SESSION II

VALUING PAIN AND SUFFERING AND LOST PRODUCTIVITY

Measuring the Pain, Suffering, and Functional Disability Associated with Foodborne Illness

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Abstract

The annual impacts of foodborne illness on the U.S. population can be estimated by multiplying the number of cases of illness at different levels of severity each year by the impact on pain, suffering, and functional disability associated with each case. In this paper, we categorize the methods that have been used to estimate the number of cases of illness into 'top-down' and 'bottom-up' approaches, depending on whether or not they start with observed cases or use dose response relationships to estimate cases. We describe these methods and identify the strengths and weaknesses of each. We then describe a methodology to estimate the impact on pain, suffering, and functional disability of a case of foodborne illness. This method first estimates the number of deaths, number of hospital days, number of restricted-activity days (bed-days or house-days), and types of symptoms associated with each foodborne illness at each level of severity. These health outcomes are then combined into a single measure of disease burden, the quality-adjusted life years (QALY's) lost by associating the disease outcomes with utility weights and duration. The paper concludes by demonstrating how these estimates of the QALY's lost can be used to estimate the impact of food safety regulations on the pain, suffering, and functional disability of the U.S. population.

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Introduction

Foods produced or imported for human consumption in the United States are regulated for safety and quality under as many as 35 different laws implemented by 12 different Federal agencies (GAO, 1990). Some of these agencies have major roles in implementing the food safety laws:

- the Food and Drug Administration (FDA), which is part of the U.S. Department of Health and Human Services;
- the U.S. Department of Agriculture (USDA) Agricultural Marketing Service (AMS), Federal Grain Inspection Service (FGIS), and Food Safety and Inspection Service (FSIS);
- The Environmental Protection Agency (EPA); and
- the National Marine Fisheries Service (NMFS), which is part of the U.S Department of Commerce (GAO 1990).

One of the chief goals of U.S. food safety laws is to reduce the presence of contaminants and adulterants in domestic and imported foods. Consuming foods that contain illegal contaminants or adulterants (e.g., pesticide residues, illegal food dyes, microorganisms) increases an individual's risk of foodborne illness**.**

The probability that a violation of the food safety laws will adversely affect a consumer's health depends on the type of violation, the level of contamination, the food processing pathway before consumption, and the typical portion size for the contaminated product. For example, a food product contaminated with salmonella is more likely to adversely affect a consumer if the level of contamination is high, the product is eaten without further cooking, and the portion size is large. In addition, excess risk of cancer from exposure to pesticides is likely to be related to both duration and intensity of exposure. Biologists and toxicologists have studied these relationships for many years, but it is still difficult to predict accurately the association between ingesting a particular product that violates the U.S. food safety laws and the probability and severity of a particular adverse health effect.

The impact of a particular adverse health effect on the patient depends on the expected symptoms, duration, and effect on functional status. Clearly, the impacts are greater for adverse health effects that have serious symptoms, require extensive treatment, last for a long period of time, and/or cause premature death.

In this paper, we describe methods that are currently used to measure the impacts of foodborne illness on the U.S. population. The focus is on non-monetary measures of these impacts; measures of pain, suffering, and functional disability. These measures include the number of deaths, number of hospital days, number of restricted-activity days (bed-days or house-days), types of symptoms, and the number of disability-adjusted or quality-adjusted life years lost. The annual impacts of foodborne illness on the U.S. population are estimated by multiplying the number of cases of illness at different levels of severity each year by the impact on pain, suffering, and functional disability associated with each case. We also describe how estimates of the population impacts of foodborne illness can be combined with information on the impacts of Federal regulation on violation rates and level of contamination to estimate the benefits of these regulations.

Measuring the Annual Number of Cases of Foodborne Illness

The non-monetary impacts of foodborne illness depend critically on the number of cases of each illness at each level of severity that occur each year. There are two main methods that have been proposed for estimating the number of cases occurring each year in the United States—a "top-down" method and a "bottom-up" method. The "top-down" method is based on the number of cases reported each year to the Centers for Disease Control (CDC) or the number of cases observed in other national surveys. The "bottom-up" method combines estimates of number of exposures to the violative food and of the level of contamination with dose-response relationships.

