Chapter 6
Burden and Risk Assessment of Foodborne Disease

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Abbreviations

DALY	Disability-adjusted life year
EFSA	European Food Safety Authority
FDA	Food and Drug Administration
FSMA	Food Safety Modernization Act
GBD	Global Burden of Disease
QALY	Quality-adjusted life year
QoL	Quality of life
RASFF	Rapid Alert System for Food and Feed
SMPH	Summary measure of population health
VSL	Value of statistical life
VSLY	Value for a statistical life year
WHO	World Health Organization
WTA	Willingness to accept
WTP	Willingness to pay

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YLD Years lived with disability
YLL Years of life lost

6.1 Introduction

Food safety is a critical global public good that has important implications for public health, economies, and food security. Globally, foodborne disease is a leading cause of mortality and morbidity, causing an estimated 600 million illnesses and 42,000 deaths annually (Havelaar et al. 2015). Children are particularly impacted, accounting for 40% of the overall burden and a third of all deaths. Foodborne disease can result in long-term health outcomes, such as irritable bowel syndrome, reactive arthritis, diabetes, hypertension, kidney disease, and neurological dysfunction (Batz et al. 2013; Porter et al. 2008; Roberts et al. 2009). Combined, these health impacts lead to reduced quality of life, shorter life spans, increased medical costs, decreased worker productivity, and lower incomes. The impact is substantial, but estimates vary by the number of pathogens, the perspective, and aspects included (e.g., tangible versus intangible costs). Regardless of the approach used, existing estimates are conservative—i.e., the true burden and costs are likely to be higher than presented.

The impact of food system failures is actually much higher than medical costs and lost productivity. Meeting food safety requirements is essential to gaining market access, particularly for developing economies (Grace 2015). The inability to meet food safety requirements has rippling effects, resulting in lower incomes, decreased purchasing power, and reduced access to food which, in turn, can lead to increased medical costs and decreased worker productivity. Recalling contaminated products that do make it to market is very costly, resulting in product losses, loss of markets and consumer confidence, damage to reputation, court cases, and company closures (Hussain and Dawson 2013; Pozo and Schroeder 2016; Ribera et al. 2012). A 2011 survey found that 77% of industry members who had experienced a recall within the past 5 years estimated the related costs to be $30 million, with 23% reporting even higher costs (Grocery Manufacturers Association 2011). In addition, over 81% of respondents described the financial consequences of a recall as either “significant” or “catastrophic” (Grocery Manufacturers Association 2011). In fact, as shown in Fig. 6.1, stock values dropped an average of 1.24% 5 days after the formal announcement of a Class I recall; for a firm with 472 million shares valued at $20/share, this would result in a $109 million loss (Pozo and Schroeder 2016). Similarly, there are significant costs to the government as public health and regulatory agencies respond to failures in the food safety system, including epidemiological investigations, product tracing efforts, enhanced environmental sampling and inspections, and ensuring of the effectiveness of recalls.

In response to the bovine spongiform encephalopathy crisis and other food safety incidents in the 1990s, the Council of the European Union and the European Parliament adopted Regulation (EC) No. 178/2002, known as the

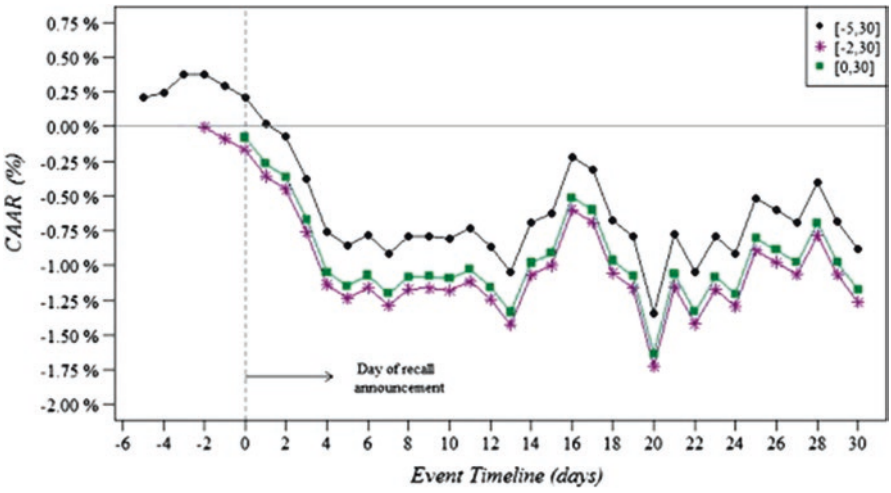

Fig. 6.1 Impact of Class I meat and poultry recalls on stock prices—USA 1993–2013 (Pozo and Schroeder 2016). The average loss in market equity 5 days after recall equaled $109 million

General Food Law of 2002 (http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32002R0178). One of the key principles of the food law is that "measures adopted by the Member States and the Community governing food and feed should generally be based on risk analysis." The Regulation further created the Rapid Alert System for Food and Feed (RASFF), and the European Food Safety Authority (EFSA), an independent agency that provides scientific advice and risk assessments to relevant bodies in the European Commission, the European Parliament and Member States. In 2010, recognizing the importance and infrastructure needs around food safety, the United States Congress passed the Food Safety Modernization Act (FSMA), the first comprehensive reform of the Food and Drug Administration's (FDA) food safety oversight since 1938 (FDA 2017). FSMA mandates FDA to adopt a science-based, risk-informed approach to food safety and holds the food industry more accountable for producing safe products.

Central to the risk-informed framework are risk analysis and burden of disease estimates, which provide the foundation for decision-making and allocation of resources. Information gathered on the burden of foodborne disease provides important data for risk assessment and, subsequently, scientifically grounded risk reduction strategies. For example, burden of disease estimates are currently being used by the FDA to designate high-risk foods that will be prioritized in product tracing measures and design data-driven preventive controls and food safety standards (FDA 2014). In this chapter, we present an overview of risk analysis and disease burden as both are the foundation of a risk-based food safety system. Subsequent chapters present an overview of the research that has been conducted by the World Health Organization (WHO) and in the United States to provide useable estimates of the health impact and economic burden of foodborne disease.

