Pergamon

Food Policy 24 (1999) 605–623

FOOD POLICY

www.elsevier.com/locate/foodpol

Benefits and costs of food safety regulation

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Abstract

This paper begins with a review of the concepts and methods that can be used to quantify the benefits and costs of food safety regulations. On the cost side, where research is only beginning to emerge, this paper also provides an analytical framework for measurement of the costs of statutory regulations in the form of design and performance standards. This paper also discusses the use and limitations of currently available benefit and cost information for quantitative regulatory impact assessment, using the assessment of the mandatory HACCP and pathogen reduction regulations in the United States as an example. The paper concludes with suggestions for future research on quantifying benefits and costs of food safety regulations.

Keywords: Benefits; Costs; Food safety; Regulation; Regulatory impact assessment

Introduction

Until recently, food safety regulation was the domain of food technologists and government regulators; neither economic efficiency nor the possible distributional effects of regulations played a role in the design of most legislation or regulations dealing with food safety. The convergence of two trends has begun to change the way food safety legislation is written and the way food safety regulations are designed and implemented. First, consumer concerns have increasingly shifted from the availability of food to food quality, including attributes such as taste, nutritional content, and safety. Second, since the 1980s, governments have been striving to improve the effectiveness, efficiency and transparency of regulations, both to reduce budget costs

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0306-9192/99/$ - see front matter
PII: S0306-9192(99)00068-8

of government programs and to improve the efficiency and international competitiveness of their economies (Jacobs, 1997). The upshot of these convergent trends has been the progressive implementation of regulatory impact assessment (RIA) in public decision making. Benefit–cost analysis is the principal analytical tool of quantitative RIA.

Only recently has quantitative RIA begun to be applied in the food safety regulation arena. Major new regulations are being implemented in the United States requiring the use of Hazard Analysis Critical Control Points (HACCP) methods in combination with performance standards for control of pathogens in fish, seafood, and meat and poultry slaughter and processing plants. Federal agencies prepared quantitative RIAs for the proposed regulations, as required by Executive Orders under the Reagan, Bush, and Clinton administrations.

The purpose of this paper is to provide an overview of the literature that can be used to model and measure the benefits and costs of food safety regulations such as new HACCP regulations in the United States. On the cost side, where research is only beginning to emerge, this paper also provides an analytical framework for measurement of the costs of statutory regulations in the form of design and performance standards. This paper also discusses the use and limitations of currently available benefit and cost information for quantitative RIA, using the recent RIA of the mandatory HACCP and pathogen reduction regulations in the United States as an example. The paper concludes with an assessment of directions for future research on quantifying benefits and costs of food safety regulations.

Regulatory impact assessment and food safety

Demsetz (1969) laid the intellectual foundations for regulatory impact assessment based on benefit–cost analysis. He was critical of the view that regulation was needed to correct every perceived market imperfection, and insisted that policy should be guided by an assessment of "which alternative real institutional arrangement seems best able to cope with the economic problem..." It is increasingly recognized by policy makers and the public that the existence of market failure does not mean that government regulations can necessarily improve upon the unregulated market, especially when one considers the positive role that market mechanisms such as liability and product quality reputation play in the provision of safe products, including foods. Moreover, even when some form of regulation can yield positive net benefits, experience in the field of environmental regulation has shown that the costs of regulations can depend crucially on how the regulations are designed. Additionally, knowledge of the distributional consequences of regulations, even if designed efficiently, can affect their social desirability and their political feasibility.

The earliest attempts at regulatory impact assessment appear to be the work begun under the Ford and Carter administrations in the 1970s to assess the impacts of regulations on inflation (Morall, 1997). In 1982 President Reagan issued an Executive Order requiring that major new regulations pass a benefit–cost test (Smith, 1984). This Executive Order was renewed by both Presidents Bush and Clinton with some

modifications. The US Congress also passed the Government Performance and Results Act in 1993 which requires federal agencies to review and justify their programs in terms of quantifiable performance indicators, which could include benefit–cost assessments. Until these actions were taken, federal agencies were not required to demonstrate that health and safety regulations produced benefits in excess of costs, except in a few special cases such as pesticide regulation. Responding to increased demands for assessment of its programs, the US Department of Agriculture instituted an Office of Regulatory Assessment and Cost–Benefit Analysis in 1995.

The United States government has taken the lead in making regulatory impact assessment, based on benefit–cost analysis, a part of the policy formation process. Present US policy requires an assessment of all major regulations, i.e. regulations likely to have an impact of at least $100 million (Morall, 1997). Many other countries have implemented some form of regulatory review, and governments in all OECD countries have agreed to use some form of RIA, but most do not yet require benefit–cost analysis (Jacobs, 1997).

Economists have continued to play the role as advocates of efficiency in regulation, inspired initially by the sizeable inefficiencies of certain environmental and health regulations in the United States (Hahn and Hird, 1991). Following this trend towards application of benefit–cost criteria to federal regulations, economists have advocated principles for benefit–cost analysis of environmental, health and safety regulation (Arrow et al., 1996).