Buzby et al. (1999) identify several sources of data that can be used for estimating the number of new cases of different illnesses attributable to the food supply each year in the United States. These include data from large national surveys such as the National Ambulatory Care Survey or the Hospital Discharge Survey or the Healthcare Cost and Utilitization Project that give estimates of annual US physician visits or hospital stays by diagnosis. A second data source is the CDC, including annual reporting data and epidemiologic data, such as outbreak investigation and surveillance data. A third data source is case studies of individual cases or groups of cases from the same causative organism that are published in the medical literature. Other data sources include risk models that combine information on the prevalence of pathogens in food and on the size of the infectious dose (i.e., exposure assessments) and dose response relationships to obtain estimates of the distribution of disease severity (i.e., hazard characterization). The first three data sources are generally used to derive "top-down" estimates and risk models are used to derive "bottom-up" estimates.

CDC has recently proposed a methodology that should be used for estimating the number of cases of foodborne illness by severity using a "top-down" approach. Their approach uses an inverted pyramid (see figure 1). In developing this model, CDC augmented the data on reported cases from the Foodborne Diseases Active Surveillance Network (FoodNet) with laboratory, physician, and population surveys from the eight sentinel sites. This top-down approach enabled CDC to sequentially develop several estimates:

- culture-confirmed cases, culture/testing of submitted specimens from the laboratory surveys;
- specimens collected as part of treatment regime from the physician surveys; and
- individuals becoming ill and proportion seeking medical care from the population surveys.

They used these estimates to arrive at an overall estimate of the number of cases of foodborne illness (CDC, 1999). Mead et al. (1999) expands this approach to develop estimates of foodborne illnesses and deaths in the United States.

The CDC approach has been used by Buzby et al. (1999) to estimate the number of cases of several bacterial foodborne diseases. For example, for salmonellosis cases, they use an extrapolation method based on CDC's surveillance system and outbreak data. CDC's surveillance system for salmonellosis includes reporting from the State health departments based

on physician reports as well as reports from State health department laboratories. Since both surveillance data and outbreak data are underestimates of the total number of cases, these data are adjusted upwards.

The upward adjustments in the Buzby study were calculated using multipliers derived by Chalker and Blaser (1988) to account for the underreporting inherent in passive surveillance systems. Three methods were employed by Chalker and Blaser to derive these multipliers. In the first approach, information on carriage rate and median duration of excretion were obtained from the literature and used to calculate an annual incidence of infection for a particular pathogen. The second method uses the passive surveillance system as a starting point then, through a literature review of the sequential steps required for a case to be reported, identifies or develops corresponding estimates of those sequential artifacts resulting in underreporting. The sequential steps that are required for a foodborne illness to be reported to the CDC as defined by Chalker and Blaser (1988) are:

1) The patient must be infected with the organism;
2) The patient must be ill;
3) The patient must consult a doctor;
4) The doctor must obtain a culture;
5) The culture must be positive;
6) The laboratory must report the isolation to the county or State health department;
7) The State health department must report the isolation to the CDC.

The resulting underreporting estimate is multiplied by the number of reported cases to obtain an annual incidence rate. The third approach involves a review of outbreak investigation data (case definition is the presence of acute gastroenteritis) and the ratio of cases initially reported to those cases identified upon completion of the outbreak investigation provides an overall estimate of underreporting. This adjustment is applied to the number of cases reported to the CDC to give the total number of salmonellosis cases in a year. The estimates of annual incidence obtained for *Salmonella* using each of these approaches were 3.7 million, 1.6 million, and 800,000, respectively and this range of estimates was used in the Buzby study.

An alternative data source was used for estimating the number of people and days with symptoms of acute foodborne illness by Golan et al. (2000) in their study of the distributional consequences of improvements in food safety. They used estimates of total days with symptoms of foodborne illness that caused at least half a day of restricted activity or required a physician visit as reported in the National Health Interview Survey. This is a good measure of the total impact of acute foodborne illness on the U.S. population, but the impact of specific diseases cannot be measured and so it would be hard to estimate the impact of food safety regulations targeted at specific diseases on these restricted-activity days. In addition, the estimates from the NHIS may not include the mildest cases of illness, may not include foodborne illnesses with primarily neurological symptoms, and may include illness from non-foodborne causes with similar symptoms. Finally, the NHIS does not include the institutionalized population.

To estimate the losses associated with these cases of salmonellosis (either in terms of cost of illness or in measures of pain, suffering, and functional disability), it is necessary to subdivide them by degree of severity. In the Buzby study, salmonellosis cases are subdivided into four

categories, those who do not seek medical attention, those who visit a physician, those who are hospitalized, and those who die prematurely.