6.2 Risk-Based Food Safety

Due to the complexity and changing nature of the food supply, ensuring its safety has been identified as a *wicked problem*, i.e., a problem that arises in complex and interdependent systems and that is difficult or impossible to solve because of incomplete, contradictory, changing, or incomprehensible requirements (Institute of Medicine 2012). Indeed, the food system is multifaceted, with a large number of stakeholders with diverse interests. The international food production and distribution systems play a major role in the global economy, with significant impacts on income, employment, rural and urban economies, and the environment. Historically, the approach to ensuring food safety has been reactive—responding to crises as they occur—rather than preventive (Koutsoumanis and Aspridou 2016). In the United States, food oversight is distributed across 15 federal and thousands of state and local agencies and regulated by a patchwork of regulations that can be difficult to navigate. Internationally, many countries lack the infrastructure needed to meet international food safety standards which, in turn, impacts trade and local access to safe food. To address the food challenges of the twenty-first century, the paradigm must shift to an integrated, multidisciplinary, systems-based approach that is informed by the best available science, and focus on prevention is needed. At the same time, there is a very real need to utilize limited resources so that they effectively address the most important issues and provide the greatest benefits to the most people. Risk analysis, which consists of risk assessment, risk management, and risk communication (Fig. 6.2), provides an integrated and structured framework for supporting decision-making; it is internationally accepted as the best approach to food safety (FAO 2006).

A risk-based food safety system is one that uses "a systematic means by which to facilitate decision-making to reduce public health risk in light of limited resources and additional factors that may be considered" (Havelaar et al. 2007; National Research Council 2010). Central to the risk-based framework (Fig. 6.3) is an understanding of the risks and burden of disease. Once we understand the burden, we can begin to quantify, attribute, and rank the risks. From there, we can establish public

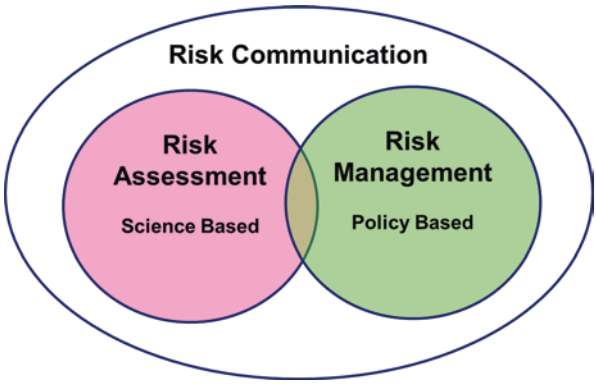

Fig. 6.2 Components of risk analysis

Fig. 6.3 Framework for a risk-based food safety system (National Research Council 2010)

health goals—such as the United States Healthy People 2020 goals or the United Nations Millennium Development Goals—and determine potential prevention and control interventions. We must then evaluate each intervention or policy to determine its ability to positively impact public health at a reasonable cost in a fair manner. After we have identified our prevention and control strategies, we must set priorities and allocate resources to those that will have the biggest public health impact. Finally, we must measure the effectiveness of our efforts in meeting public health goals and objectives.

Risk assessment is used to quantify and characterize risk, which is defined to be a function of the probability of exposure (incidence) and the effect of that exposure (severity) (Codex Alimentarius Commission 2006). The classic risk assessment paradigm assesses exposures and characterizes hazards across the supply chain to predict risk to human health (Fig. 6.4). There are four steps in a risk assessment: hazard identification, exposure assessment, hazard characterization, and risk characterization. *Hazard identification* focuses on identifying the hazards, transmission pathways, associated health effects, and at-risk populations of concern and requires information on the hazard characteristics; exposure routes; epidemiologic link between foods, hazards, and illness; health outcomes (acute and chronic); and sensitive populations. *Exposure assessment* focuses on estimating the probability of exposure and the dose of the pathogen in the food at the moment of consumption. Information needs include data on food consumption trends; the ecology of the hazard, including the prevalence and concentrations of pathogens across the food supply; and processing, packaging, storing, and preparation practices and their impact on hazard growth/die-off. *Hazard characterization* (or dose-response assessment) focuses on estimating the probability, severity, and duration of adverse events due to the presence of the hazard in the food. Typically, data from human and animal models or outbreaks are used to develop a dose-response curve, which estimates the

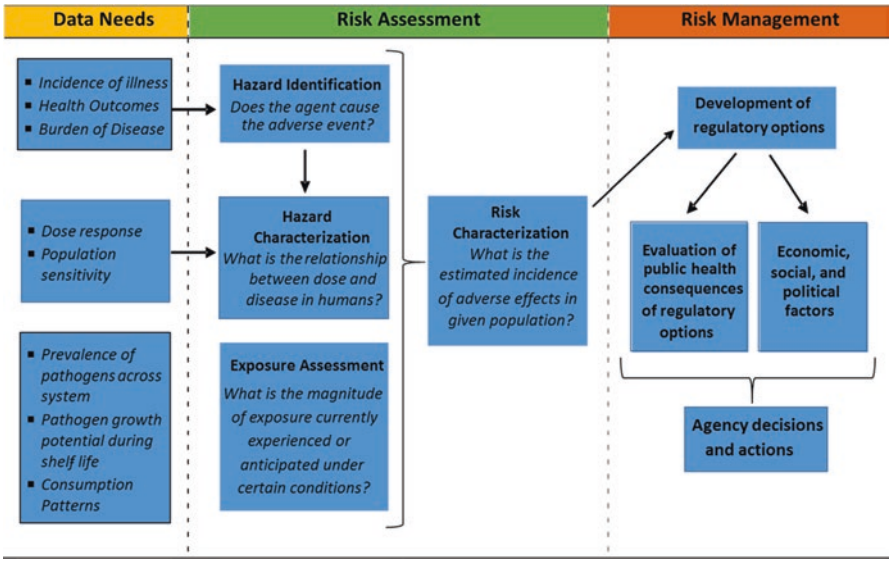

Fig. 6.4 Risk assessment paradigm and areas of focus. Adapted from National Research Council (2009)

relationship between dose, or level of exposure to the hazard, and the incidence and severity of the effect (WHO/FAO 2009). *Risk characterization* combines the information from the hazard identification and characterization and exposure assessment to produce a complete picture of risk, that is, an estimation of the incidence and severity of effects likely to occur in a population due to exposure and the attendant uncertainty.