Antle (1995, 1996) argues that regulation in the food safety arena has not been based on efficiency criteria, and presents principles for efficient food safety regulation based on benefit–cost concepts. Following the literature on environmental regulations such as clean air legislation (Council of Economic Advisers, 1990), Antle also argues that as a general principle, performance standards are to be preferred to design standards on efficiency grounds. Interestingly, the mandatory HACCP regulations being implemented by US government agencies (the Food and Drug Administration (FDA) of the Department of Health and Human Services, and the Food Safety Inspection Service (FSIS) of the US Department of Agriculture) appear to have elements of both design standards and performance standards. Public statements by FSIS declare that the agency's goal is to replace design standards with performance standards.

These recent regulatory changes by FDA and USDA have spawned a literature on the benefits and costs of these regulations (McDonald and Crutchfield, 1996; Roberts et al., 1996; van Ravenswaay and Hoehn, 1996; Crutchfield et al., 1997; Klein and Brester, 1997; Antle, 1998b; and various chapters in Unnevehr, 1999).

Benefits of food safety regulation

The benefits of food safety regulation are reductions in risks of morbidity and mortality associated with consuming foods that could be contaminated with microbial pathogens and other hazards. Theoretical analysis of the benefits of food safety regulations is based on the economic approaches that have been developed to model and

value reductions in health risk. Berger et al. (1994) provide an overview of the general literature; van Ravenswaay (1995) provides a review of theory and methods for valuing food safety; and Bockstael et al. (1994) provide a critical review of the literature.

At the theoretical level, Antle (1998a) shows that an individual's demand for risky foods depends on income, prices, the objective risk associated with the food, the perceived risk of the food, the likelihood that an individual will be exposed to the risk, and the individual's susceptibility to the risk. It follows that the market demand functions for foods that pose a health risk depend on income and prices, and also on the factors that determine how individual characteristics, such as risk perceptions and susceptibilities, are distributed in the population of consumers. These factors are likely to include demographics (age, education, etc.) and policy (product labeling, availability of food safety information).

Theoretical models can also be used to derive expressions for willingness to pay (WTP) for reduced risk of morbidity and mortality. These models show that WTP for reduced morbidity risk can be decomposed into four basic components: the costs of treating the illness; forgone income from lost work time; costs of averting illness; and the disutility of illness (Harrington and Portney, 1987; Cropper and Freeman, 1991; Berger et al., 1997).

Several approaches to valuing health risks have been developed. The most basic, and most often used approach to value morbidity is to estimate the cost-of-illness (COI) (Kenkel, 1994). The COI approach is based on the measurement of the medical costs of an illness plus the forgone market income due to lost work time. The COI approach is intuitively appealing to non-economists and empirically tractable, but it lacks a solid theoretical foundation and has obvious shortcomings. The COI approach is not equivalent to WTP, and although it can be shown to be a lower bound on WTP for reduced morbidity under certain conditions (Harrington and Portney, 1987), it is not necessarily a lower bound in general when both morbidity and mortality are considered (Berger et al., 1987). Nor is COI necessarily a good approximation to WTP, and one can identify a number of situations in which the use of COI could seriously bias a benefit–cost analysis (Kenkel, 1994). Empirical evidence shows that mean WTP in a sample does typically exceed mean COI for certain health symptoms (Kenkel et al., 1994).

Risk of death can be valued using the value of a statistical life (Landefeld and Seskin, 1982; Cropper and Freeman, 1991; Viscusi, 1993). Various methods have been used to infer the value individuals place on risk of death, such as discounting forgone income, and using wage differences between occupations with different risks. The different methods produce a wide range of values of a statistical life, from less than $1 million to tens of millions of dollars. None of the studies in the literature has utilized avoidance of death caused by food borne illness. An unexplored issue is whether the values derived from a non-food context necessarily transfer to the food risk case.

Empirical studies of the value of food safety

There is a sizeable literature on measuring the value of food safety, including studies of the cost of illness and death, and survey and experimental methods for measurement of willingness to pay. Cost of illness and death studies are reviewed in Council for Agricultural Science and Technology (1994), and were used as the basis for regulatory impact assessments (FSIS, 1996). Most studies put the total annual cost of illness associated with food borne disease in the United States in the range of $5–$10 billion, although some studies obtain values in the range of $20–$30 billion annually by using higher values for a statistical life or by assuming larger numbers of illnesses and deaths (Crutchfield et al., 1997).

A number of studies have estimated the willingness to pay for food safety. Some of these studies use contingent valuation surveys (e.g. Lin and Milon, 1995; Buzby et al., 1995; van Ravenswaay and Wohl, 1995). Another group of studies has utilized contingent valuation methods combined with experimental methods (Fox et al. 1995, 1998; Wessells and Anderson, 1995). While this literature should in principle provide the basis for benefit valuation in regulatory analysis (as discussed in the fifth section) it is difficult to make use of these studies because they cover different consumer populations and measure willingness to pay for specific risks that are not generalizable. Several studies use socioeconomic variables to attempt to explain variation in valuations (income, age, gender, attitudinal characteristics, education, etc.), with mixed results. Several studies also find substantial regional variation in willingness to pay. Shin et al. (1992) attempt to extrapolate their values to the US population and find that aggregate willingness to pay could be several times larger than cost of illness estimates.