Death rates for salmonellosis in the Buzby study were estimated based on a 1984-85 survey by the CDC that estimated the death rate for reported cases. This was applied to the estimated number of salmonellosis cases. The proportion of people who were hospitalized or who visited a physician were estimated using survey data from the largest recent U.S. outbreak of salmonellosis (Chicago, 1985). This survey provided estimates of the percent hospitalized among those who had symptoms and the percent who visited a physician among those who had symptoms. These percentages were applied to the total number of cases. The number of people who had symptoms but received no medical attention and did not die was then calculated as the difference between the total number of cases and those who received medical attention and/or died.

The main strength of the "top-down" approach is that it is based on observed data. Its main weakness is that no explicit relationship is derived between the number of exposures to the pathogen and the level of contamination and the resulting disease incidence by severity. Thus, using this approach, it is not immediately obvious how to estimate the impact on the number of cases of foodborne illness of regulations that have as their goal a reduction in the number or intensity of exposures to different contaminants. Another weakness of this approach is that it can be used to estimate only the number of cases of acute or chronic illness that can readily be associated with a foodborne cause and thus form part of the CDC surveillance system. Cancer cases from ingested pesticides would not be included, nor would chronic conditions unless they were reported as sequelae to diagnosed acute illness.

An alternative method that has been proposed and is now being used for the estimation of cases of foodborne illness is the "bottom-up" approach. In this approach, the number of cases of foodborne illness of different degrees of severity are estimated based on the:

- probability of foods having a specific violation of the food safety laws and the level of contamination;
- number of people eating these violative foods and their estimated level of exposure to the violation; and
- probability distribution of different levels of severity of illness that result from this exposure.

These three estimation steps will be described below and illustrated using estimates of the number of cases of foodborne illness associated with imported foods and estimates of the number of cases of foodborne illness associated with shell eggs.

The probability of foods' having a specific violation of the food safety laws and the level of contamination will depend on multiple factors including the:

- likely association of the violation with different types of food; and
- conditions of growth and/or preparation, handling, and distribution of the food before it reaches the consumer.

For example, imported foods may have different probabilities of being in violation of the food safety laws both because of different natural growth conditions as well as different local

regulations about pesticide use and food processing. Foods from different parts of the United States may also vary in their likelihood of being violative because of different growing conditions. In a study of imported foods, Martin et al. (1993) assumed that the probability of a given imported foodlot's having a specific violation of the FD&C Act was dependent on the history of violations in similar foodlots and import alerts for that foodlot issued by FDA's Office of Compliance. The results from government testing laboratories were used in the Martin study to estimate the levels of contamination likely to be observed.

A USDA/FDA risk assessment for *Salmonella* Enteritidis (SE) in shell eggs and egg products (USDA, 1998) simulated the probability of contamination of eggs with *Salmonella* Enteritidis based on the total number of egg-producing flocks, the prevalence of SE in these flocks, flock size, and frequency of molting. This resulted in an estimated total number of contaminated eggs produced annually by the U.S. egg industry. For example, using U.S. Agriculture Census data from 1992, a simulation estimated a total of 5,028 flocks, stratified according to flock size (< 20,000, 20,000-49,999, 50,000-99,999, and 100,000 or more), had either high or low SE prevalence. An estimated 22 percent of flocks producing eggs on any given day were assumed to have molted previously, and an increased frequency of SE-positive eggs for 70 days post-molt was assumed. This simulation resulted in estimates that on average, 37 percent of egg-laying flocks were SE-positive, 11 percent of which were high-prevalence flocks, and a mean frequency of 1 in 20,000 SE-positive eggs were produced per year.

The level of exposure to the violation for people eating violative foods depends on the level of contamination, whether or not the contamination is detected before the food is eaten, serving size, handling, and preparation before eating. Whether or not the contamination is detected before the food is eaten will depend on government inspections as well as the consumer's inspection. Martin et al. (1993) estimated the probability that the violative food reached the consumer based on whether or not the food is inspected and/or tested and the accuracy of the instrument used to test the sample. Another relevant factor is the likelihood that a violative substance would not be in the actual sample taken for analysis, even though the food lot did include the violation. Some violations are detected by the consumer before use. An example of this type of violation is filth. Standard serving sizes are used to estimate the amount of the violative food ingested per person. Final exposures to the contaminant are then estimated based on common food preparation practices and the persistence characteristics for the contaminant**.** The exposure assessment of the USDA/FDA SE risk assessment models identifies two key factors that affect the growth of the organism in eggs—cumulative ambient storage temperatures and length of storage as the eggs move from production to processing, transportation, and distribution (see figure 2). For example the relationship between the number of SE at time of use of a shell egg and the number of SE at laying, can be illustrated with the following simplified equation:

Number SE at use (e.g., 10,000) = Number of SE at laying (e.g., 100) x (Weeks to use (e.g., 13) – Weeks to yolk membrane breakdown (e.g., 1)) x Average growth rate per week (e.g., 8.33)

The values for the independent variables in this equation depend on processing time and temperature.

