

7. Linking risk assessment and economic analysis

7.1 Introduction

Economic analysis is a powerful tool to support decision-making. It provides a common denominator for evaluating diverse outcomes, ranging from public health outcomes to trade impacts. With benefits and costs in the same (monetary) units the net benefits of alternative strategies to reduce risks can then be compared.

A risk assessment model is likely to compare scenarios with and without alternative interventions for a specific pathogen. The risk manager can compare the baseline human health risk with the changes in risk for each of the interventions. The problem is how to value the diverse range of human health outcomes ranging from mild illness to death.

Economic analysis permits changes in human health impact to be evaluated in monetary terms or healthy life-year equivalents, often expressed as QALYs or Disability-adjusted life years (DALYs) (see Section 7.2.1). Once the public health protection benefits have been estimated, changes in industry and government sector costs, in both the short and long term, can be estimated for each intervention under consideration. The same approach can also be used to prioritize food for a single pathogen or to prioritize pathogen+food combinations to be considered for action. This economic analysis can inform the risk manager about the size of the likely gains and losses by different groups for each intervention option. Those options with the largest net benefits are preferred, unless the risk manager has other important considerations that would make that option unacceptable, or that are not readily translated into economic values, e.g. for ethical or cultural reasons.

However, the linkage between risk assessment and economic analysis as a means of supporting decision-making in the area of food safety is a very new approach that is still in development. One example is an economic analysis of the impact of labelling eggs with the objective of changing consumer behaviour, following a positive evaluation of this intervention in a risk assessment of *Salmonella* Enteritidis in eggs (DHHS-FDA, 2000). As part of United States of America law, new or amended regulations that are 'significant', i.e. if they have an annual effect on the economy of US\$ 100 million, adversely affect a sector of the economy in a material way, adversely affect competition or adversely affect jobs, must undergo a Preliminary Regulatory Impact Analysis (PRIA). In this case, the PRIA showed that the economic analysis calculated US\$ 260 million of health benefits in the first year of introduction of the new rules, and US\$ 260 million in health benefits thereafter, compared with a cost of US\$ 56 million in the first year and US\$ 10 million dollars in increased costs thereafter.

Methods of economic analysis that could be used for evaluating the costs and benefits of food safety and of different states of health are described in the following section, prior to discussion of their application in food safety risk assessment and management.

7.2 Economic valuation issues

Economic value can be determined for most products and their attributes by examining prices in the marketplace. Although a market for food safety may emerge, a market price for food safety does not exist yet, or is at least not measured. Food is not marketed, nor prices differentiated, on the basis of 'safe', 'less safe' or 'not safe'. In the absence of clear market prices for food safety, economists and other health researchers have developed a number of approaches for valuing the benefits of reductions in morbidity and premature death for foodborne pathogens.

7.2.1 Valuation of health outcomes

To evaluate the benefits of different risk management interventions in risk assessment, reduction in cases of illness (acute illnesses and their complications) needs to be estimated. While generally a low probability event, most foodborne illnesses can also cause some type of complication (see Appendix 1; Foegeding and Roberts, 1994). It is useful to organize the medical data into a disease outcome tree (see Appendix Figure A1) to recognize and document the full range of acute illnesses and longer-term complications. Because the range of health outcomes is so broad, a simple outcome ranking, such as deaths, will leave out many other health outcomes. As a result it is difficult to describe and evaluate the full costs of the risk management strategies and to prioritize spending alternatives.

To establish a basis for comparing diverse health risks and for ranking policy alternatives, analysts must translate diverse outcomes into a common unit of analysis. Economists have played a major role in establishing a common unit of analysis for risk ranking and cost-benefit analysis. The Cost-of-illness (COI) and Willingness-to-pay (WTP) methods convert diverse outcomes to monetary units, and the QALY approach converts diverse outcomes to healthy-time equivalencies (Kuchler and Golan, 1999; Golan et al., 2003; Haddix et al., 1996; Tolley, Kenkel and Fabian, 1994).

To illustrate the complex sequence of events that can occur over one's lifetime after an occurrence of foodborne illness (FBI), consider Figure 7.1, where the linkage between arthritis and exposure to foodborne pathogens is shown (Raybourne et al., 2003). At the first node of the tree is the estimate of the probability that a person exposed to a foodborne pathogen develops reactive arthritis. At the second node, either full recovery or the possible progression to ongoing arthritis is estimated. The final node characterizes the consequences of lifetime arthritis into: mild or intermittent joint pain; severe/chronic joint pain; or sacroiliitis/spondylitis (involving spine).