Two general approaches, based on the data sources used in model construction, are used to assess human health risk (National Research Council 2010). In the *top-down*, surveillance-based approach, information on human disease gathered from epidemiological systems is used directly to estimate risk at the point of consumption (Fig. 6.5). The metrics for likelihood and severity are estimated using population attributable fractions derived from information gathered from epidemiological systems, such as surveillance or cohort studies. Thus, a top-down approach relies on the availability of epidemiological data. In the *bottom-up* approach, estimates are derived using the classic risk assessment paradigm that assesses risk using exposure and dose-response information. In theory, both approaches should result in similar estimates for likelihood and severity; in reality, significant data gaps and biases and uncertainty in the metrics make that unlikely (Bouwknegt et al. 2014). The approach selected will likely depend on the risks under consideration and available data. For example, epidemiologic data are typically less specific to assess risks of exposure to specific food products such as a particular brand of raw milk cheese, making the bottom-up approach more appealing. Alternatively, epidemiological data are typically more reliable to estimate the total incidence of disease by a foodborne

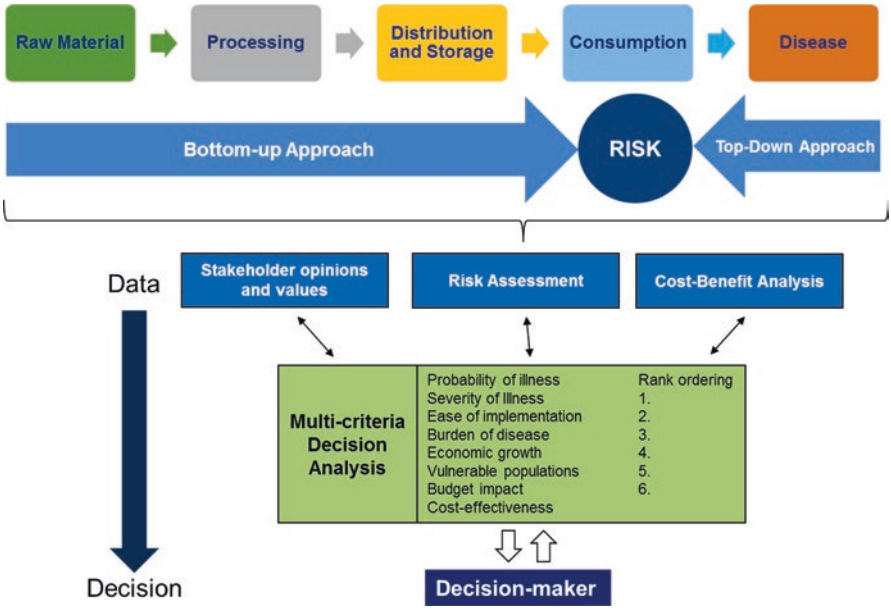

Fig. 6.5 Approaches to assessing risk. Adapted from EFSA Panel on Biological Hazards (BIOHAZ) (2012)

pathogen such as campylobacteriosis, making the top-down approach more appealing. EFSA has proposed a strategy to integrate top-down and bottom-up approaches in a scientific opinion about risk ranking (BIOHAZ 2015).

The outputs of risk assessment are used to inform risk management, where the goal is to control or limit the risks. Risk managers need to make decisions about the acceptable levels of risk and the selection and evaluation of intervention strategies: Is this a risk of public health concern? Should exposures be reduced? Should regulations be put into place? Should a material or substance be labeled or banned? Often resources are limited and priorities must be set; in these cases, risk-ranking exercises may be undertaken to aid prioritization. Ultimately, risk management decisions are often informed by other nonpublic health factors, such as economic, social, and political considerations; decision analysis, which is outside the purview of this chapter, can be used to identify and analyze decision alternatives in a transparent manner.

6.3 Burden Assessment

Burden of disease (or disease burden) refers to the total impact of a disease, including physical, social, and financial impacts, on society (population burden) and on the individual affected (individual burden). Burden of disease can be measured

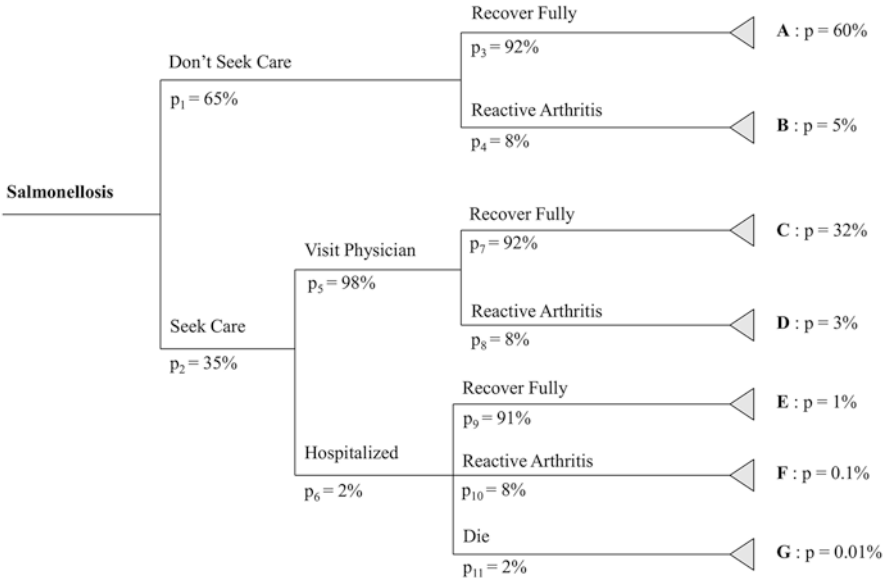

Fig. 6.6 Disease outcome tree for *Salmonella* spp. Based on Scallan et al. (2011) and Keithlin et al. (2015)

using a variety of metrics. Frequently, burden is estimated using the number of illnesses, hospitalizations, and deaths or the cost-of-illness (e.g., medical care, lost wages, and productivity). However, while these metrics provide a picture of the population-level occurrence of foodborne disease, they fail to account for the severity and duration of illness or the resulting disabilities and/or impacts on quality of life (Batz et al. 2012; Devleesschauwer et al. 2015; Mangen et al. 2010). Burden of disease is therefore increasingly quantified using summary measures of population health such as disability-adjusted life years or quality-adjusted life year losses.