Other factors influencing final human exposure, such as pooling of eggs, institutional versus home use, and the effect of "bacterial kill steps" including common preparation and cooking methods, on levels of contamination are also incorporated in modeling the associated probability and level of contamination in consumed eggs (see figure 3). For example, for an undercooked egg eaten by a single consumer, the relationship between the number of SE in the consumed egg and the number of SE at time of use can be illustrated with the following simplified equation:

Number of SE consumed (e.g., 100) = Number of SE at use (e.g., 10,000) x Proportion of SE remaining in undercooked egg (e.g., 0.01) x Proportion of egg eaten (e.g., 1)

The proportion of SE remaining in the undercooked egg depends on the cooking type and time.

The probability distribution of different levels of severity of illness that result from specific exposures to a violative food product is the final piece of information that is needed in the "bottom-up" approach for estimation of the number of people experiencing foodborne illness. There is likely to be a dose-response relationship between the level of the contaminant and the likelihood that the person exposed will experience different levels of severity of illness. In addition, this dose-response relationship will likely be different for different population subgroups. For example, susceptible populations such as those with conditions that adversely affect the immune system such as HIV/AIDS, diabetes, chemotherapy for cancer, solid organ and other transplants, pregnant women, and children or the elderly, are likely to experience more serious disease at lower exposure levels.

Martin et al. (1993) assumed that the population was a mix of susceptible and non-susceptible people and obtained estimates for the total population only. Potency factors estimated by the EPA for pesticide residues were used to estimate dose-response relationships for exposures to carcinogens. Dose response relationships for the microbial violations were developed through an expert elicitation procedure similar to procedures that have been used in the past by EPA for estimating the health impacts of lead exposure and ozone exposure (Whitfield and Wallsten, 1989; Whitfield et al., 1991). These elicitation procedures were based on a fact sheet for each microbial agent. These fact sheets included all the available data on the dose-response relationship derived from both animal and human studies. The elicitation procedure resulted in estimates of the likelihood of observing both acute and chronic sequelae from the microbial violations at different levels of severity (mild, moderate, severe) for different exposure ranges of the contaminants.

The hazard characterization of the USDA/FDA risk assessment linked exposure to contaminated eggs with a dose-response relationship to model public health outcomes of varying severity. The morbidity and mortality outcomes of concern that were modeled included acute gastroenteritis followed by uneventful recovery without medical care, recovery following a physician visit, recovery following hospitalization, death, and chronic reactive arthritis. These outcomes were estimated for both susceptible and normal populations, and resulting simulations demonstrated more severe outcomes in susceptible populations including a disproportionate contribution to deaths. To demonstrate the differing outcomes in susceptible and normal populations, a simulation was conducted for two hypothetical populations of 100,000 persons, each exposed to 1,000 cfu of the bacteria, one population with normal susceptibility and one with high

susceptibility. The results of the simulation are presented in table 1. Of particular relevance are the differences in case fatality rates between these two populations with mean estimates of 20 and 98 deaths in the normal and highly susceptible populations, respectively.

One of the main strengths of the "bottom-up" approach is that it can be used to estimate the number of chronic sequelae from acute illness and the number of cancer cases attributable to pesticide residues as well as the number of cases of acute illness. This approach also explicitly relates contaminant exposure levels to the number of cases of illness at different levels of severity. Because of this, the health impacts of regulations designed to reduce contaminant exposures, for example through more targeted inspections or through required changes in food processing techniques, can readily be estimated. The main weakness of this approach is that it is not based directly on observed cases of foodborne illness. However, the dose-response relationships are generally derived from observed outbreak data. In addition, estimates of the number of cases derived using the "bottom-up" approach can be validated using surveillance or outbreak data.

Measuring the Pain, Suffering, and Functional Disability from a Case of Foodborne Illness

Most foodborne illness can be subdivided into three categories:

- Acute illness, which occurs with a very short latency period after exposure, has a well-defined duration, and ends in death, complete cure, or transitions into a chronic illness.

