this book, outline a risk assessment of drinking water supplies in New York City and the risk of infection with *Cryptosporidium*. They estimate that the risk is some two orders of magnitude greater than the acceptable level. Such results back up the work of Payment and Hunter (see Chapter 4) who claimed that a very high proportion of gastrointestinal illness could be attributed to tap water, even if it met current water quality guidelines.

10.3 A 'CURRENTLY TOLERATED' APPROACH

The basic argument here is that any risk that is currently tolerated is considered to be acceptable. This approach was used by the US EPA in setting the allowable bacterial indicator densities for bathing waters (US EPA 1986). The work of Cabelli and Dufour (Cabelli *et al*. 1979, 1982, 1983; Dufour 1984) allowed health effects, in terms of swimming-associated gastroenteritis rates, to be estimated. It was established that previous standards had resulted in a gastrointestinal illness rate of 8/1000 bathers at freshwater sites and 19/1000 bathers at marine sites. These levels were considered to be tolerated (as people still used the bathing areas) and were therefore assumed to be acceptable. The new standards were based around this acceptable level.

A similar approach has been suggested by Wyer *et al*. (1999) in their experimental health-related classification for marine waters, using other risk factors as measures of acceptability. This work was based on extensive epidemiological studies conducted around the UK coastline that resulted in a dose–response relationship between the bacterial indicator faecal streptococci and gastroenteritis experienced by bathers. The dose–response relationship was found to be independent of, and not confounded by, other predictors of gastroenteritis, including the transmission of gastroenteritis from household members (termed person-to-person transmission) and a composite factor termed non-water-related risk. Each of these factors had an associated probability against which the dose–response to sea bathing could be compared. The combination of the exposure distribution (based on five years of water quality data), dose–response relationship and independent risk factors provide a standard system which is health-related. Such detailed data, however, do not exist for most countries; predictors of gastroenteritis are likely to vary markedly between different locations, and their 'acceptability' may also be culturally specific.

If an informed choice element is factored into such an approach (which is the case in the examples outlined above) such an approach may provide a promising way forward. The use of accepted risk as synonymous with acceptable risk should, however, be treated with great caution. A number of authors have noted that there is a difference between the two (Jones and Akehurst 1980; O'Riordan 1977). Using smoking as an example, until recently this has been widely accepted but is regarded today by many as unacceptably risky (Royal Society 1983). Such usage also ignores aversion behaviour on the part of the public and the fact that any risk (such as bathing in coastal waters) may only be accepted by a sub-section of the population.

10.4 A DISEASE BURDEN APPROACH

In everyday life individual risks are rarely considered in isolation. Similarly, it could be argued that a sensible approach would be to consider health risks in terms of the total disease burden of a community and to define acceptability in terms of it falling below an arbitrary defined level. For example, it may be thought that drinking water supplies should not be responsible for more than 5% and food no more than, say, 15% of cases of gastroenteritis. Such an approach is clearly useful in terms of setting priorities. In reality, attributing cases of illness to a specific cause when there is more than one route of transmission is fraught with difficulties (see Chapters 4 and 5). This, coupled with known under-reporting of gastroenteritis in countries with surveillance systems (Chapter 6) and the difficulties in extrapolating illness data to countries with limited surveillance systems experiencing very different sanitation conditions, may reduce the value of this approach.

A further problem with the disease burden approach is that the current burden of disease attributable to a single factor, such as drinking water, may not be a good indicator of the potential reductions available from improving water quality. For diseases where infection is almost universal, such as viral gastroenteritis, reducing the disease burden by one route may have little impact on the overall burden of disease. Those people who have not acquired their infection (and hence degree of immunity) from drinking water may well acquire their infection from another source (see Chapter 5).

10.5 AN ECONOMIC APPROACH

In the strict economic sense a risk is acceptable if the economic savings arising out of action to reduce a risk outweigh the cost of such action. This approach is, in effect, a simple cost-benefit analysis (Sloman 1994). For example, consider

the situation that may arise over improving the quality of sea bathing waters. Following investigations it may be estimated that the cost of installing new sewage treatment facilities are some £10,000,000. The risk to bathers may be acceptable if the cost of illness from swimming in the sea over the lifetime of the new treatment works is only some £1,000,000 after taking account of inflation. The risk would be unacceptable if the cost of illness would be £20,000,000.

There are, however, many difficulties with this apparently simple approach. These include the fact that the exact amount of illness may not be known with any certainty, especially if much illness is related to specific outbreaks. Even if the amount of illness is known, the costs of that illness may be difficult to identify. Even if the costs are identifiable, the costs of illness are borne by different groups in society to those that bear the cost of the new sewage plant. Furthermore, in a humane society, we would argue that identifiable financial costs are not the only and probably not the main reason for change. These difficulties with the simple cost-benefit model will be discussed below and possible solutions identified.