The health impact of foodborne disease is defined by the health effects (health states) associated with infection with or exposure to the concerned foodborne hazard. The recommended approach is to design disease outcome trees to clearly define the potential outcomes associated with consuming food contaminated with a specific pathogen. A deterministic example using salmonellosis is illustrated in Fig. 6.6 based on Centers for Disease Control and Prevention estimates of probabilities associated with care seeking, hospitalization, and death (Scallan et al. 2011) and an estimate of the probability of reactive arthritis resulting from the acute infection (Keithlin et al. 2015). The probabilities associated with eight outcomes (A to G) can be assessed using this tree. For example, the probability of recovering fully without seeking care is 60% for an individual with salmonellosis ($Pr(A) = p_1 \times p_2$). Alternatively, the probability of being hospitalized and acquiring reactive arthritis as a sequela is only 0.1% ($Pr(F) = p_2 \times p_6 \times p_{10}$).

There are several things to note about the outcome tree in Fig. 6.6. First, the tree makes it clear that the sequela is assumed to be equally likely under all severity

levels. Whether this is correct or the science just has not been able to discern these differences yet is unclear, but it is important to understand. Second, this is a relatively simple tree, even for salmonellosis. Other outcomes, such as whether the sick person provides a stool sample, is prescribed pharmaceuticals, misses work, or utilizes home health-care services, could be added. Depending on the economic technique used to examine the costs associated with illness, these additions to the model may be warranted. Third, uncertainty is not expressed in this tree, though most high-quality studies today do include uncertainty intervals, sensitivity analyses, or both.

Finally, the choice of values used often relies on the expertise of the modeler. For example, in Fig. 6.6, an estimate (8%) from a recent meta-analysis was used for the likelihood of reactive arthritis that focused on diagnoses made by specialists (Keithlin et al. 2015). Using the same meta-analysis, the value for all studies (6%), for those that had follow-ups within 90 days of the acute illness (12%), or for those studies involving more than 10,000 persons who had had salmonellosis (0.2%) could also have been used. Given the wide range of estimates available, modelers are forced to make judgments about which estimates to use and whether to include other estimates in sensitivity analyses.

Similarly, our choice to limit sequelae to reactive arthritis is not an easy one. There are many sequelae that have been associated with salmonellosis, including irritable bowel syndrome, inflammatory bowel disease, Crohn's disease, ulcerative colitis, Guillain-Barré syndrome, Miller Fisher syndrome, and hemolytic uremic syndrome (see Chap. 8 for further discussion). Generally speaking, health outcomes should be included in burden of illness estimates if causation between the acute illness and the outcomes can be sufficiently established. There are both empirical and theoretical criteria for demonstrating causation, including the Bradford Hill criteria (Hill 1965).

6.4 Quantifying the Health Impact of Foodborne Disease

As stated previously, the health impact of foodborne diseases may be defined based on the number of prevalent or incident cases or the number of deaths. However, these simple measures of population health do not provide a complete picture of the impact of foodborne diseases on human health (Batz et al. 2012; Devleesschauwer et al. 2015; Mangen et al. 2010). Indeed, these measures quantify the impact of either morbidity or mortality, thus prohibiting a comparative ranking of highly morbid but not necessarily fatal diseases (e.g., mild to moderate diarrhea) and diseases with a high case fatality (e.g., perinatal listeriosis). On the other hand, they only quantify occurrence of illness or death, thus treating each illness case, or each fatal case, alike. Foodborne diseases may however differ in clinical impact and duration of the concerned symptoms, such that the severity of different illness cases may differ. Likewise, fatal cases occurring at different ages will result in different numbers of potential life years lost, such that the impact of different fatal cases may differ.

To overcome the limitations of these simple measures, various summary measures of population health (SMPHs) have been developed as an additional source of information for measuring disease burden. What the wide range of proposed SMPHs all have in common is that they use time as a general unit of measure; they can further be divided into two broad families: health gaps (i.e., time not lived in good health) and health experiences of expectancies (i.e., time lived in good health) (Devleesschauwer et al. 2014a). The most powerful SMPHs allow combining information on mortality and nonfatal health outcomes, which requires weighting the time lived with disease or disability according to the health experienced or lost. Currently, the two most important SMPHs are the disability-adjusted life year (DALY) and the quality-adjusted life year (QALY).

The *DALY* belongs to the family of health gap measures and is currently the most widely used SMPH in epidemiological research. DALYs find their origin in the Global Burden of Disease (GBD) studies and are officially adopted by the WHO for reporting on health information (Murray et al. 2012; World Health Organization 2013).

DALYs measure the health gap from a life lived in perfect health and quantify this health gap as the number of healthy life years lost due to morbidity and mortality. A disease burden of 100 DALYs would thus imply a total loss of 100 healthy life years, irrespective of how these healthy life years were lost. Diseases, hazards, or risk factors accounting for more DALYs thus have a higher public health impact.

DALYs extend the notion of mortality gaps to include time lived in health states worse than ideal health (Devleesschauwer et al. 2014b). Specifically, they are the sum of years of life lost (YLL) due to premature mortality and years lived with disability (YLD), adjusted for severity:

$$\mathrm{DALY} = \mathrm{YLL} + \mathrm{YLD}$$

YLLs are the product of the number of deaths (M) and the residual life expectancy (RLE) at the age of death:

$$\mathrm{YLL} = M \times \mathrm{RLE}$$

Two approaches exist for defining YLDs. Following an incidence perspective, YLDs are defined as the product of the number of incident cases (N), the duration until remission or death (D), and the disability weight (DW), which reflects the reduction in health-related quality of life on a scale from zero (full health) to one (death):

$$\mathrm{YLD}_{\mathrm{inc}} = N \times \mathrm{D} \times \mathrm{DW}$$

The incidence perspective assigns all health outcomes, including those in future years, to the initial event (e.g., *Campylobacter* infection). This approach therefore reflects the future burden of disease resulting from current events.