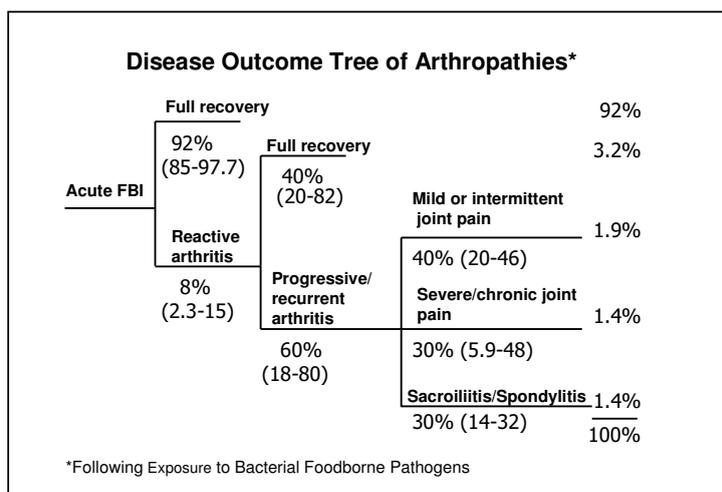


Figure 7.1 Disease outcome tree of Arthropathies (Raybourne et al., 2003). The values shown are estimates of the mean proportion of cases in each category. Values shown in parentheses indicate the range of those estimates.

Cost-of-illness method

The COI method estimates the dollars spent on medical expenditures and the value of the productivity of the patient foregone as a result of foodborne illnesses, complications and deaths. The value of productivity is a notional value, e.g. based on average adult wage. The strength of the COI approach is the use of money as the common unit of measurement to provide a full ranking of policy options and a context for determining social desirability. The COI method translates health outcomes into monetary equivalents that can be added and permit analysts to rank different health outcomes. The net benefits of different policy options can be estimated by comparing, for each policy option, the change in public health protection benefits with the change in costs to the government, industry and consumers. If the net benefits of a programme exceed the estimated net costs, the programme is considered worthwhile in economic terms. Examples of application of the COI method for food safety include Roberts and Marks (1995) and Buzby et al. (1996).

Willingness-to-pay method

The WTP method involves solicitation of stakeholders about the maximum amount they are willing to pay for a specified theoretical service or good, e.g. to be guaranteed that a particular food would not cause them illness. This approach is the most consistent with economic theory. The WTP method for estimating the benefits of public health programmes rests on the observation that individuals can and do make trade-offs between health and other consumption goods and services. Individuals routinely and voluntarily accept many small risks in exchange for finite benefits. Some risks rank quite low when preferences are considered. For example, skiing carries a risk of injury and death, but very few skiers would welcome a government programme that banned skiing on the basis of risk. Similarly, some consumers prefer the taste and texture of rare hamburgers and are willing to assume some risk. There are profound differences in the way that individuals value reductions in different risks. The WTP method

provides a means of ranking diverse risks, not just by the size of the risk, but also by how concerned stakeholders are about the risk. WTP estimates what risk reduction is worth to individuals whose health might benefit, provided they understand the full consequences of exposure to the foodborne pathogen being evaluated. This technique is beginning to be applied to foodborne disease risks (e.g. Golan and Kuchler, 1999; Brown, Oranfield and Henson, 2005).

Disability-adjusted life years

Some analysts or policy-makers prefer not to assign monetary values to human illness or death (Haddix et al., 1996). To avoid using money as a unit of account, one of the most popular methods is to construct a health index that accounts for changes in both length and quality of life. These may be surrogates for economic measures.

The DALY is based on the amount of 'life quality' lost, multiplied by the duration of that loss of life quality. For example, a DALY related to diarrhoea might be estimated as 50% disability (or 50% loss of life quality lost) for three to four days (equal to 1/100th of a year). Thus, the DALY is 0.5 times 0.01 = 0.005. For a foodborne illness leading to the premature death (100% loss of life quality) of a 35-year-old adult, the duration can be estimated as the number of years that the person might have been expected to still live (e.g. 40 years). Thus, the DALY in this case is 35. In a study of Shiga-toxin-producing *Escherichia coli* O157 in the Netherlands, acute gastroenteritis was estimated to be 6% of the total disease burden. The major disease burden (94%), despite there being far fewer cases, was associated with deaths from haemolytic uraemic syndrome and from the few cases that develop end-stage renal disease (Havelaar et al., 2003), a chronic and debilitating disease. The QALY concept is analogous, but measures the *increase* in quality of life, and its duration, as a result of an actual or putative intervention.