Perhaps the most obvious problem is the issue of costing risk when this involves an element of probability. We may know that the probability (risk) of a major untoward event, such as an outbreak, in any given year is 0.02, say, but how does this help in deciding what to do when financial planning cycles last say five years? The most likely outcome ($p = 0.904$) is that no outbreak will occur in the five years and so any money spent on reducing this risk will be wasted nine times out of ten. This problem can be dealt with by simply multiplying the cost of the event saved by the probability of its occurrence (Sloman 1994). For common events, such as the risk of gastrointestinal disease in people taking part in sea bathing the annual number of cases of illness are likely to be more consistent from one year to the next and it may then be possible to do a more straightforward cost-benefit analysis. Unfortunately, other problems are less easily resolved with this simplistic economic approach.

The next problem for many societies is that the costs of risk reduction are incurred by different groups to those that benefit from the reduction in risk. Let us return to the bathing beach study. For a privatised sewage utility, the costs of the additional sewage treatment works would be incurred by the shareholders if the costs could not be passed on in higher bills and by the customers if these costs could be passed on. Identifying the groups that would benefit is more difficult. Those people who go swimming in the sea would benefit from a lower risk of illness. If such illness led to absence from work, employers would benefit. If illness led to use of health-care systems then the health service may benefit. To add further complexity to the issue, it may be the case that improvements in bathing beach quality would lead to

increased tourism with further financial benefit to the local society and industry. It may, however, be possible to calculate the costs and benefits of the new treatment works to society as a whole. However, it is likely that different stakeholders will not be able to agree on the methods used to calculate these different costs and benefits. Clearly the resolution of these issues is political rather than economic in nature.

So far, in our discussion of costs we have assumed that all costs can be derived in monetary terms. Consequently we have been able to include in the costs of illness such things as loss of income due to absence from work and cost to health services from patients seeking treatment. But the major impact of illness associated with polluted beaches may not be measurable in such terms. For example, the upset from a ruined holiday or the pain and distress associated with illness cannot be directly measured in monetary terms. In any caring society, these factors must also be taken into consideration when assessing whether any risk is acceptable. For dealing with these types of issues, economists have developed a variety of cost-utility measures (McCrone 1998; Sloman 1994).

In general terms, utility can be defined as the satisfaction or pleasure that an individual derives from the consumption of a good or service (Pass and Lowes 1993). Cost-utility analysis attempts to place a value on the 'satisfaction' gained from an intervention and relate this to the cost of the intervention. In health economics one technique has tended to become a standard, that of Quality Adjusted Life Years, widely known as QALYs (McCrone 1998; Weinstein and Stason 1977). QALYs are designed to combine two independent concepts of utility, length of life and its quality. This assumes that such concepts can themselves be measured. The QALY can then be used to derive a monetary value using a marginal cost per QALY gained (National Association of Health Authorities and Trusts 1992). This financial estimate can then be inserted into the cost-benefit models described above. The problem is that QALYs have been subject to a significant amount of criticism which has led to various alternative measures being suggested (Nord 1992; McCrone 1998). An additional problem is that the allocation of a marginal cost per QALY is also highly subjective and would vary from one community to another.

A further economic insight into the issue of defining acceptable risk comes from the concept of opportunity cost. Opportunity cost can be defined as the measure of the economic cost of using scare resources to produce one particular good or service in terms of the alternatives thereby foregone (Pass and Lowes 1993). In our seawater and sewage example, if the water utility had available only £10,000,000 to spend on capital works, would it be better to spend it on improving the treatment of sewage or on another project to improve drinking

water treatment to reduce risk of cryptosporidiosis? Fairley and colleagues (1999) recently used a simple form of opportunity cost analysis to argue against the introduction of regulations requiring regular monitoring of drinking water for the presence of *Cryptosporidium* oocysts. For wider issues, how can a developing nation determine how best to spend its scarce resources, between funding improved water treatment to meet stricter microbiological standards for drinking water and spending this money on improving obstetric care?

In conclusion, the science of economics does not provide society with absolute tools for determining what risks are acceptable. Nevertheless, no assessment of acceptable risk can afford to ignore economic imperatives. Economics can and should inform this debate in a very powerful way. It seems to us that cost-benefit analysis and cost-utility analysis should be part of any review of microbial standards and acceptable risk. Perhaps the most powerful economic tool in this context, however, is the issue of opportunity costs. No society can afford to tackle all risks simultaneously and thus priorities have to be set. An economic definition of acceptable risk now becomes: any risk where the costs of reducing that risk exceed the financial and utility benefits that would arise from that reduction and where such resources required in this risk reduction would not be better spent on other public health issues.