Another difficulty with the application of contingent valuation methods to regulatory analysis is the controversy surrounding their validity (e.g. Hausman, 1993; Portney, 1994). Until these values are shown to be more reliable, government authorities may not want to use them or may not be allowed to use them by law (see Belzer and Theroux, 1995).

Cropper (1995) observes that, despite the shortcomings of the cost of illness concept in valuation of health risk, cost of illness studies remain important to valuing the risk of food borne disease for two reasons. First, the cost of illness approach can account for important details, such as the various consequences and different severities of disease that are possible. Second, medical costs are often not borne by the respondents in a contingent valuation study and will need to be added to obtain an accurate estimate of the total amount that society is willing to pay.

Costs of food safety regulation

The costs of food safety regulation include the industry's cost of compliance, borne by both industry and the consumers of their products, as well as administrative costs borne by taxpayers and the deadweight loss associated with taxation. The focus here is on the plant-level costs of compliance with regulations. If these costs are

large enough to affect the market price, then a complete analysis would need to consider market equilibrium effects of the regulations. The administrative cost of regulation also should be included in the overall regulatory impact assessment. That component of the cost is routinely measured by the government agencies who have the regulatory responsibility and is not discussed further here.

Analysis of the costs of food safety regulation begins at the level of the production process, i.e. at the plant level. For convenience, this discussion makes the simplifying assumption that each firm operates a single plant; for some purposes, such as analysis of market structure and competition, the distinction between plants and firms should be considered. Also, this discussion focuses on the costs of statutory regulation taking the form of either performance standards or process standards. Analysis of other regulatory approaches, such as liability or product certification, would involve considerations beyond the structure of the firm's production technology.

Analysis of food safety requires consideration of production models that allow for quality-differentiated products (Antle, 1998b). Consider a firm operating a single plant and producing a single product, y, with quality q. Here q is treated as a scalar, whereas in most cases food quality spans several dimensions such as taste, nutritional characteristics, and safety. We return to this point below. Further, define the firm's production inputs as the vector $\mathbf{x}$ and capital stock k. The general form of the firm's production function is $f(y,q,\mathbf{x},k)=0$, where $f(\bullet)$ satisfies the standard properties of multiple output technologies (Chambers, 1988). In this form, quality can be interpreted as a second output of the production process, and the literature on multiple output technologies can be utilized.

If the production technology is non-joint in inputs then separate production functions can be defined for y and q. Typically, some aspects of quality control, such as temperature controls, cleaning of equipment, and removal of contaminated product, are integrated into the production process, while other aspects such as record keeping and testing are separate from the production process. Therefore, production technologies for quality-differentiated products take the form of multi-output processes that are joint in production inputs and some quality control inputs, but may also be non-joint in inputs that are used strictly for quality control. Thus, the cost function for production processes with quality control take the general form

$$c(y,q,\mathbf{w},k,\alpha,\beta,\gamma)=vc(y,q,\mathbf{w},k,\alpha)+qc(q,\mathbf{w},k,\beta)+fc(k,\gamma), \quad (1)$$

where total cost $c(\bullet)$ is composed of a component of variable cost $vc(\bullet)$ that is joint in conventional production inputs and some quality control inputs, a component of variable cost $qc(\bullet)$ that is non-joint in conventional inputs and certain quality control inputs, and a conventional fixed cost component $fc(\bullet)$ that is independent of both output and quality. Here α, β and γ are parameters of the respective components of the cost function. In this formulation, the function $vc(\bullet)$ captures the jointness of quality control and production, whereas $qc(\bullet)$ captures quality control costs that are non-joint in inputs. Cost is generally non-decreasing in quality, hence $\partial vc/\partial q \geq 0$ and $\partial qc/\partial q \geq 0$.

Measuring costs of performance standards and design standards

Performance standards impose the requirement that a firm must achieve a specified level of product quality, q_p, without specifying the technology that the firm must use to achieve the standard. In most cases a firm will need to modify its process to achieve the mandated quality standard efficiently. Modifications of the existing plant and equipment or other operating characteristics of the plant would result in a change in the parameters of the cost function; it may also be necessary to invest in new plant and equipment, changing the firm's capital stock. Let the firm's modified production process under the performance standard be represented by the parameters α_p, β_p, and γ_p and the capital stock k_p. The change in cost of production induced by compliance with the performance standard is then:

$$\Delta c(y,q_0,q_p,\mathbf{w},k_0,k_p,\alpha_0,\beta_0,\gamma_0,\alpha_p,\beta_p,\gamma_p)=\Delta vc(y,q_0,q_p,\mathbf{w},k_0,k_p,\alpha_0,\alpha_p) \quad (2)$$
$$+\Delta qc(q_0,q_p,\mathbf{w},k_0,k_p,\beta_0,\beta_p)+\Delta fc(k_0,k_p,\gamma_0,\gamma_p),$$

where

$$\Delta vc(y,q_0,q_p,\mathbf{w},k_0,k_p,\alpha_0,\alpha_p)\equiv vc(y,q_p,\mathbf{w},k_p,\alpha_p)-vc(y,q_0,\mathbf{w},k_0,\alpha_0)$$
$$\Delta fc(k_0,k_p,\gamma_0,\gamma_p)\equiv fc(k_p,\gamma_p)-fc(k_0,\gamma_0).$$