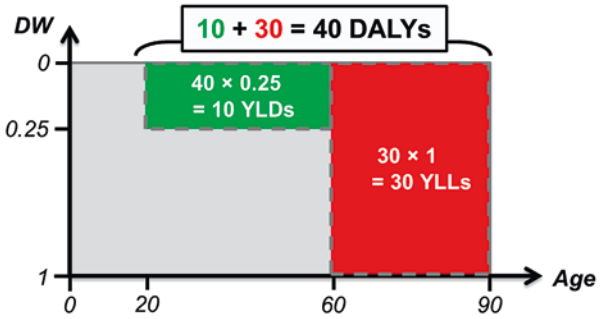

Fig. 6.7 Visual example of the disability-adjusted life year metric. *DW* disability weight, *YLD* years lived with disability, *YLL* years of life lost, *DALY* disability-adjusted life year

An alternative formula for calculating YLDs follows a prevalence perspective and defines YLDs as the product of the number of prevalent cases (P) with the disability weight (Murray et al. 2012):

$$\mathrm{YLD}_{\mathrm{prev}} = P \times \mathrm{DW}$$

In this prevalence perspective, the health status of a population is assessed at a specific point in time, and prevalent diseases are attributed to events that happened in the past. This approach thus reflects the current burden of disease resulting from previous events. Although both perspectives are valid, the incidence perspective is more sensitive to current epidemiological trends (Murray 1994), including the effects of intervention measures, and therefore often preferred for assessing the burden of foodborne diseases (Devleesschauwer et al. 2015).

Figure 6.7 presents a theoretical example of calculating DALYs, following the incidence perspective. An individual is born with a perfect state of health. At age 20 years, a given event (e.g., foodborne disease) leads to a 25% decrease of his/her quality of life, and thereafter the person lives in this new health state for another 40 years, at which point he/she dies prematurely. The burden associated with this disease for this individual (total DALYs) is calculated by summing up the years lived with disability (YLD) with the years of life lost (YLL) due to premature death.

The recommended approach for quantifying the health impact of foodborne diseases is the *hazard-based* DALY calculation approach (Devleesschauwer et al. 2014c). This approach defines the burden of a specific foodborne disease as that resulting from all health states, i.e., acute symptoms, chronic sequelae, and death, which are causally related to the concerned hazard and which may become manifest at different time scales or have different severity levels (Mangen et al. 2013). The starting point for quantifying DALYs is therefore the construction of a disease model or outcome tree, such as Fig. 6.1 (Devleesschauwer et al. 2014c).

The *QALY* belongs to the family of health expectancies, and is a standard tool in health economic evaluations, and cost-utility analyses in particular. QALYs are healthy life years, obtained by weighting life years according to utility weights, or

simply QALY weights, which reflect individual preferences for time spent in different health states. A number of methods are used to elicit QALY weights, including the standard gamble, time trade-off, and visual analog scale (Torrance 1986). Common to all methods is their use of a scale that measures health as being between 0 (death) and 1 (perfect health). The use of QALYs across multiple pathogens was made possible by the development of standardized QALY weights associated with multiple dimensions of well-being which has allowed for the generation of condition-specific QALY estimates without costly studies focused specifically on each pathogen in question (though expert opinion is needed to assign QALY weights in this case). For instance, in the EQ-5D multi-attribute utility scale, developed by the EuroQoL group, five dimensions of well-being are included (hence the acronym): mobility, self-care, usual activities, pain/discomfort, and anxiety/depression (Herdman et al. 2011).

The health impact of foodborne diseases may be quantified as QALY losses, i.e., the utility losses associated with foodborne disease that include both disability losses and pain and suffering losses. The measurement of QALY losses must account for the typical sufferer's initial QALY state, which is generally less than 1. Ideally, the initial state should be based on that of the typical person who gets a foodborne disease (who is older or younger and typically more immunocompromised than the average person), though the average population QALY level is typically used (Batz et al. 2014; Minor et al. 2015; Scharff 2015).

6.5 Quantifying the Economic Impact of Foodborne Disease

6.5.1 Costs Associated with Foodborne Disease

Decisions in a risk-based food safety system are driven by more than just public health impacts. Risk managers must also consider economic, social, and political factors in the decision-making process (Fig. 6.4). Therefore, it is important to understand the costs associated with foodborne disease: the individual who becomes sick from consuming tainted food, the retailer who sells the contaminated product, the food producer who allows contamination, and the government agencies that monitor, investigate, and regulate all incur costs from foodborne diseases. Figure 6.8, an adapted version of the taxonomy originally developed by the USDA Economic Research Service (Roberts 1989), illustrates these costs. Understanding each of these costs is important in a risk-based food safety system, though most efforts to measure economic cost have focused on household costs.

The *household* incurs costs whether or not an individual in the household has been made ill by their consumption of food. Specifically, consumers who are aware of risks associated with foods may face costs if they engage in self-protective efforts. For example, a consumer may choose to buy pasteurized products, avoid risky foods that he/she likes, or cook foods until any potential pathogens are destroyed (at an

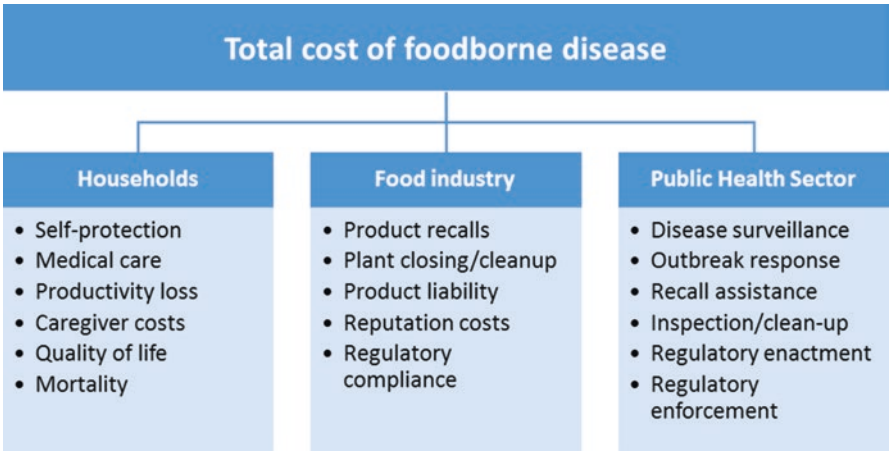

Fig. 6.8 Costs associated with foodborne disease

expense to taste). Each of these measures has a cost to the consumer, either monetary or through lost utility (well-being).