10.6 THE PUBLIC ACCEPTANCE OF RISK

This approach to determining acceptable risk is based on what is acceptable to the general public. In other words, a risk is acceptable when it is acceptable to the general public. In democratic societies, so the theory goes, the views of the general public are pre-eminent when determining what is and what is not acceptable risk. While perhaps superficially appealing as a model for determining levels of acceptable risk, this approach immediately raises a number of theoretical and practical problems.

For a public-based approach to acceptable risk to work, all sections of the community must have full access to all information required on levels of risk and have the skills to interpret that information. There must also be an effective means of reaching consensus within the community and canvassing that consensus opinion. Unfortunately, each of these preconditions are unlikely to be met in most circumstances. Some of the difficulties concerned will be addressed in this section.

Many acceptable risk decisions have to be made on the basis of incomplete information even by professionals specialising in the issues of concern (Klapp 1992). It is not surprising, therefore, that even if a society existed with a fully open government, information would not be complete. Even for information that is readily available, individuals' knowledge will often be flawed. For

example, it has been known for some time that individuals' judgements about risk levels are systematically distorted. In general, people systematically overestimate the number of deaths due to uncommon causes and underestimate the numbers of deaths due to common causes (Slovic *et al*. 1979).

People's judgements about risk are frequently subject to bias (Bennett 1999); an issue from which experts are not immune. The most common sources of bias are availability bias and confirmation bias. Availability bias increases the perception of risk of events for which an example can be easily recalled. Confirmation bias occurs when individuals have reached a view and then choose to ignore additional information that conflicts with this view. In addition, public acceptability may well depend upon what Corvello (1998) has termed 'framing effect'. An individual lifetime risk of one in a million in the US is mathematically equivalent to approximately 0.008 deaths per day, 3 deaths per year or 200 deaths over a 70-year lifetime. Corvello (1998) notes that many people will view the first two numbers as small and insignificant, whereas the latter is likely to be perceived as sufficiently large to warrant societal or regulatory attention.

A further problem is that individuals perceive the nature of risk in different ways. These differences are often based on deeper societal processes. One model for describing these differences is cultural theory (Thompson *et al*. 1990). Cultural theory divides society along two axes. The first axis is the influence of the group on patterns of social relationships; the degree to which people depend on reference to socially accepted peers for influence. The second axis concerns the degree to which people feel constrained by externally imposed rules and expectations. Using these two axes, four types have been described:

- fatalists
- hierarchists
- individualists
- egalitarians.

Each of these four types differs substantially in their approach to risk (Adams 1997; Langford *et al*. 1999). For example, hierarchists believe that managing risk and defining acceptable risk is the responsibility of those in authority supported by expert advisors. Individualists scorn authority and argue that decisions about acceptable risk should be left to the individual. Egalitarians believe that definitions of acceptable risk should be based on consensus that requires trust and openness. Fatalists see the outcome of risk as a function of chance and believe they have little control over their lives.

Nevertheless there does seem to be some consistent themes in the general public's approach to identifying acceptable risk. These themes are often referred to as 'fright factors' (Bennett 1999). Risks are deemed to be less acceptable if perceived to be:

- involuntary
- inequitably distributed in society
- inescapable, even if taking personal precautions
- unfamiliar or novel
- man-made rather than natural
- the cause of hidden and irreversible damage which may result in disease many years later
- of particular threat to future generations, for example by affecting small children or pregnant women
- the cause of a particularly dreadful illness or death
- poorly understood by science
- the cause of damage to identifiable, rather than anonymous, individuals
- subject to contradictory statements from responsible sources.

While these fright factors result in different priorities amongst the general public than may be generated by professionals relying on statistical estimates of risk, they should not be dismissed as unreasonable (see also Chapter 14). The authors of this chapter would certainly agree with concerns about risk affecting future generations and causing particularly dreadful illness or death. Issues concerning the inequality of risk will be discussed below. Nevertheless, the influence of fright factors makes it very difficult to define acceptable risk based on the public's perception. Using approaches to defining acceptable risk on economic or epidemiological criteria may not be acceptable to society if fright factors are not taken into consideration.