Because DALYs and QALYs provide a common unit of measure for different health outcomes, they provide a means for ranking and prioritizing funding allocation across diverse types of programmes, such as nutrition and dialysis programmes. All things equal, those programmes with the highest QALY per monetary unit should be funded before those with lower DALY per monetary unit. However, DALYs do not produce a net benefit measure. They do not provide a framework for evaluating the worth of a programme, i.e. how much money should be spent per QALY, nor would they be expected to equate naturally to health-care costs.

7.2.2 Valuation of non-health outcomes

In the context of international trade in food, microbiological food risk assessment focuses only on food safety as it relates to public health. Within nations, however, the introduction of new regulations often needs to demonstrate net benefits from the proposed regulations compared with the costs of their implementation. As such, in some risk assessments, non-health benefits, such as maintenance of access to export markets that are attributable to safe food and a strong food safety system, may also be important (Golan et al., 2003; Buzby and Roberts, 1997), and methods for their estimation are considered briefly here. In principle, market prices are available to estimate all non-health outcomes. However, the linkages to food safety risks can be difficult to quantify in advance. The economic consequences of BSE on British beef sales and exports, in which market losses have been extensive, is such an example.

Value of reductions in market risks

Food safety concerns may trigger market fluctuations that are only loosely related to the real value of health risks. Hazards that have a very low ranking in terms of health risk can trigger market reactions that rank high in terms of economic impact. The global nature of food trade has the potential to amplify food safety scares. In these cases, the measure of the value of a food safety system should include its ability to reduce disruptions in domestic and international markets and in the economic losses these disruptions entail.

Value of access to foreign markets

A strong food safety system may also reap benefits in terms of access to foreign markets (Spriggs and Isaac, 2001; Roberts et al., 1997; Krissoff, Bohman and Caswell, 2002; Kaelin and Cowx, 2002). Many countries limit food imports to those countries with comparable or more stringent food safety systems. For many food producers, access to foreign markets is vital to the success of their business. For producers in these exporting countries, the value of a strong food safety system goes beyond the value of reducing domestic public health risks associated with foodborne pathogens

For example, a series of bans were imposed on fish exports from Uganda because of *Salmonella* and *Cholera* contamination and toxic levels of pesticides. From 1996 to 1999, an estimated 10 000 fisherfolk lost their jobs (Nasinyama, pers. comm., 2002). The economic loss to Uganda has been estimated at US\$ 100 million. In 2000, the European Union lifted the ban on imports of fish. In 2001 Uganda was placed on the list of countries for export without restriction. Today, fish almost surpass coffee as Uganda's number one export (Kaelin and Cowx, 2002)

Value of consumer confidence and tourism lost due to unsafe food

A strong food safety system builds consumer confidence and can lend credibility to government programmes. Consumers' confidence in the food safety system makes them less susceptible to passing food scares and limits market volatility. Following the salmonellosis and BSE crises in the United Kingdom, for example, consumers became concerned about their food regulatory system, which ultimately led to the creation of a new food standards agency. Additionally, if a country's food supply is not considered safe, some tourists will decide not to visit. This will have wide impacts on a variety of businesses, including hotels, restaurants, transportation, crafts and many other local industries.

7.3 Integrating economics into risk assessments to aid decision-making

The outcome of a quantitative risk assessment will generally provide an estimate of the baseline human health risks. Usually, quantitative risk assessments give complete probability distributions rather than just point estimates of population risk. An example of incorporating both means and range for estimated health outcomes is shown in Figure 7.1, the disease outcome tree for arthritis after exposure to a foodborne pathogen. The mean and range can become the basis for developing a distribution of this health outcome. The economic costs for the baseline risk can be evaluated using one of the three techniques discussed (COI, WTP, QALY).

There are two basic methods for evaluating the benefits and costs of proposed changes to policy or regulations:

- Cost–benefit analysis is most appropriate for human health risks evaluated using the COI or WTP approaches.
- Cost-effectiveness analysis is most appropriate for human health risks evaluated using the QALY approach.

The nature of each policy decision needs to be clearly understood to allow the identification of those who benefit and those who are disadvantaged by that policy (see Appendix Table A2)(Buzby and Roberts, 1997). In particular, it is important to ensure that benefits and disadvantages accrue fairly, e.g. that one group does not benefit at the expense of another being exposed to increased risk. The anticipated economic costs of the public health intervention (e.g. requiring changes in the behaviour of industry, government and possibly consumers) can then be compared with the economic evaluation of improvements in health outcomes.