Note that to estimate the cost change in Eq. (2), both pre- and post-regulation data are needed to estimate the cost functions and the capital stocks in order to make accurate estimates of the cost of the regulation. Alternatively, it can be assumed that technology or capital stock are not changed to meet the performance standard, in which case ex ante data alone can be used to estimate the cost of the performance standard.

A strict process or design standard specifies the technology that a firm must use, without specifying the outcome that must be achieved as in a performance standard. A process standard will generally require firms to modify their plant and equipment and the production process to meet the government standards defined as k_g, α_g, β_g,γ_g. However, in the case of the process standard, the new level of product quality that is achieved, q_g, is not specified in the regulation. Thus, following the definitions in Eq. (2) the process standard's cost is given by

$$\Delta c(y,q_0,q_g,\mathbf{w},k_0,k_g,\alpha_0,\beta_0,\gamma_0,\alpha_g,\beta_g,\gamma_g)=\Delta vc(y,q_0,q_g,\mathbf{w},k_0,k_g,\alpha_0,\alpha_g) \quad (3)$$
$$+\Delta qc(q_0,q_g,\mathbf{w},k_0,k_g,\beta_0,\beta_g)+\Delta fc(k_0,k_g,\gamma_0,\gamma_g).$$

Whereas a performance standard establishes a level of quality or safety q_p that must be achieved by every plant, the level of safety q_g achieved by a design standard will vary across plants because each plant is actually designed and operated differently.

Because a performance standard allows plant managers to tailor quality control to fit their particular plant's design, economists often presume that the cost of the performance standard will be less than the cost of the design standard in achieving a given level of safety (e.g. Antle, 1995). In principle, this would appear to be a

testable hypothesis. However, this is difficult to do with observed data because typically all firms in an industry at a given point in time are subject to the same type of regulations, whether they be design or performance standards. Likewise, comparisons across industries with different types of regulations would be difficult to interpret because a meaningful comparison would need to hold constant safety and other factors.

Regulations may also combine elements of both performance and process standards, as the in the case of the US Department of Agriculture's recently implemented meat inspection regulations that combine a mandatory quality control system with performance standards for certain microbial contaminants. In this case, the cost is measured as in (3) with the mandated quality level q_p replacing q_g. In addition, quality normally spans several dimensions, including one or more safety dimensions. An example is the recent meat and poultry regulations in the United States that involve design standards in the form of standard sanitary operating procedures. These regulations also put in place performance standards for *Salmonella* and generic *E. coli* as a way to verify the performance of HACCP. Thus, an accurate representation of these regulations would require a model with a quality *vector* for a combined design standard and performance standard, with some elements of this vector representing the safety level achieved with the design standard and some elements representing the quality level required by the performance standard.

Other factors determining regulatory efficiency

The overall efficiency of either a design standard or a performance standard also depends on what level of food safety a regulation is attempting to achieve. While economists argue that performance standards are likely to be more efficient than design standards in achieving a given level of safety, the crucial decision of what level of safety is socially desirable, given the benefits and costs of attaining them, still remains to be determined. Either a too lax or a too stringent goal will be inefficient (will entail social loss), even if it is achieved in a cost-effective way.

Another key factor that needs to be incorporated into the above discussion of regulatory costs is the dynamics of the adjustment process. The above discussion compares design standards and performance standards in a static sense of before and after regulation. In reality, of course, firms implementing either design or performance standards will require time to learn how to incorporate new quality control methods efficiently. Therefore, the time path that regulations follow may have important implications for their implementation costs. For example, in the implementation of the USDA's HACCP and pathogen reduction regulations discussed below, small plants were given several years longer than larger plants to implement HACCP. This gradual phasing in of the HACCP regulations may significantly reduce the short-term adjustment costs associated with the regulations for these smaller plants.

The issue of dynamic adjustment also has implications for the ex ante estimation of regulatory costs. Economic models that do not incorporate the learning that firms go through as they adopt new quality control procedures may overestimate the

impacts that regulations have on costs of production after such adjustments have taken place.

Methods for estimating plant-level regulatory costs

The preceding discussion shows how the costs of performance and design standards can be measured, given knowledge of the plant-level cost of production before and after the regulations are implemented. Until recently, however, there was a dearth of literature on the cost structure of meat and other food processing plants and on potential costs that food safety regulations might impose on plants. Three approaches have been used recently to estimate regulatory costs, described here as the accounting approach, the economic-engineering approach, and the econometric approach.