In the presence of illness, the costs include medical costs, productivity losses (to both sick persons and caregivers), pain and suffering losses, and mortality losses. Medical costs include costs for hospitalizations, physician services (both inpatient and outpatient), and drugs used (both prescription and over-the-counter). Ancillary medical services, such as tests of stool samples and urgent care/emergency room costs, are also included in this category.

Productivity losses occur when an individual is unable to perform productive tasks due to illness (either their own or someone they must care for, such as a child). Often this is measured as the costs of absenteeism from paid work. But some researchers have chosen to value the time of all ill persons at the average wage in the United States, regardless of their work status or age (the average wage is a proxy for the opportunity cost of the individual for time spent ill rather than engaging in his/her normal activities). There are also likely to be reductions in productivity for those that go to work sick, though these losses are likely to be significantly less than those for persons who stay home. Lost household production is also a cost of foodborne disease.

In some economic assessments, a monetary value is assigned to the intangible costs, i.e., the quality of life losses, associated with foodborne disease. The physical discomfort or pain associated with foodborne disease is one way an individual's quality of life is affected, but it is not the only way. Inability to engage in pleasurable activities (or reduced pleasure from those activities) also is an economic cost from foodborne disease. For example, if an individual with a mild case of illness decides not to go with friends to a concert because they do not want to deal with the consequences from a diarrheal illness in such a situation, their utility is reduced by an amount equal to the value they would have gotten from going to the concert while healthy minus the value they actually got from staying home with the illness.

Quality of life losses may also be borne by friends and family who must enduring seeing a loved one suffering. These may be quite high, especially when a parent is caring for a very ill child. Similar costs are borne when an individual dies due to a foodborne disease. In some instances, such as when chronic sequelae occur, other household cost categories, such as professional home health-care assistance, may be appropriate to include.

A number of costs accrue to *industry* as a result of foodborne diseases. First, if a firm determines that its product has the potential to make people sick, it is likely to institute a recall of the product. Costs associated with this effort include lost product sales equal to the market value of the recalled product and the cost of collecting and disposing of the product. If the recalled product has been in contact with processing and/or holding facilities, these facilities must conduct a thorough cleaning process, often entailing a lengthy closure of the operation. Next, if anyone was made ill due to the contaminated product, the firm responsible may be exposed to litigation and its attendant costs. Also, media coverage of outbreaks, litigation, and product recalls can have an effect on the reputation/value of the brand. Retailers and wholesalers may also suffer from costs associated with collecting and disposing of recalled product, as well as suffering from potential reputation costs if their customers perceive them as sourcing from unscrupulous suppliers. Finally, if the problem is not an isolated one and there are intervention measures that could remedy the problem, government may respond with costly regulation.

The *public health sector* also incurs costs as a result of foodborne disease. The various surveillance systems that track illnesses (see Chap. 13) are costly to maintain and often lead to the detection of outbreaks that are investigated and monitored. When recalls are initiated, government personnel are involved, whether or not illnesses have occurred. Inspections and assistance with cleaning up contaminated facilities are also activities that government funds. Finally, the promulgation of regulation involves costs, as do enforcement activities associated with the regulation.

6.5.2 Methods Used to Estimate the Costs

A number of methods have been developed to estimate the economic burden associated with foodborne disease. United States federal agencies that evaluate food safety interventions generally use benefit-cost analyses based on a cost-of-illness approach. Stated or revealed preference methods that generate willingness to pay/accept measures are used in some cases to supplement cost-of-illness studies and in others (primarily by academics) as a substitute for cost-of-illness. QALY losses or DALYs are in some cases monetized for use in cost-of-illness studies. Industry costs are often estimated using event studies using publically available data such as stock prices due to the proprietary nature of granular cost data. Attempts have been made to estimate recall and litigation costs, but these measures are generally very crude.

6.5.2.1 Cost-of-Illness

The cost-of-illness method is the most widely used approach among regulatory economists. The goal of this method is to calculate costs separately and aggregate them for presentation as a single cost number. The following equation illustrates a simple cost-of-illness formula for household costs:

$$\text{Cost}_i = \text{Medical}_i + \text{Productivity}_i + \text{QoL}_i + \text{Death}_i$$

The cost for individual *i* from an illness due to unanticipated risk is the sum of expected medical, productivity, quality of life (QoL), and death-related costs. Relevant industry and public health agency losses have also been added in by some, though not as much as they should be (perhaps due to the dearth of studies in this area). Total costs are defined as the sum of individual costs $\left(\sum_{i=1}^{n}\text{Cost}_i\right)$ and are often used by policymakers as a measure of problem scope, which can be used to set agency priorities and argue for expanded statutory authority. Cost per case measures is typically used in regulatory analyses as a means of demonstrating the economic value of an intervention. Costs per case is total costs divided by the number (*n*) made ill by the pathogen $\left(\sum_{i=1}^{n}\frac{\text{cost}_i}{n}\right)$. Cost per case is multiplied by number of cases averted by (or expected to be averted by) a given intervention to determine intervention effectiveness. The primary focus on household costs means that costs to industry and public health entities are often undervalued.

A number of valuation methods (and controversies) have arisen in response to the need for cost-of-illness estimates. Assuming the case of imperfect information (see Chap. 2), we explore the methods used to estimate medical costs, productivity losses, deaths, and lost utility below.

Medical costs are typically evaluated in one of two ways. Early efforts often relied on interviews or surveys of those that had been sickened in an outbreak. In this case, individuals report what they (or their insurance companies) spent on physician services, medication, hospital costs, and other costs. The primary problem with this approach is that the results may not be generalizable to the broader population outside of the outbreak area. That said, when other values are not available, estimates from outbreak reports can be useful.