- Chronic illness, which has a short or long latency period after either a short or prolonged exposure, may be a sequel to an acute illness, has a prolonged duration, and ends in either premature or natural death.

- Cancer (a subcategory of chronic disease), which has a long latency period after either a short or prolonged exposure, has a short or prolonged duration, and ends in premature death, natural death, or complete cure.

The amount of pain, suffering, and functional disability is very different for these different types of illness. However, it is possible to use a uniform set of measures to describe the patient impacts.

In general, foodborne illness can occur at various levels of severity. Each level of severity affects a person to a different extent. To simplify the analysis, we can consider three levels of severity for all acute and chronic illnesses, mild, moderate, and severe. The severity levels vary in severity and types of symptoms, functional disability, and mortality risk. Cancers can be categorized in terms of extent of spread at first diagnosis in terms of local, regional, and distant. For each severity level of the illness, we can describe the effect of the illness in terms of typical symptoms, mortality rate, duration of treatment and recovery, frequently used medical treatments including time spent in the hospital, and functional status of the patients during treatment and recovery. This information can be derived from the medical literature (e.g., Bryan, 1982; the

Merck Manual). This information can be used to compare the impact of different diseases and levels of severity on proxy measures for pain and suffering (e.g., deaths, symptom days, hospital days) and functional status (e.g., restricted-activity days). For example, based on Bryan (1982) and Cohen (1978) and Mauskopf et al. (1988), we estimated the following patient impacts for salmonella:

- Mild disease—1 bed day and 1 house day with nausea/vomiting, diarrhea, abdominal pain, anorexia, and weakness and a zero risk of mortality;
- Moderate disease—4 house bed days and 3 house days with the same symptoms as for mild plus fever, headache, and prostration and a zero risk of mortality; and
- Severe disease—5-14 hospital days, 3 house bed days, 3 house days, with the same symptoms as for moderate disease plus enteric bacteremia or septicemia and a mortality rate of 13 percent.

To determine the relative burden on patients of different illnesses, it is useful to have a single measure that combines the mortality and various morbidity effects. One measure that is currently used by the World Health Organization (WHO) for estimating the combined impact of mortality and morbidity associated with a specific disease is the disability-adjusted life-year (DALY) (Murray, 1994). The DALY is the product of four factors:

- A disability weight (ranging between 0 and 1 depending on productivity levels with the illness);
- Age at onset and duration of the illness;
- An age weighting function to reflect social value for each year lost (ranging from 0 at birth peaking to 1.5 at age 25 and then declining slowly with age); and
- A discounting function.

The DALY thus measures the impact of an illness in terms of the loss in productivity. It does not include any weighting for pain and suffering.

Another unit frequently used in economic evaluations of health care interventions for measuring the total impact of a disease on the patient in a single unit of measure is the quality-adjusted life-year (QALY). A QALY has been defined by Zeckhauser (1985) as 1 year in perfect health or its equivalent. QALY's lost because of illness are computed as follows: assume the illness lasts for 2 years, during which time the patient is in a health state that is less than perfect and has, for example a utility weight of 0.35. Thus, during the 2 years, the patient experiences only 0.70 QALY. In this case, the QALY loss relative to perfect health is 1.3 QALY's. Gold et al. (1996) suggest for a "reference case" cost- effectiveness analysis that the utility weights used to compute the QALY's lost be derived from community-based surveys and reflect both the financial (e.g., productivity losses) and health status impact (e.g., pain, suffering, and functional disability) of morbidity. The surveys should be designed so that the utility weights reflect people's overall well-being in different health states.

In the most general sense, a health status index converts the concepts of healthy and unhealthy into quantifiable measures of an individual's perception of the impact of their health status on their general sense of well-being. For example, Bush, Chen et al. (1972) classified all possible health states based on the degree of restriction of mobility, social interaction, and physical activity, and the pain or other symptoms a person may experience. The utility weights for these health states were derived using a survey of 867 subjects in California. The subjects were asked

to indicate the relative disutility of different health states, assuming that each health state lasted for only 1 day, that zero was as bad as dying, and that 1 was perfect health. Another set of health states was constructed by Rosser and Kind (1978) using a two-dimensional description of health, based on disability and distress level. There are eight disability levels based on ability to work, social interactions, and mobility. There are four levels of distress. The weights were derived from 70 subjects, and they were told to assume that the health states were permanent and that zero represented death and 1 perfect health. The resulting indexes are very different for the two studies, possibly because of the different time horizons assumed for the surveys. One possible strategy is to use the Bush, Chen et al. (1972) utility weights for estimating the loss in patient well-being for acute illness and cancer and the Rosser and Kind (1978) utility weights for estimating the utility losses for chronic illness.