Accounting approach

The FDA and the FSIS estimated the costs of mandatory HACCP regulations for their Regulatory Impact Assessments using an accounting approach (FDA, 1994; FSIS, 1996). This type of approach has also been used in several recent studies of HACCP implementation (e.g. Cato and Lima dos Santos, 1998; Colatore and Caswell, 1999). In this approach, the effects of regulations on plant labor requirements and capital stock are identified and calculated, without estimating a parametric representation of the cost function. Data from pilot programs or from surveys of plants that have adopted quality control systems are used to construct estimates of the costs of the components of the quality control system, such as higher labor costs needed to operate a HACCP system, or additional capital requirements for process controls.

The accounting approach is operationally straightforward and can accommodate details of quality control systems. However, there are several methodological shortcomings. First, observations of a small number of plants are not likely to provide estimates of the industry average costs of production or of the heterogeneity among plants in the population (e.g. differences between small and large plants, or between older and newer plants). Second, the accounting approach is unable to measure the effect of the regulations on the overall operating efficiency of a plant, hence, the effect of quality control on cost of production represented by the term $\Delta vc(\bullet)$ in Eqs. (2) and (3) is not counted.

Economic-engineering approach

Prior to the development of duality-based econometric models for production analysis, the economic-engineering approach was widely used. French (1977) provides an overview of the economic-engineering approach to the analysis of the cost structure of processing operations. In this approach, detailed engineering data are combined with data on input costs to construct a quantitative model of the production process. This process-based model of the plant's production function can be used to derive a parametric cost function. This approach provides a detailed picture of a plant's production process, but it is costly to implement for each plant studied. For an analysis of the costs of regulation in an industry with many distinct plants, the

costs of using this approach for a large number of plants is usually prohibitive, so a small number of 'representative' plants is typically modeled. Consequently, like the accounting approach, the economic-engineering approach fails to capture the heterogeneity that is typical of many industries and may not provide cost information that is representative of the industry.

A recent study by Jensen and Unnevehr (1999) utilized the economic-engineering approach to estimate the costs of carcass rinses, sanitizing sprays, steam vacuums and water pasteurizers in pork processing. They found that the cost function is upward sloping for microbial pathogen reduction, thus verifying the hypothesis that cost of production is increasing in product safety (defined as absence of pathogens). They also found that some interventions or combinations of interventions are more cost effective than others. The costs of these specific interventions were found to be on the order of less than 2% of processing costs. These cost estimates can be interpreted as corresponding to the term qc(•) in Eq. (1). If the production process is non-joint in output and safety, then these results can be used to estimate the impacts of these technologies on total cost of production. However, if these processes affect the speed of slaughter lines or other aspects of plant operation, they would need to be treated as joint with the overall production process and the effect of quality control on the term vc(•) would also need to be measured to obtain an accurate estimate of the impact on total cost of production.

Econometric approach

Econometrically estimated cost functions also can be used to measure the potential costs of food safety regulations. While these models usually cannot provide the level of process detail that is possible with accounting or economic-engineering models, they provide other advantages. Econometric methods are able to utilize data sets, such as the Census of Manufactures data maintained by the United States Bureau of the Census, that are representative of the industry. Being based on the observed behavior of plants in the industry, econometric models reflect actual production choices of plant managers. Econometric methods also provide a statistical basis to test hypotheses related to behavior and production structure, such as the hypothesis that the technology is joint in output and product quality.

At the time of this writing, several econometric studies have been reported in the literature. Klein and Brester (1997) estimated a translog cost function to examine the effects of USDA's 'zero-tolerance directive' on the cost of production in beef slaughter plants. This directive requires plants to remove all identifiable feces, ingesta and milk found on carcasses before they are washed. The Food Safety and Inspection Service of USDA instructed its inspectors to slow slaughter lines if inspection procedures could not be adequately performed (Reed, as cited in Klein and Brester, 1997), thus demonstrating that the production process is joint in output and safety (assuming the procedures for removing fecal matter actually reduce pathogens). Klein and Brester estimated a translog cost function based on the general cost function specification c(y,**w**,R) where y is output, **w** is a vector of prices of capital, labor, cattle, energy and other inputs, and R is a measure of regulatory compliance costs. Their data consisted of 70 observations obtained from the financial statements for

five plants of a major US beef packing firm, covering semi-annual periods from November 1988 through May 1995. Regulatory compliance costs were calculated as the amount of down time on production lines caused by complying with the zero tolerance directive since its enforcement in March 1993. The estimated model strongly rejected the null hypothesis of non-jointness in output and safety. Assuming their results are representative of the industry, Klein and Brester estimated the costs of the zero tolerance directive for meat plants to be in the range of $3 billion. They also noted that plant managers expect these costs to fall over time as they learn how to implement the regulations more efficiently.