An alternative means of estimating medical costs is by matching outcomes in a disease outcome tree with cost estimates from hospital and physician services databases. In the United States, for example, the National Inpatient Sample has cost data for hospitalizations and emergency room visits by ICD-9 classification. For example, in 2013 NIS has data on 6455 discharges with a primary diagnosis related to infection with *Salmonella*. The average cost was $9531 for an average of 5.1 days in the hospital, and 35 deaths were recorded. For physician services, there are references books, such as "Medical Fees" by PMIC, that catalog the costs of physician services and lab fees. Of course, these resources are only useful if the researcher has

information about what services are expected to be used by persons made ill due to the pathogen of interest. Similarly, knowledge of prescription medicine costs is only useful if likelihood of use is known.

Productivity losses theoretically include lost work in both the paid and household sectors. Where work is compensated, costs include both wages and other compensation for the time away from work. Uncompensated work, or household production (Becker 1965), may also be lost, but it is unclear how much of this an ill person is able to do. A number of studies have looked at lost wages for persons who are ill (Scharff 2015; Buzby and Roberts 2009; Hoffmann et al. 2012, 2015; Scharff 2012). The most accurate of these have taken into account both wages and benefits using estimates for cost of compensation, rather than only wages. Also, some studies have included work loss due to caregiving for children (e.g., Scharff 2015). The availability of good surveillance data for some pathogens allows for the generation of age profiles for those made ill, which can be used to better predict work status and child care needs.

The inclusion of *quality of life losses* in cost-of-illness analyses is controversial. Originally, no cost-of-illness studies attempted to quantify pain and suffering. In the 1990s, however, the FDA began using a monetized QALY estimate for the value of lost quality of life, as suggested by Mauskopf and French (1991). Some have argued that the monetization of QALYs is not appropriate because it requires the imposition of a number of restrictive assumptions (Hammitt and Haninger 2007). Others have argued that the QALY is the best measure of welfare loss available (Adler 2006).

The monetization of QALYs typically involves obtaining the product of the average person's QALY losses from an illness and their value for a statistical life year (VSLY). VSLY is calculated using a value of statistical life (VSL) measure, a discount rate (r), and expected longevity (L): $\mathrm{VSLY} = \dfrac{r \times \mathrm{VSL}}{1-(1+r)^{-L}}$. Note that both QALY and VSLY values reflect annual losses, suggesting that resulting estimates need to be scaled for duration. For example, an individual who suffers a 0.3 QALY loss for 1 day of diarrheal illness and who faces a VSLY of $300,000 would be calculated as losing $0.3 \times 1/365 \times \$300{,}000 \approx \$247$ from quality of life losses. It is important to note that productivity losses for the ill person are typically not included in cost-of-illness studies alongside QALY losses because QALYs account for utility losses due to loss of mobility, including internal productivity losses. External productivity losses may be included, however.

Losses from death due to foodborne disease are similar to quality of life losses in that there is a loss of utility and productivity from premature mortality. There are two methods used to assess these costs. First, some have simply used lost productivity for the remaining life span of the sick person, discounted appropriately. Alternatively, most policymakers in the United States now use a broader measure, the value of a statistical life (VSL).

The VSL measure generally used is based on labor market trade-offs between mortality risk and compensation (Viscusi and Aldy 2003). This is a revealed preference measure that essentially works as follows: if the typical individual is willing to accept (WTA) an increase in risk of 1/10,000 in exchange for $800, the implicit VSL is $8 million (VSL/10,000 = $800). Though the theoretically correct measure for a new risk reduction is a willingness to pay (WTP) measure, the revealed preference WTA measure is less likely to suffer from hypothetical biases that inflate stated preference WTP estimates because it is based on actual behavior rather than reported preferences (Murphy et al. 2005). In any case, it has been shown that for small changes in risk, such as those in most policy contexts, WTP and WTA are virtually identical (Kniesner et al. 2014). Note that VSL is not indexed by individual, illustrating the general use of an egalitarian assumption (all statistical lives are equally valuable). This assumption is typically used despite United States government guidance suggesting that VSL should be scaled to account for the population affected (U.S. Office of Management and Budget 2003). Specifically, research has demonstrated that the value for VSL varies by age, first increasing and then decreasing (Aldy and Smyth 2014). Given that many foodborne diseases have greatest incidence among the old and the young, this too suggests that government estimates of VSL are likely to be overestimates. USDA policymakers, however, have stricter food safety standards for the National School Lunch Program so that children are given stronger protection, based on the role of the state as a protector of children (Ollinger et al. 2014).

Despite the inclusion of many cost categories in cost-of-illness studies, some are not accounted for and others can be best seen as rough estimates. For example, the exclusion of self-protective actions and, often, quality of life losses leads to estimates that are likely to be underestimates of true cost, while the egalitarian assumption and assumption of uniform risk preferences may lead to values that are overestimates of true value. In response, some have suggested that the cost-of-illness approach leads to point estimates that give a false sense of precision. Though uncertainty intervals and sensitivity analyses are increasingly included in these analyses, these typically do not completely account for the structural deficiencies of the approach. Other approaches have been suggested as alternatives to the cost-of-illness approach.

6.5.2.2 Willingness to Pay

Foodborne disease cost-of-illness estimates have been criticized as being too limited, not including all of the losses to an individual who is made ill. An alternative is to assess the willingness to pay (WTP) to avoid foodborne disease. Theoretically, this is the most complete measure of utility loss for the affected individual because the individual is allowed to take into account all losses in making their assessment. The principal methods that have been used to elicit WTP for foodborne disease are experimental auctions and dichotomous choice experiments.

Early efforts to estimate WTP generally used experimental auction techniques (Hayes et al. 1995; Shin et al. 1992; Shogren et al. 1994). In these experiments, individuals bid to replace a product having a given risk with another that has a smaller (typically close to 0) risk. The winning bid pays the next highest bid to obtain the product (a mechanism designed to elicit accurate preferences and discourage gaming the auction). The best of these experiments are conducted using real products (and money exchanges) and are conducted using shoppers in a realistic setting (e.g., a grocery store). To be most meaningful, experimenters specify risks associated with the products in a manner that includes both probabilities of illness and likely consequences from becoming ill.