Even if the difficulties so far described in this section can be overcome, there remains the problem of adequately canvassing the consensus of the general population. Even in democratic societies it is frequently difficult to directly gauge public opinion. In such a situation, surrogates for public opinion are usually sought. Perhaps the most powerful surrogate for public opinion is the media. However, the media is far from a perfect indicator of public opinion. Indeed, the factors that influence media interest are quite distinct from the fright factors listed above. Factors that increase media interest in an issue (media triggers) include (Bennett 1999):

- blame
- alleged secrets or cover-ups
- the presence of 'human interest' through heroes or villains
- links with other high-profile issues or people
- conflict
- whether the story is an indication of further things to come (signal value)
- many people exposed
- if there is a strong visual impact
- sex and/or crime.

The other main source of presumed public viewpoints in determining acceptable risk is the various activist or pressure groups (Grant 2000; Pattakos 1989). However, it is a mistake to believe that pressure groups necessarily reflect public opinion. Each group has its own objectives and will use science and risk assessments that support their viewpoints. Pressure groups are just as likely to be subject to confirmation bias as other members and groups in society. A key source of influence of pressure groups, especially those that use direct action, is the media. Using scientifically balanced risk assessments does not attract the media. Such pressure groups may overestimate risk in order to attract media attention or force change in public opinion in favour of their primary objectives.

In conclusion, it appears that the concept of public opinion as the primary determinant of acceptable risk has serious difficulties. Nevertheless, this does not mean that public opinion can or should be ignored. It has to play a central part in the decision-making process. How this is done can only be a political process; this is the subject of the next section.

10.7 POLITICAL RESOLUTION OF ACCEPTABLE RISK ISSUES

The reader sufficiently interested to have read this far may be forgiven for wondering how society can ever define the 'acceptable' in issues of acceptable risk. It is clear from the discussion to this point that there are many different ways to define acceptable risk and that each way gives different weight to the views of different stakeholders in the debate. No definition of 'acceptable' will be acceptable to all stakeholders. Resolving such issues, therefore, becomes a political (in the widest sense) rather than a strictly health process. This process becomes even more difficult when one considers that most of the evidence

brought forward in acceptable risk decisions has wide confidence intervals. In other words, there is a considerable degree of scientific uncertainty about many risk decisions (Klapp 1992).

Whilst the, apparently, more objective approaches to acceptable risk would seem to offer a value-free option, there is still considerable uncertainty around the outcomes of these models. Klapp (1992) describes four types of uncertainty:

- extrapolation
- data
- model
- parameter.

Extrapolation uncertainty arises when experts disagree over whether findings in experimental studies can be extrapolated to real world situations. An example of this is the extrapolation of infectious dose studies to low levels of pathogens. Data uncertainty occurs when experts disagree over which data is relevant to include in risk models. This is especially important when there is conflicting data. Model uncertainty is when experts disagree over which model to use in their risk assessment models, and parameter uncertainty exists when experts disagree on how to estimate parameters for which little data is available. In general, experts are just as likely to fall prey to confirmation bias as are the lay public (Bennett 1999). Indeed, professional pressures for scientists and experts to support their original viewpoints can be immense. If an academic's reputation and future grant and consultancy income is based on his/her earlier work, then there are very strong pressures to disregard new work which devalues that early work. Expert scientific opinion is not, therefore, free from value.

In the absence of scientific certainty, Klapp (1992) argues that acceptable risk decisions arise from a process of bargaining. She draws on the rational choice theory of relations between legislators and the public but argues that legislators do not enact the wishes of the public. Instead she argues that legislators, and courts, make decisions that change the behaviour of bureaucrats. In this she draws on the economic game theory of sequential bargaining with incomplete information (Sutton 1986). This is in turn based on the Sobel-Takahashi multi-stage model of bargaining (Sobel and Takahashi 1983). Basically this revolves around a game involving two players, a buyer and seller, trying to agree on a price for an indivisible good. If both players had complete information on how much the other values the good, then a bargain could be struck immediately. The buyer knows how much both he and the seller value the good, but the seller does not know how much the buyer values the good. To discover this information, the seller has to continue to offer prices until the buyer accepts. The longer the process takes, the more information the seller has

about the buyer's valuation of the good. Assume that in acceptable risk decisions, the buyer is the citizen and the seller the bureaucrat. The bureaucrat offers an initial level of risk that may or may not be acceptable to the citizen (or other stakeholder). The bureaucrat does not know at this stage what level of risk the citizen will accept. Clearly it is in the interest of the citizen to continue to reject these offers up to the point that the bureaucrat seeks an alternative route to resolving the problem.