Antle's (1998b) study of US beef, pork and chicken slaughter and processing plants was designed to estimate the variable cost function vc(•) in Eq. (1) and test for the jointness of output and quality, using plant-level data from the US Census of Manufactures. To account for the fact that product quality is not observable, Antle showed that the cost function can be estimated by combining a hedonic model with a cost function model, under the assumption of a competitive product market structure. The cost functions reject the hypothesis that output and quality are non-joint, and show that cost of production is increasing with product quality, implying that more stringent quality regulations (such as food safety regulations) will result in higher costs of production. The data were also stratified into small and large plant size groups. The results showed that the potential regulatory costs per unit faced by small beef plants were similar to the costs for large beef plants. Antle's analysis indicates that the increased production costs associated with higher quality standards lead to much higher estimates of the cost of regulation than the estimates in the USDA's regulatory impact assessment of the recent HACCP and pathogen reduction regulations.

Ollinger (1998) also used the US Census of Manufactures data to estimate total cost functions for beef, pork, and miscellaneous meat products of the form c(y,**w**,D), where y is output, **w** is a vector of factor prices, and D is the number of plant deficiencies, i.e. the number of violations of sanitary regulations noted by the Food Safety Inspection Service. These plant deficiencies are interpreted as a proxy for the safety attributes of a plant's products, in the sense that a lower value of D is interpreted as indicative of a safer product. Ollinger also found that cost of production was decreasing in deficiencies, again verifying that higher product safety is associated with a higher cost of production. Note that one problem in using variables such as plant deficiencies as a proxy for product safety is that these deficiencies are not necessarily related to pathogen levels in products. Thus, the use of deficiencies as a proxy for product safety may result in an underestimate of regulatory cost.

Benefit–cost analysis of food safety regulations: HACCP and pathogen reduction in the United States

Recent regulatory impact assessments in the United States utilized the kinds of benefit and cost data discussed in the preceding two sections. This section discusses procedures and assumptions required for such an analysis, using the recent regulatory

impact assessment conducted by the Food Safety Inspection Service (FSIS) of the US Department of Agriculture as an example.

Benefit–cost analysis methods and related methods for regulatory decision making have been discussed in detail elsewhere (e.g. Boardman et al., 1996; Viscusi, 1997). The conventional form of the benefit–cost analysis is to compute the present discounted value of benefits and costs associated with the regulatory intervention. The benefits are derived from the reductions in food borne illness and death associated with the regulation, whereas the costs are based on the changes in cost of production in the industry, as well as costs associated with regulatory oversight. The issue of discounting in benefit–cost analysis has been discussed at length in the literature and will not be elaborated here. In the United States, the Office of Management and Budget advises federal agencies to utilize a 7% rate. Suffice it to say that the magnitude of measured net benefits is inversely related to the chosen discount rate. When benefits and costs are experienced at different points in time, discounting can have a significant effect on measured net benefits. In such cases, it is prudent to subject benefit–cost analysis to a sensitivity analysis in which net benefits are calculated over a range of plausible discount rates.

The FSIS regulatory impact assessment concluded that over a 20-year time period the benefits of implementing HACCP and pathogen reduction regulations would range from $0.99 to $3.69 billion annually (1995 dollars) if the regulations were completely effective in eliminating the risk of illness and death from four major pathogens. Discounted over a 20-year time horizon at 7% (the rate typically used by US government agencies for regulatory impact assessment), these benefits range from $7.13 to $26.59 billion. The costs of sanitation procedures, pathogen sampling, and HACCP plan development and operation were estimated to be on the order of $100 million annually, and the discounted present value of all costs was estimated to be in the range of $1–1.2 billion over a 20-year period. The FSIS analysis concluded that the net benefits of the regulations were likely to be positive for all levels of regulatory effectiveness in excess of about 16%. Summaries of the assessment can be found in Roberts et al. (1996) and Crutchfield et al. (1997).

Benefit calculations

The discussion in the third section showed that there is a substantial literature on the costs of illness associated with food borne pathogens, and there is an emerging literature on the willingness to pay for safe foods. This literature can be combined with other scientific data to estimate the benefits that could be derived from a regulation that increases food safety. To illustrate, consider the following calculation for annual benefits B (measured in dollars) that could be performed for a regulatory impact assessment:

$$B = e \cdot p \cdot n(c \cdot s \cdot f_s + v \cdot d \cdot f_d). \tag{4}$$

Here e is the effectiveness of the regulation in preventing the incidence of the disease associated with a foodborne pathogen; p is the percent of food borne illnesses associated with food; n is the size of the population; c is the cost of illness (in dollars)

associated with that disease, or the average willingness to pay to avoid that illness; v is the value of a statistical life (in dollars); s and d are the observed frequencies of illness and death in the population associated with this pathogen; and f_s and f_d are expansion factors for illness and death that translate observed frequencies of illness or death into estimated rates for the population. These expansion factors are used to account for the fact that numbers of illnesses and deaths associated with food pathogens are typically under-reported. These annual benefits can be capitalized over some time period using a suitable discount rate.

The regulatory impact assessment carried out by FSIS applied Eq. (4) to each relevant pathogen (see, e.g. FSIS, 1996, Table 5). While Eq. (4) is straightforward to apply, given estimates of the parameters, the assumptions required to derive it are difficult to justify on scientific grounds.