Based on the disease symptoms and estimates of their duration, any specific adverse health effect can be translated into the time spent in different health states. These health states can have utility weights assigned to them such as those estimated by Bush, Chen et al. (1972) or Rosser and Kind (1978). The health utilities index (HUI) (ref) is a more recent set of health states for which utility weights have been estimated. In order to take the duration estimates for each health state into estimate of the QALY's lost with each illness, assumptions also need to be made about some or all of the following:

- Age at onset (e.g., 30 years);
- Remaining life expectancy (e.g., 46 years);
- Quality of life in the absence of the foodborne illness (e.g., 1);
- Discount rate (e.g., 3 percent);
- Number of different functional states (e.g., hospital days, bed days, and house days);
- Morbidity for those dying from acute conditions (e.g., none);
- Pattern of utility loss for chronic conditions and cancer (e.g., constant utility loss); and
- Life expectancy loss for chronic conditions (e.g., no life expectancy loss).

The adverse health effects for each illness can then be assigned utility weights and durations. For example, a moderately severe case of salmonellosis is estimated to result in an adverse health effect consisting of gastrointestinal symptoms as well as fever and headache that results in about 7 days lost from work. Using the Bush, Chen et al. (1972) measures, we assumed:

- 4 days in bed, in the house, needing help with self care and with symptoms of vomiting, diarrhea, fever, headache, and spells of feeling hot, nervous, or shaky (utility weight = 0.4407); and
- 3 days in the house, no problem walking and performing self care with symptoms of diarrhea and spells of feeling hot, shaky, or nervous (utility weight = 0.6533).

Based on these utility weights and duration, the QALY's lost associated with a moderate case of salmonellosis can be estimated (0.00932**).**

In a recent regulatory impact analysis of food labeling for trans fatty *acids (Federal Register*, 1999), FDA used an estimate of the utility weight for a survivor of coronary heart disease (CHD) of 0.71 (Cutler and Richardson). Their estimate of remaining life expectancy after onset of CHD was 13 years or 8.4 discounted life years (7 percent discount rate). Thus, the loss attributable to a nonfatal case of CHD was estimated to be 0.29 x 8.4 or 2.436 QALY's (*Federal Register*, 1999). The loss attributable to a fatal case of CHD was 8.4 QALY's.

Hypothetical Estimate of the Impact of Federal Regulations

The benefits of different government inspection programs, measured as the reduction in pain, suffering, and functional losses, depends critically on:

- The ability of the inspection program to prevent products that violate food safety laws from reaching the consumer;
- The probability that violations would cause foodborne illness; and
- The impact of the foodborne illness on the patient.

A hypothetical example will illustrate this. For example, assume that there is a choice between inspecting product A for *C. botulinum* toxin or product B for pesticide residue. Second, assume that the proportion of products like A that are contaminated with *C. botulinum* toxin is 0.001 and the probability of product B being contaminated with the pesticide residue is 0.001. Further, we assume that if product A contains *C. botulinum* toxin, there is a 0.25 probability that the person eating it will get a severe case of botulism (QALY loss = 5.96), a 0.25 probability they will get a moderate case (QALY loss = 0.03), and a 0.25 probability they will get a mild case (QALY loss = 0.005), and a 0.25 probability that they will not get ill (QALY loss = 0). For a person eating product B contaminated with the pesticide residue, we assume that there is only a 0.000001 excess probability of getting liver cancer (QALY loss = 10.16) if they eat one serving of the contaminated product. The expected benefits for preventing product A from being consumed are given by:

EBA = (0.001 x .25 x 5.96) + (0.001 x .25 x 0.03) + (0.001 x .25 x 0.005)
= 0.0015 QALY's

The expected benefits for preventing product B from being consumed are given by:

EBB = (0.001 x 0.000001 x 10.16)
= 0.00000001 QALY's

Thus the expected benefits of preventing product B from being consumed are much lower than those of preventing product A from being consumed, even though the value of the utility losses associated with a case of liver cancer is higher than that associated with a case of botulism. However, in this calculation we did not consider that, if the product with *C. botulinum* toxin is consumed, the contamination will be detected and other similar products prevented from reaching the consumer. By contrast, if the product with the pesticide residue is consumed, that contamination will not be detected and more exposures may take place so that value of inspecting for pesticide residues is, in fact, higher than our calculations indicate.