Klapp (1992) then goes on to discuss the principal-agent model of Moe (1984). This model has the advantage in that it specifically focuses on the hierarchical relationship between citizen and bureaucrat, assuming conflict of interest and asymmetries in information. Here the citizen enters into a contract with the politician/bureaucrat in the expectation that the latter will act in the best interests of the citizen. The contract is necessary because the citizen may not have the technical information necessary to make certain regulatory decisions and the task of regulation may be too large and complex for him to undertake. However, for various reasons this relationship is problematic in that the citizen will find it difficult to control the bureaucrat's compliance with the contract. Scientific uncertainty is used by the bureaucrat to enhance his power over the public, who may not have access to such information. The bureaucrat may have his/her own interests which conflict with the citizen's ideas, and it is likely that there will be a gap in the desired and achieved performance of the bureaucrat, at least as far as the citizen is concerned. This model is also problematic in that the bureaucrat starts out as the agent of the citizen, but he subsequently gains control over the citizen.

In her own model, the bureaucratic bargain, Klapp (1992) also proposes that the bureaucrat is in a dominant position relative to the citizen, but still has an incentive to make concession in order to obtain co-operation from the citizen. Although, bureaucrats may have the power to impose their decision, they also want to gain benefit. In particular, they want the voluntary compliance of the citizen in order to avoid potential legal challenges. The bureaucrats also want to 'look good' in administering their regulatory decisions. Thus the bureaucrat has the incentive to negotiate with the public in order to obtain agreements that are mutually satisfactory. Indeed, the bureaucrat expects that such an agreement will be reached. In this model scientific uncertainty is a tool used by the citizen, or experts employed by pressure groups, to make the bureaucrat look incompetent and thus influence the debate and gain concessions.

The three models of bureaucratic bargaining that have been discussed illustrate very important points in the acceptable risk decision-making process. In particular, the hierarchical relationship between some of the key decision-makers and stakeholders, the bargaining nature of the decision-

making process, and the use of uncertainty as a political tool by one side or another. The fact that the nature of this bargaining process is increasingly being superseded by recourse to the courts (Klapp 1992) does not substantially alter these conclusions.

Although not explicitly addressed by Klapp, much of the discussion about bargaining between bureaucrats and the public could also apply to bargaining with other stakeholder groups such as industry, health-care providers or other health-care groups.

If we accept this view of risk decisions arising from a bargaining process rather than formal expert analysis, two problems are raised. The first is the problem of satisficing and the second is the problem of stakeholder inequality.

10.7.1 Satisficing

A major weakness of decisions reached through the bargaining process is that frequently the optimal solution is not produced. In other words, instead of the best solution for society, one gets the solution that is acceptable to most/all stakeholders. This is known as satisficing. A problem with satisficing is that not all relevant stakeholders may be considered in defining the acceptable criteria. This will now be discussed in more detail.

10.7.2 Stakeholder inequality

In any national or international policy decision on risk, the list of stakeholders is large. This list will include academic and other experts, government agents, various pressure groups and representatives of business interests. Among the list of stakeholders will also be the public. Each stakeholder will have differing levels of power and interest in the bargaining process. One of the major concerns for the public health professional is that health differs between different sections of society. There has been considerable interest, particularly in the UK, in the issue of health inequality in society (Bartley *et al*. 1998; Townsend *et al*. 1992; Wilkinson 1996). Surprisingly, given the very obvious inequality in infection-related illnesses in both national and global societies, there has been little academic interest in the issue of inequality in infectious disease. The two areas that have been addressed in detail are probably HIV and tuberculosis (Farmer 1999), two diseases that are almost certainly not waterborne. Nevertheless, those working in the diagnosis, treatment and prevention of infectious disease are aware that the distribution and effects of infectious disease is clearly unevenly distributed within society. Different sections of society are more or less likely to suffer from various infectious diseases and, when they do acquire such diseases, they vary in their outcome.

The causes of these health inequalities are various, and include genetic, geographical, behavioural and socio-economic factors (Table 10.1).

Table 10.1. Examples of factors that lead to inequality of health risk in relation to waterborne disease