First, this equation represents a proportional relationship between pathogens in meat products and food borne illness, where the factor of proportionality e is the effectiveness of the regulation in reducing pathogens in meat products. This proportionality assumption was made in the regulatory impact assessment conducted by FSIS and was strongly criticized in public comments. In its final regulatory impact assessment, the FSIS stated, "FSIS has not viewed proportional reduction as a risk model that would have important underlying assumptions that merit discussion or explanation. For a mathematical expression to be a risk model, it must have some basis or credence in the scientific community. That is not the case here. FSIS has acknowledged that very little is known about the relationship between pathogen levels at the manufacturing stage and dose, i.e. the level of pathogens consumed." (FSIS, 1996, pp. 38,945–38,946).

To accurately represent the relationship between pathogen levels and health, a model would need to account for the factors affecting food production and distribution, as well as food demand, exposure to pathogens, and dose–response relationships. Theoretical economic models show that income, education, age, and other demographic characteristics of individuals affect their food consumption behavior, exposure, and vulnerability to certain pathogens (Antle, 1998a). These considerations imply that the benefits of a regulation are not likely to be directly proportional to the effectiveness of the regulation in reducing the prevalence of pathogens in food. An example of a more complete risk assessment is the model developed for *Salmonella* Enteritidis in shell eggs and egg products (FSIS, 1998). This model includes components for production, distribution, food preparation and consumption, and public health outcomes.

Whether or not the relationship between pathogens and health is proportional, a critical piece of information required for benefit estimation is the effectiveness (e) of the regulation in reducing pathogens in foods. When new approaches to regulation are being implemented, such as the use of mandatory HACCP, there is little experience or data upon which to base an estimate of regulatory effectiveness. This was true in the case of the HACCP regulations implemented in the United States. In its preliminary regulatory impact assessment, FSIS assumed that the regulations would be 100% effective in eliminating foodborne pathogens. Upon being criticized for this assumption, in its final assessment FSIS assumed a range of effectiveness between 10

and 100% and calculated the minimum level necessary to generate net benefits. According to FSIS, "A general comment related to the effectiveness issue stated that while HACCP remains an interesting theoretical concept, it is still only a concept that has never been tested on a meaningful scale under actual meat establishment conditions, and never proven to significantly improve the microbial quality of the finished product. FSIS recognizes that the actual effectiveness of the final requirements in reducing pathogens is unknown at the present time." (FSIS, 1996, p. 38,968).

A third key assumption regards the expansion factors used to apply the valuation data to the population at large. There are some scientific data for the estimation of unreported illnesses and deaths, although comprehensive estimates of the number of human illnesses caused by many food borne microorganisms are unavailable (Council for Agricultural Science and Technology, 1994). The interpretation of the data that are available is controversial (Wilson, 1998). Based on two studies of illnesses and deaths associated with food borne disease, recent estimates for the United States are from 6.5 to 33 million annual cases of acute illness caused by food borne microorganisms, and from 500 to 9000 deaths (Council for Agricultural Science and Technology, 1994). Clearly, these wide ranges of estimates present a great deal of uncertainty about the magnitude of the problem.

Eq. (4) also is based on the assumption that the expected value of avoiding illness or death applies equally to all members of the population, as the expected value is multiplied by the size of the population (n). This extreme simplifying assumption ignores the well established fact that different sub-populations experience different exposures to risk and vulnerabilities to disease (e.g. Steahr, 1996; National Research Council, 1993). The economics literature also shows that willingness to pay for safer foods varies with incomes and other soci-economic characteristics, as noted above (third section). However, until data are available from the literature for each factor in the model for consistently defined sub-populations, it is not possible to calculate a benefit term for each such sub-population. Cost-of-illness data will most likely continue to be used in regulatory assessments because comparable estimates can be made for many of the key pathogens. Another factor is that, until there is a convergence of scientific consensus about the validity of contingent valuation and related methods, government agencies are likely to continue to use cost of illness data, regardless of their theoretical shortcomings (Belzer and Theroux, 1995).

In view of the uncertainties surrounding each of the components in the benefits calculation, it can be concluded that despite efforts to estimate the costs of food borne disease, any benefits estimates will be highly unreliable. Clearly, as better estimates of each of the variables in Eq. (4) become available, it will be possible to reduce the uncertainty associated with the benefits estimates in regulatory impact assessments.

Cost calculations

The plant-level costs of food safety regulations are identified in the fourth section in terms of the costs of complying with regulations, plus the effects of regulations

on the operating efficiency of the plant. The discussion above showed that, for a complete estimate of the cost of a mixed design standard and performance standard, information would be required on a number of variables: the performance standard being implemented; changes in the capital stock required to meet the design standard and to comply with the performance standard; the effects of the design and performance standards on the efficiency of the production process; and the variable and fixed costs associated with quality control that are non-joint with the production process. In an ex ante regulatory impact assessment, many of these factors are clearly not known. Under certain assumptions, the accounting, economic-engineering, and econometric methods discussed in the fourth section each can be used to construct estimates of these costs.