More recently, dichotomous choice experiments have been used in which individuals are asked to choose between two price/risk combinations for a given food product, where each person chooses between lower-risk/lower-price and higher-risk/higher-price options (Haninger and Hammitt 2011; Nayga et al. 2006; Teisl and Roe 2010). Experimenters vary the price/risk combinations across individuals and, in some cases, provide individuals with follow-up price/risk choices to more precisely assess WTP measures. Like auction experiments, these experiments are more likely to yield meaningful responses when the exchanges are not hypothetical, are conducted in realistic settings, and communicate risks in a meaningful way.

Despite the theoretical appeal of WTP measures, holistic WTP measures have not been used in policy settings for food safety. One reason for this is that the cost of conducting these experiments has led to the generation of estimates for a limited number of product/pathogen combinations. Second, WTP studies do not include external costs (e.g., costs to one's workplace from absenteeism, the costs to the insurance pool for claims made, and costs to family members for caregiving). Ideally, these costs would have to be assessed and added in. Perhaps most importantly, the values generated using these methods are not perceived as being plausible by some. This is because WTP estimates are routinely an order of magnitude higher than cost-of-illness estimates and are less sensitive to risk, duration, or consequences than would be expected. For example, Hammitt and Haninger (2007) found that people were implicitly willing to pay $8300 to avoid 1 day described as follows: "You will have an upset stomach and will feel tired, but these symptoms will not prevent you from going to work or from doing most of your regular activities." At the same time, the authors found that people were not willing to pay significantly more to avoid 3 days with the same symptoms and WTP increased less than proportionally with risk. This may be because biases such as the part-whole problem or yea-saying are at work. As a result, the linear extrapolation of individuals' WTP to reduce risk from a single meal or product in an experimental setting to a global WTP measure is likely to overestimate the value of the risk.

Though not used in a holistic fashion, WTP measures have been used to estimate VSL, which is used to place values on death and lost quality of life in some cost-of-illness studies. Many believe that VSL values are more reliable than most other food safety WTP measures because they are based on revealed preference measures derived from actual market behavior, rather than from an experimental setting.

6.5.2.3 Costs to Industry

Costs to industry are also important for both industry decision-makers and policy analysts. Though generalizable estimates of industry cost are not available, a number of event studies have been published. These studies look at effects on individual companies and industries as a result of food safety incidents.

Tangible costs accruing to companies implicated in food safety events include recalls and litigation. Recalls involve effort, destruction of product, and process changes, all of which are costly (Grocery Manufacturers Association 2010; Todd 1985). Resende-Filho and Buhr (2010) developed a model to assess recall costs and demonstrated how these costs decline significantly with the introduction of traceability into the system. Litigation is also a significant cost for those implicated in an outbreak. Buzby and Frenzen (1999) examined litigation associated with foodborne disease, providing both an overview of the system and estimates from litigated cases. The empirical estimates from this approach are of limited value, however, since, as the authors note, less than 0.01% of cases are litigated.

Perhaps the largest costs to companies implicated in a foodborne disease outbreak or recall are reputation costs. Several studies have found that food safety events can affect the stock prices of the firm implicated long after the outbreak is over (Seo et al. 2013, 2014), though this effect is not universally true for all recalls of tainted product (Salin and Hooker 2001). Researchers have also focused on changes in price and demand for products from implicated industries (Todd 1985; Arnade et al. 2009; Palma et al. 2010) finding significant industry spillover effects in some cases.

Though the literature has a number of event studies focused on costs to industry from foodborne disease recalls and outbreaks, peer-reviewed generalizable estimates are not available. Future research in this area would be beneficial.

6.6 Critical Appraisal of Foodborne Disease Burden Estimates

The preceding two sections have made it clear that there exist various methods for quantifying foodborne disease burden, which inevitably has led to large heterogeneity in published foodborne disease burden estimates (Haagsma et al. 2013). Furthermore, available foodborne disease burden studies may differ in their reference population and reference year and in their scope, i.e., the number and nature of foodborne hazards and corresponding sequelae included. Finally, it should be clear that when the underlying epidemiological and economic data are uncertain, the resulting foodborne disease burden estimates will inevitably also be uncertain. A realistic appraisal and quantification of this uncertainty should therefore be an integral part of every foodborne disease burden assessment.

Table 6.1 Comparison of the methods used to quantify the World Health Organization estimates of the global burden of foodborne disease (Devleesschauwer et al. 2015) and the Scharff estimates of the burden of foodborne disease in the United States (Scharff 2012, 2015)

	WHO/FERG	Scharff
Reference population	Global	United States
Reference year	2010	2017
What is valued	Health impact	Health-related economic impact
Metric	Disability-adjusted life years	US Dollars
Approach	Incidence-based Retrospective Top-down	Incidence-based Retrospective Mixed: Bottom-up/top-down
Number of pathogens included	31	30 pathogens + 1 set of unspecified agents
Inclusion of sequelae	Yes	Yes
Valuation of ill health	Disability weights (Salomon et al. 2015)	Dollar Values for: Medical costs Productivity losses Quality-adjusted life years Value of statistical life
Residual life expectancy	Highest UN projected life expectancy for 2050, with a life expectancy at birth of 92 years for both sexes (WHO 2013)	Age-invariant value of statistical life used
Time discounting	No	Yes: value of statistical life year based on discounted number of life years
Age weighting	No	No
Uncertainty propagation	Yes	Yes

Chapters 7 and 8 present two major efforts to quantify the burden of foodborne disease, i.e., the WHO initiative to estimate the global burden of foodborne disease and the Scharff estimates on the economic burden of foodborne disease in the United States. Table 6.1 compares the key characteristics of both studies.

6.7 Conclusion

A large body of research has developed to examine the burden of foodborne disease. This research is useful for researchers, policymakers, and industry professionals to support risk- and evidence-based food safety decision-making. The major metrics include summary measures of population health that quantify the intangible costs of foodborne disease and monetary metrics that quantify the costs to households, industry, and the public sector. There is increasing attention to include long-term

health outcomes in economic evaluations of foodborne disease. Key uses of these evaluations are to support priority setting and evaluation of the costs and benefits of food safety interventions. As the literature continues to evolve, the efficiency of decisions made will improve, and all stakeholders will be better served.

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