Factor	Affects
Age	The very young and very old are more likely to acquire infections due to naive or waning immunity and, once infected, are more likely to develop more severe outcomes.
Pre-existing disease	A person with AIDS or severe combined immunodeficiency syndrome is likely to suffer far more severe symptoms with cryptosporidiosis and other infectious illnesses.
Genetic	People with certain genotypes are more likely to experience complications such as joint problems following gastrointestinal infections.
Gender/pregnancy	Certain infections are more severe in pregnancy, either increasing the risk of fatality for the woman (hepatitis E), or damage to the foetus (toxoplasmosis).
Behaviour	The amount of unboiled tap water an individual drinks will affect their risk of a waterborne infection. Foreign travel will expose an individual to risk of waterborne diseases that he will not have encountered at home. Other behaviours such as swimming will increase an individual's risk of acquiring infections by routes other than drinking water.
Socio-economic	The poorest members of society may suffer more severe disease due to malnourishment. The poorest members of society may suffer more serious economic consequences of illness because they are in jobs that do not pay sick leave or are not covered by health insurance. The poorest members of society may not have ready access to health care. Many waterborne diseases are more likely to spread to family members in overcrowded conditions.
Geography	Various waterborne diseases have marked geographical distributions; hepatitis E is largely restricted to tropical countries and tularaemia is more common in northern latitudes. The quality of water treatment and distribution systems differ markedly from one country to another and between locations in the same country.

One of the important conclusions that arises naturally out of any consideration of the factors that lead to inequality of health risk in relation to

waterborne disease is that many of these same factors – age, gender, disability and poverty – are associated with the causes of social exclusion (Byrne 1999; Jordan 1996). The main danger of any bargaining process for risk is that of ignoring the concerns of the socially excluded groups within society. Powerful groups in the bargaining process will be industry, the wealthy and the educated. These groups will have greater access to information, and the resources and confidence to prepare their arguments. Those groups who are most likely to suffer the adverse risks are less likely to influence the debate. This is of particular concern when bargaining is resolved through satisficing. Who will know whether the solution proposed is acceptable to the socially excluded?

10.8 CONCLUSIONS

From this chapter we can conclude that acceptable risk decisions are rarely easy. In general terms one can broadly classify those approaches that emphasise formal analysis and expert opinion such as the probabilistic, economic or disease burden approaches and those that emphasise the political bargaining processes. This division of approaches could be taken to imply a clash between objectivity and subjectivity or between value-laden and value-free approaches.

The implication is that the approaches based on expert knowledge and methods are scientifically exact. Experts will be able to develop appropriate standards based on existing epidemiological and economic knowledge. Unfortunately, as we have already discussed there remains significant uncertainty around many of the processes and models that experts rely on to make their judgements. Furthermore, most experts typically do not directly express uncertainty about facts (Morgan *et al*. 1978). Indeed, professionals' opinions are frequently value-laden. Professionals derive their own values from a variety of sources (Fischhoff *et al*. 1981). As members of society, these individuals will clearly derive many of their own values from the wider society. However, professionals will also derive values from their profession. Some experts views will also be governed by pecuniary interests and take on the values of their employing organisation. These values will have a strong role in influencing the advice that experts give and the processes they go through to arrive at this advice. Consequently, we have to accept that experts form just one of several different stakeholder groups that does not necessarily have higher status over other stakeholders.

On the other hand, we have also considered the problems involved in taking a purely bargaining approach. Bargaining approaches often produce less than optimal solutions to problems especially when different stakeholders have different power, knowledge and resources. Even in societies that wish to include the public's view, it may be impossible to

accurately determine the public viewpoint. The public's view on risk is often contradictory and at times may be considered irrational. There are dangers in relying on pressure groups or the media as proxies for the public view. More important for any bargaining approach was the problem of health inequality and social exclusion. Those groups most at risk are likely to have least influence in any debate in many societies.

Given all these problems, the reader may then be forgiven for despairing of ever finding an appropriate acceptable risk approach to setting standards. What can be done? We suggest that this is where public health professionals and public health organisations such as the World Health Organization have an important role.

The role of public health medicine in many societies has changed in recent years. Nevertheless, the broad responsibility of public health practitioners can be summarised as the prevention of disease and promotion of health (Connelly and Worth 1997). Given the major issues of health inequality discussed above, we would suggest that a major role of these public health professionals and organisations is one of advocacy for the disadvantaged in society. Perhaps the most important function of public health is to represent the interests of the socially excluded in policy decisions where these decisions are likely to directly or indirectly impact on health. Risks are unacceptable to public health professionals if the health gains *across society as a whole* achieved by a reduction in risk outweigh the adverse health impacts and resources required from *society as a whole* to reduce that risk. In order to make this judgement, public health practitioners will have to rely on all the models and approaches we have discussed in this chapter.

Given this approach, what are the processes in setting standards for acceptable risk? We would suggest the following systematic approach:

(1) Bring together the group of experts. Ideally this group of experts should represent a broad range of skills and professional backgrounds, and include individuals with skills and expertise in the primary area of interest of the group. In addition, there should also be individuals with broad experience of public health.
(2) Agree the objectives of the group and any constraints to which the group needs to work.
(3) Determine the strength of evidence in support of an association between the environmental factor or indicator under consideration and illness. Make explicit any uncertainties in the data and any assumptions made.