In FSIS's accounting analysis, various data sources were utilized, including UDSA data from previous quality control initiatives, a pilot HACCP program undertaken in the early 1990s with nine plants, databases maintained for its meat inspection system, and private sector financial databases. The FSIS's method for covering the relevant population of plants was to utilize their lists of inspected plants to stratify the population into groups based on plant size, type of process (slaughter versus processing), and type of species (beef, pork, poultry). Using these data, FSIS then constructed estimates of the costs of each component of the regulations for each plant type: training employees to develop and maintain a HACCP system; costs of implementing standard sanitary operating procedures; and costs of assumed process modifications. Included in the costs of operating the HACCP system were labor and materials costs of keeping records and conducting product quality tests, and estimates of the capital requirements for additional controls that would need to be added to typical plants. The data used for this accounting exercise present several significant limitations. While the Food Safety and Inspection Service inspects over 6000 establishments, much of its cost data came from a voluntary pilot program involving only nine plants. Clearly, such data cannot be representative of the larger population of regulated establishments. Additional information was apparently based on expert judgement of USDA personnel, without validation against a representative sample of data from plants in the industry. As noted by Belzer (1995, p. 20), "... the analysis contains several material errors in its cost assessment that severely understate the likely costs of the rule. First, the estimated cost of required SSOPs (standard sanitary operating procedures), HACCP (hazard analysis critical control points) plans, and generic *E. coli* testing includes only the cost of writing the plans themselves, training current employees, and performing the microbiological tests. The costs associated with the operational changes necessary to comply with SSOPs and HACCP plans were not included."

The accounting approach followed by FSIS also requires the assumption that quality control costs are additive to other costs in the production process. Thus, the FSIS cost estimates can be interpreted as the component $\Delta qc(\bullet)$ in the above discussion of performance and design standards [Eqs. (2) and (3)]. The estimates of process modifications made in the FSIS analysis correspond to $\Delta k(\bullet)$ in Eqs. (2) and (3). Effective higher quality standards are also likely to reduce the overall operating efficiency of slaughter and processing, by affecting key factors such as the speed at

which a slaughter line can operate, how frequently the line must be stopped, and the amount of time and labor required for cleaning and maintenance. This effect is represented by the presence of the quality variable in the variable cost term vc(y,q,**w**,k) in Eqs. (2) and (3). As noted in the fifth section, econometric studies have found evidence indicating that the impacts on overall operating efficiency represents a significant cost of quality regulations. Under the assumption that regulations would be 20% effective, Antle's data show that an upper-bound cost estimate would be in the range of $600 million to $5.4 billion (1995 dollars). With 20% effectiveness, the annual benefits of the regulations would be in the range of $200–738 million. Clearly, these higher costs raise questions about the social value of the regulations.

Conclusions

The goal of statutory food safety regulation is to mandate that firms produce higher quality, i.e. safer, products for consumers. The key reason why it is difficult to design regulations to do this, and why it is difficult to measure the benefits and costs of these regulations, is that food safety itself is difficult to measure. Information about the various quality attributes of food products is imperfect for consumers, producers, government regulators, and researchers, and this is particularly true when microbial pathogens are involved. These pathogens cannot be readily observed or tested in the production process, and their health effects are often difficult for consumers to identify after a food product is consumed. Thus, a key challenge in modeling and measuring the benefits and costs of food safety regulation is to devise methods that can make the best use of the limited and imperfect data that are available. As recent experience in the United States with regulatory impact assessment shows, the data that are currently available provide, at best, highly uncertain estimates of benefits and costs of new regulations.

It is important to emphasize also that the US example discussed in this paper is only one type of regulatory intervention. Various other types of regulatory programs are being used in the European Union and other countries, ranging from self-regulation, to labeling and product certification, to statutory regulation of the type discussed for the United States (OECD, 1997). The larger question of which type of regulation, or which combination of types of regulation, best suit an individual country's needs, is an issue that needs to be addressed. It remains to be seen whether or how these various policy approaches can be compared in a RIA framework.

Future research on key parameters underlying both benefits and costs will no doubt reduce the high degree of uncertainty currently associated with quantitative regulatory impact assessment. Topics needing further attention include the valuation of benefits, including further development of the willingness to pay approach. Research needs to advance our understanding of the differences in vulnerabilities in segments of the population, and differences in responses among segments of the population to information about food safety. Another gap in knowledge is the actual effectiveness of alternative types of regulation—such as HACCP, performance standards, and

product information—in reducing the occurrence of food borne illness. More complete risk assessment models are needed that avoid some of the simplistic assumptions used in the RIAs that have been conducted in the United States. The availability of better data on pathogen occurrence, in combination with better economic data that are representative of different types of plants in the industry, will make it possible to associate production costs with alternative types of quality control processes and obtain better estimates of the costs of regulation. In addition to research that could improve the reliability of estimates of total benefits and costs, there is clearly a need for research that will provide the ability to measure the distributional consequences of food borne disease in the consumer population, as well as the distributional consequences of food safety regulations in the producer population.

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