7.3.1 Cost–benefit analysis

Cost–benefit analysis is a useful tool to evaluate the impact on society of alternative food safety interventions. The benefits of reduced risk are primarily the improvement in public health, although other impacts may be important in specific cases (such as trade or tourism). All benefits are estimated in monetary units. The improvements in public health are estimated using either the COI or WTP technique discussed above. The benefits are then compared with the costs of the intervention. Costs are also estimated in monetary units and can include changes in industry, government and consumer behaviour (see Appendix Table A2). For example, if the intervention is to put information on food labels asking consumers to change their kitchen practices, the value of the increased time involved can be estimated as a cost. Some technical finance issues in the cost–benefit analysis include deciding on the time horizon and the discount rate (Dinwiddy and Teal, 1996; Laylard and Glaister, 1996). The net benefits from alternative food safety interventions can then be compared. Those with the highest net benefits are preferred, although the decision-maker may have other considerations to take into account.

An analysis of the United States Department of Agriculture Pathogen Reduction/Hazard Analysis at Critical Control Points (PR/HACCP) rule for raw meat and poultry (Crutchfield et al., 1997) demonstrated the use of cost–benefit analysis. The public health benefits were predicted to derive from preventing diseases caused by four foodborne pathogens. Using the most conservative assumptions, the PR/HACCP was estimated to provide net benefits of US\$ 7 billion or more over a 20-year period. When the analysis assumed higher rates of pathogen control and lower interest rates, the present value of the net benefits provided by PR/HACCP was US\$ 42 billion (Table 7.1).

7.3.2 Cost effectiveness analysis

Cost-effectiveness analysis is often used by health economists to evaluate alternate methods of achieving a specific public health goal, such as reducing the number of deaths. The number of deaths can either be assessed directly or QALYs can be used to assess the net improvement in all health-related quality of life changes over the baseline due to a food safety intervention. The change in QALYs is then compared to the net costs. Costs evaluated include medical costs and lost productivity. The decision criterion is the cost-effectiveness ratio, where the gain in QALYs (or number of deaths) is the numerator and the net costs are the denominator. Those with the highest ratio are preferred.

Table 7.1 An example of cost–benefit analyses of the Pathogen Reduction/HACCP of the United States of America using four sets of assumptions (based on Crutchfield et al. (1997) and supplemented by T. Roberts pers. comm., 2004).

Scenarios	Pathogen control	Interest rate	Present value ¹ evaluated over 20 years		
			Industry costs	Public health benefits	Annual net benefits
			percent		US\$ billion (2000)
Low-range benefits estimate	20	7	1.3 to 1.5	8.5	6.8 to 7.2
Mid-range benefits estimates I	50	7	1.3 to 1.5	21.2	19.7 to 19.9
Mid-range benefits estimates II	50	3	1.7 to 2.1	24.3	22.2 to 22.6
High-range benefits estimates	90	3	1.7 to 2.1	43.8	41.7 to 42.1

Key: (1) Present value is the discounted value of either the stream of costs of the programme or the benefits of the programme over the 20-year time horizon.

NOTES: For more detail, see: www.ers.usda.gov/briefing/FoodSafetyPolicy/features.htm and 'An Economic Assessment of Food Safety Regulations: The New Approach to Meat and Poultry Inspection' that describes the methodology used in deriving the benefit/cost analysis: www.ers.usda.gov/publications/aer755/

7.3.3 Risk–cost trade-off curves

Economists have another tool, the risk–cost trade-off curve, which can be combined with risk assessment data and distributions. Industry often uses this tool informally. A more formal example is shown in the box (Figure 7.2), where the risk-reduction on one axis is compared with the increase in marginal cost on the other axis. This allows a number of pathogen reduction options to be compared. It is often difficult to quantify the actual linkage of these interventions with existing plant practices and how the management system enhances that linkage. Economists often assume that reducing risk comes at a cost. This is not always the case. Marginal costs may even decrease, e.g. if there are offsetting efficiency gains, such as reduction in product returns or a longer shelf-life because treatments to reduce pathogen prevalence can also decrease loads of spoilage organisms.

7.3.4 Uncertainty in economic analysis

Both risk models and cost estimates have uncertainties, thus there are uncertainties in the economic analysis. The primary sources of uncertainty associated with the results of economic analyses should be identified, characterized, stated explicitly and communicated clearly. Consequently the results of an economic analysis should not be expressed as precise measures, but the entire distribution of potential costs and benefits should be taken into account. In principle, the methods described in Section 5.4 for dealing with uncertainty and variability can be used.