(4) Quantify the impact on the community's health of the postulated illnesses, again being explicit about assumptions and areas of uncertainty. Consider the issue of particularly susceptible groups.
(5) Model the impact of any proposed change in standards on the community, taking into consideration the wider health, the social and the economic impacts.
(6) Consider whether the resources required to implement changes in any standard are worth the improvement in health (cost-utility analysis) and, even if they are, whether the resources required would be more effectively directed at other health goals (opportunity-cost analysis). Again make explicit any assumptions and uncertainties and identify the impact on susceptible groups.
(7) Expose the analytical phase of the standard-setting process to wide scrutiny by stakeholders of every type including pressure groups, expert groups, and industry. In particular seek out views from the wider public health community.
(8) Modify proposals in the light of this consultation exercise.

It is clear that the proposed approach is based firmly on a multi-disciplinary group process. We consider this approach to be the only viable option for such complex issues. However, groups are not infallible in decision-making. One particular type of pathology is known as 'group-think' (Janis 1972). Janis identified six major defects in decision-making associated with this problem. These are paraphrased below for acceptable risk decisions:

- Limiting group discussions to a limited number of options.
- Failing to re-examine the options initially preferred by the majority for non-obvious drawbacks.
- Neglecting options initially evaluated as unsatisfactory for non-obvious benefits.
- Members make little or no attempt to obtain information from experts who can supply sound estimates of benefits and disadvantages to be expected from alternate options.
- Selective bias is shown in the way the group reacts to factual information and opinion from experts and others, spending much time discussing evidence that supports their preferred options but ignoring that which does not.
- The group spends little time discussing how the implementation of the chosen option may be hindered by others outside the group.

Given these potential defects in group decision-making, we would suggest that any proposals for acceptable risk decisions be refereed by independent

experts or groups to consider whether the processes that were applied to any decisions were satisfactory.

Finally, we hope we have shown that, despite their difficulty, acceptable-risk decisions can be reached, provided individuals and groups are prepared to take a broad view of the issues, consider all groups in society and accept and confront the areas of uncertainty in their information and their own biases.

10.9 IMPLICATIONS FOR INTERNATIONAL GUIDELINES AND NATIONAL REGULATIONS

Although only making up a small input to the harmonised framework, the issue of acceptable risk is an important and extremely complex area. Acceptable risk is very location-specific and for this reason it does not fit within international guidelines, but should play an important role in adapting guidelines to suit national circumstances, where local stakeholder involvement is vital.

10.10 REFERENCES

Adams, J. (1997) Cars, cholera, cows, and contaminated land: virtual risk and the management of uncertainty. In *What Risk? Science, Politics and Public Health* (ed. R. Bate), pp. 285–304, Butterworth Heinemann, Oxford.

Bartley, M., Blane, D. and Smith, G.D. (1998) *The Sociology of Health Inequalities*, Blackwell, Oxford.

Bennett, P. (1999) Understanding responses to risk: some basic findings. In *Risk Communication and Public Health* (eds P. Bennett and K. Calman), pp. 3–19, Oxford University Press, Oxford.

Byrne, D. (1999) *Social Exclusion*, Open University Press, Buckingham.

Cabelli, V.J., Dufour, A.P., Levin, M.A., McCabe, L.J. and Haberman, P.W. (1979) Relationship of microbial indicators to health effects at marine bathing beaches. *American Journal of Public Health* **69**, 690–696.

Cabelli, V.J., Dufour, A.P., McCabe, L.J. and Levin, M.A. (1982) Swimming-associated gastroenteritis and water quality. *American Journal of Epidemiology* **115**, 606–616.

Cabelli, V.J., Dufour, A.P., McCabe, L.J. and Levin, M.A. (1983) Marine recreational water quality criterion consistent with indicator concepts and risk analysis. *Journal of the Water Pollution Control Federation* **55**(10), 1306–1314.

Connelly, J. and Worth, C. (1997) *Making Sense of Public Health Medicine*, Radcliffe Medical Press, Abingdon, Oxon.

Corvello, V.T. (1998) Risk communication. In *Handbook of Environmental Risk Assessment and Management* (ed. P. Callow), pp. 520–541, Blackwell Science, Oxford.

Cotruvo, J.A. (1988) Drinking water standards and risk assessment. *Regulatory Toxicology and Pharmacology* **8**, 288–299.

Dufour, A.P. (1984) Bacterial indicators of recreational water quality. *Canadian Journal of Public Health* **75**, 49–56.