Picking up on the egg example again, the USDA/FDA *Salmonella enteritidis* (SE) risk assessment model was constructed to allow simulation of the effects of different mitigations on total human illnesses due to SE from egg consumption. Sensitivity analysis was conducted as a first step in identifying the possible strategies for reducing the foodborne illnesses associated with SE in eggs. Then selected mitigation strategies chosen and modeled either singly or in

combination to demonstrate their comparative effect on public health outcomes of interest. For example, simulating the reduction of either storage time or ambient temperature by 25 percent at the home, institutional, or retail setting resulted in an estimated reduction in mean number of SE cases by 13 percent and 11.6 percent respectively; while a reduction in both time and temperature resulted in a 21-percent reduction. Reducing prevalence rates of SE in large flocks (> 100,000) by 25 percent resulted in an estimated 15.2-percent reduction in mean illnesses. A combination of mitigations which included 25% reduction in storage time in homes, institutions, and retail coupled with an equivalent reduction in prevalence rates in large flocks resulted in an estimated 32% reduction in illnesses. In the simulated examples, combining several mitigation strategies aimed across the continuum resulted in a greater reduction in mean numbers of cases than any single mitigation strategy alone, implying that broad-based policies may be more effective in achieving a desired improvement in public health.

When estimates of the number of cases of foodborne illness avoided due to a regulation are derived using the "top-down" approach, the reduction in number of cases of illness is generally assumed to be equal to the reduction in pathogen levels attributable to the regulation. For example, Roberts et al. (1996) estimated that a HACCP program for inspection of meat and poultry would reduce levels of pathogens between 10 and 100 percent and would reduce the incidence of the relevant foodborne illnesses by the same percentage amounts.

Conclusions

In estimating the pain, suffering, and productivity impacts of foodborne illness, it is critical to be able to measure both the annual number of cases subdivided by disease severity as well as the impact of each case. There are two methodological approaches for estimating the number of annual cases, the top-down and bottom-up approaches. The advantage of the top-down approach is that it is based on observed cases. The advantage of the bottom-up approach is that one can estimate the number of chronic conditions and cancers attributable to food causes and one can more readily estimate the impact of new regulations on the number of cases. Both methods are currently used by the U.S. Government for evaluations of food safety regulations.

The impact on a patient of each case of foodborne illness in terms of pain, suffering, and productivity loss can be measured by proxies for pain and suffering such as deaths, hospital days, and restricted-activity days and by direct measures of productivity loss such as work loss days. Alternatively, a single measure can be derived that combines these factors into a single measure, either the DALY or the QALY. The QALY is frequently used in the United States in the economic evaluation of programs designed to improve health outcomes. Utility weights representing general well being in different health states are combined with estimates of the duration of those health states to compute the QALY's lost attributable to specific foodborne illnesses.

There are many uncertainties in the measurement of the number of cases of illness and in the measurement of the impact of that illness whatever methods are used. Thus the results of such measurement should be viewed with caution and subject to sensitivity or threshold analyses. Threshold analyses can be especially useful when decisions have to be made despite uncertain

data. Threshold values can be chosen that would result in different decisions, and then scenarios identified that give the threshold values.

If the impact of foodborne illness on pain, suffering, and productivity is measured in QALY's, then the benefits of new regulations can be measured in QALY's gained. These QALY's gained can be compared with the net costs of the regulation (the cost of implementing the regulation minus any direct medical care cost savings because of the reduction in foodborne illness). This comparison can occur by computing a ratio of the incremental cost per QALY gained (Gold et al. 1996). Alternatively, Stinnett and Mullahy (1998) have proposed a method for estimating net benefits from new health care programs by assigned a value to a QALY equal to the benchmark value for cost effectiveness in a society—say $50,000 per QALY. Each QALY gained can be converted into dollars by multiplying it by $50,000. The net costs are then subtracted from these dollar benefits to give an estimate of the net benefits. If the net benefits are positive, then the intervention is acceptable based on the $50,000 per QALY threshold.