Value-of-information (VOI) analysis is, like sensitivity and uncertainty analysis, a formal method that can be utilized to quantify the relative impact of various uncertainties. Such analysis can be either qualitative or quantitative and, when quantitative, a probability-modelling approach is appropriate (Hammitt and Cave, 1991). The distinguishing difference between VOI versus sensitivity or uncertainty analysis *per se* is that, in a VOI analysis, an explicit linkage to some measure of the societal value or utility of risk reduction is used to replace the model output 'risk' by 'value or utility of changes in risk'. Clearly, such linkage requires some choice as to an economic (or societal) valuation method for risk reduction, such as WTP or COI. Given

a measure of societal utility of risk reductions, a VOI analysis can be used to investigate the expected value of additional information with respect to one or more of the modelled scenarios.

Malcolm et al. (2004) considered an example of a private company comparing the ‘trade-off’ of costs versus risk-reduction for three methods of improving food safety in a beef abattoir (Figure 7.2). The three food safety improvements reduce generic *E. coli* in hamburger patties.

Additional study of a specific topic or area of assessment would be determined to be valuable if the ‘value or utility of changes in risk’ was sensitive to the expected amount of information that could be obtained from the additional research. At the present time, formal VOI techniques have not been applied to microbiological risk assessment problems. However, with a wide range of identified microbiological risks and potentially limited resources available to effect regulatory process controls, VOI analysis is a potentially useful tool in the decision-making process when the results of a risk assessment and cost–benefit analyses prove too uncertain to justify more specific actions.

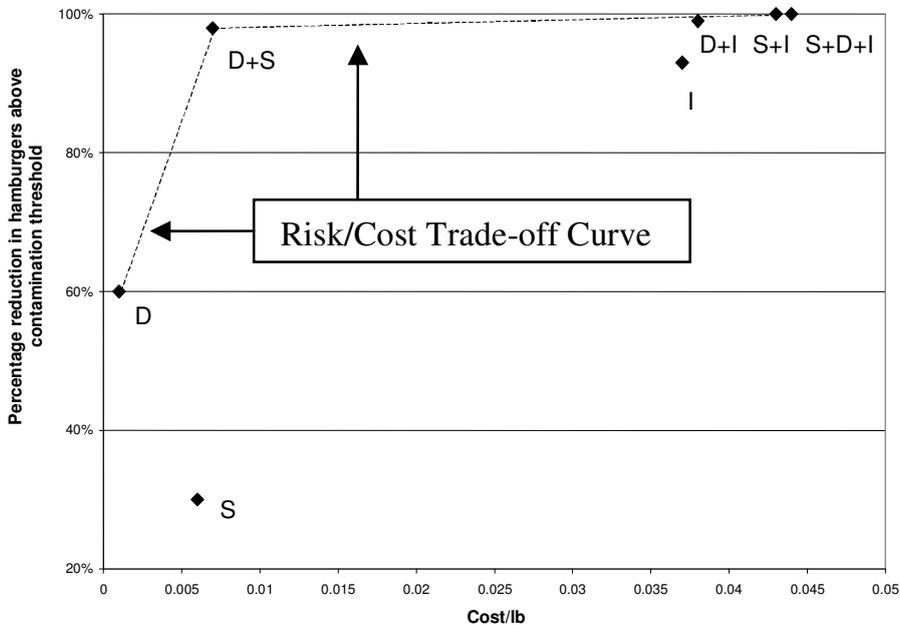


Figure 7.2 An example of a risk/cost trade-off curve for improving food safety in a large steer and heifer abattoir plant, based on three potential approaches (after Malcolm et al., 2004).

NOTES: D = improved de-hiding of carcasses; S = steam pasteurization equipment and use; I = irradiation equipment and use. Each risk-reducing improvement has an associated distribution of pathogen reduction. The model considers the seven possible combinations of the possible improvements (one at a time, two at a time, or all three together). Economic cost data are added and a Monte-Carlo simulation is run to develop the risk–cost trade-off curve. On the horizontal axis is the cost per unit weight (pounds; lb). On the vertical axis is the mean expected reduction risk over a threshold level of contamination. Points on the risk–cost trade-off curve are the most cost-effective. Note the improved de-hiding procedures are the most cost-effective, as risk is considerably reduced at relatively little cost.