Fairley. C.K., Sinclair, M.I. and Rizak, S. (1999) Monitoring not the answer to *Cryptosporidium* in water. *Lancet* **354**, 967–969.

Farmer, P. (1999) *Infections and Inequalities*, University of California Press, Berkely, CA.

Fischhoff, B., Lichtenstein, S., Slovic, P., Derby, S.L. and Keeney, R.L. (1981) *Acceptable Risk*, Cambridge University Press, Cambridge.

Gerba, C.P., Rose, J.B. and Haas, C.N. (1996) Sensitive populations: who is at greatest risk? *International Journal of Food Microbiology* **30**, 113–123.

Grant, W. (2000) *Pressure Groups and British Politics*, Macmillan, Basingstoke, Hampshire.

Janis, I.L. (1972) *Victims of Groupthink,* Houghton Mifflin, Boston, MA.

Jones, D.R. and Akehurst, R.L. (1980) Risk assessment: an outline. *Bull. Inst. Maths Appl.* **16**, 252–258.

Jordan, B. (1996) *A Theory of Poverty and Social Exclusion*, Polity Press, Cambridge.

Kelly, K.A. and Cardon, N.C. (1994) The myth of 10-6 as a definition of acceptable risk. *EPA Watch* **3**, 17.

Klapp, M.G. (1992) *Bargaining with Uncertainty*, Auburn House, New York.

Langford, I.H., Marris, C. and O'Riordan, T. (1999) Public reactions to risk: social structures, images of science, and the role of trust. In *Risk Communication and Public Health* (eds P. Bennett and K. Calman), pp. 33–50, Oxford University Press, Oxford.

Macler, B.A. and Regli, S. (1993) Use of microbial risk assessment in setting US drinking water standards. *International Journal of Food Microbiology* **18**, 245–256.

McCrone, P.R. (1998) *Understanding Health Economics*, Kogan Page, London.

Moe, T. (1984) The new economics of organizations. *American Journal of Political Science* **28**, 737–777.

Morgan, M. G., Rish, W. R., Morris, S. C. and Meier, A. K. (1978) Sulfur control in coal fired power plants: A probabilistic approach to policy analysis. *Air Pollution Control Association Journal* **28**, 993–997.

National Association of Health Authorities and Trusts (1992) Priority Setting in Purchasing, pp. 14–17, National Association of Health Authorities and Trusts.

Nord, E. (1992) An alternative to QALYs: the saved young life equivalent (SAVE). *British Medical Journal* **305**, 875–877.

O'Riordan, T. (1977) Environmental ideologies. *Environment and Planning* **9**, 3–14.

Pass, C. and Lowes, B. (1993) *Collins Dictionary of Economics*, 2nd edn, Harper Collins, Glasgow.

Pattakos, A.N. (1989) Growth in activist groups: how can business cope? *Long Range Planning* **22**, 98–104.

RCEP (1998) *Setting Environmental Standards. Royal Commission on Environmental Pollution*. 21st report, TSO, London

Royal Society (1983) Risk Assessment. A study group report.

Sloman, J. (1994) *Economics*, 2nd edn, Harvester Wheatsheaf, Hemel Hempstead, UK.

Slovic, P., Fischhoff, B. and Lichtenstein, S. (1979) Rating the risks. *Environment* **21**(3), 14–20.

Sobel, J. and Takahashi, I. (1983) A multi-stage model of bargaining. *Review of Economic Studies* **50**, 411–426.

Sutton J. (1986) Non-cooperative bargaining theory: an introduction. *Review of Economic Studies* **53**, 709–724.

Thompson, M., Ellis, R. and Wildavsky, A. (1990) *Cultural Theory*, Westview Press, Boulder, CO.

Townsend, P., Davidson, N. and Whitehead, M. (1992) *Inequalities in Health*, 2nd edn, Penguin, London.

US EPA (1986) Ambient water quality criteria for bacteria – 1986. PB86-158045, US Environmental Protection Agency, Washington DC.

Weinstein, M.C. and Stason, W.B. (1977) Foundations of cost-effectiveness analysis for health and medical practices. *New England Journal of Medicine* **296**, 716–721.

WHO (1993) Guidelines for drinking-water quality. Volume 1. Recommendations. World Health Organization, Geneva.

Wilkinson, R.G. (1996) *Unhealthy Societies*, Routledge, London.

Wyer, M.D., Kay, D., Fleisher, J.M., Salmon, R.L., Jones, F., Godfree, A.F., Jackson, G. and Rogers, A. (1999) An experimental health-related classification for marine water. *Water Research* **33**(3), 715–722.