Another method for applying a dollar value to a QALY (Mauskopf and French, 1991) is to take an estimate of the value of life and convert it into an implied value for a QALY depending on the average remaining life expectancy for the person in the value-of life study. For example, if the value of a statistical life is $5,000,000 and the discounted life expectancy for the population from which the estimate was derived is 22.5 years, then the value of a QALY is $222,222 ($5 million/22.5). This value can then be used to convert the QALY's into dollar estimates that can be compared to the net costs of the regulation. This method was used by the FDA in its evaluation of nutrition labeling for trans fatty acids.

The measures that we have described in this paper are designed to measure the impact on the patient of foodborne illness in terms of pain, suffering, and lost productivity. Although the impact of foodborne illness on productivity is frequently estimated directly as part of the cost-of-illness approach, pain and suffering have not generally been measured. In this paper, pain and suffering are measured either by proxy with death rates, hospital days, and restricted activity days or directly through the utility weight for different health states. It is critical that these benefits of regulations to reduce foodborne illness be captured in regulatory impact analyses.

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Table 1. "Bottom-Up" Approach Example, Part IV: Severity of Illness Caused by *Salmonella* Enteritidis in Eggs in 100,000 Normal and 100,000 Susceptible Persons Each Exposed to 1,000 SE Organisms Using Dose-Response Functions

Outcomes	Normal population	Susceptible population
Total number ill	65,000	82,000
Recover, no treatment	61,607	76,121
Physician visit, recover	3,146	5,150
Physician visit, hospital, recover	227	631
Die	20	98
Reactive arthritis	1,949	2,458
Percent of U.S. population	78%	22%

Figure 1: CDC Pyramid for "Top-Down" Estimates of the Annual Number of Cases of Foodborne Illness

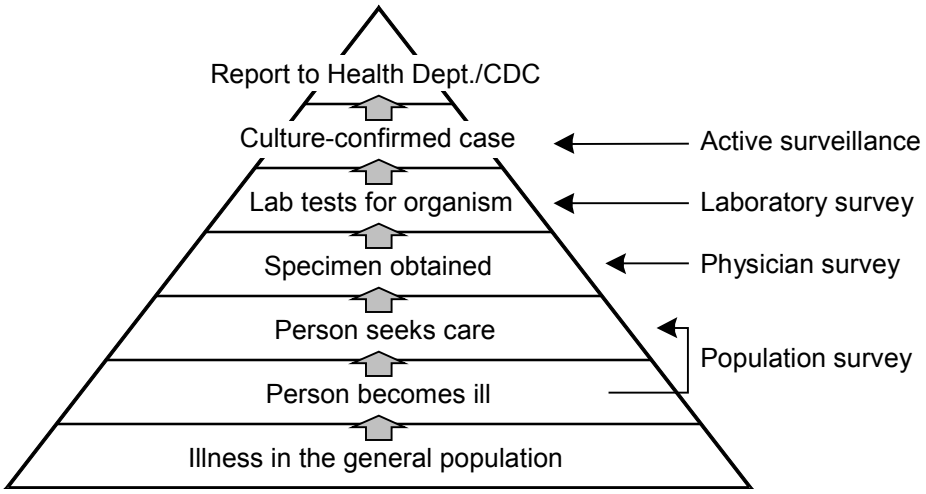

Figure 2: Number of *Salmonella* Enteritidis in Each Egg at Time of Use Using "Bottom-Up" Estimation Model

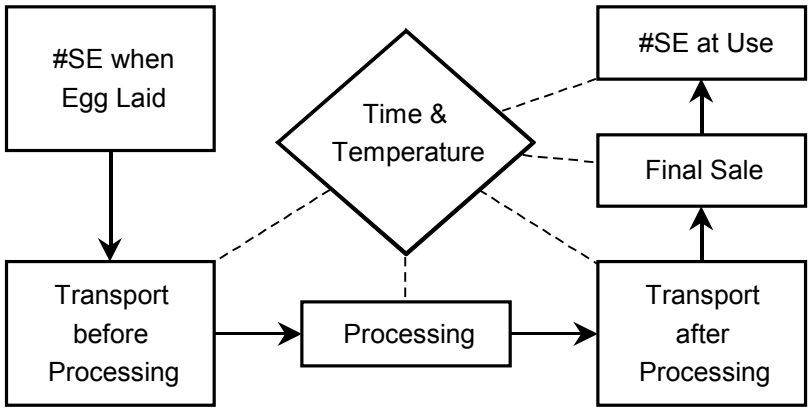

Figure 3: Number of *Salmonella* Consumed in Undercooked Egg Using "Bottom-Up" Estimation Model