Chapter VI

Methods of Estimating and Applying Costs to Regulatory Decisionmaking

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In the previous chapter, various testing methods for assessing health risks were evaluated for their usefulness in regulating environmental contaminants—i.e., setting an action level or tolerance. The primary issue involved in assessing health risks is not whether the potential risks from an environmental contaminant should be evaluated for purposes of regulation but rather what testing methods are most appropriate for assessing potential risks?

The situation is reversed, however, when the associated costs of an action level or tolerance for an environmental contaminant are assessed. The primary issue is whether the costs should be taken into account in the setting of a tolerance or action level. This is a policy issue which is addressed in chapter IX, "Congressional Captions. " In this chapter, the various approaches and techniques for estimating the costs and benefits of a proposed tolerance or action level are assessed, along with two common methods for applying cost and human risk data in the regulation of environmental contaminants. A more detailed discussion of the approaches and techniques for estimating the costs and benefits is provided in appendix E.

Two methods, the cost-effectiveness method and the cost-benefit method, are analyzed for their strengths and weaknesses as regulatory decision-assisting tools. This analysis provides a basis for the discussion in chapter IX on the role of economics in regulating environmental contaminants in food.

COST-EFFECTIVENESS

Cost-effectiveness is a regulatory decision-assisting tool that compares the estimated net costs of the proposed regulation in dollar terms with estimated reduction of human risk expressed in scientific terms. In the regulation of environmental contaminants, the cost-effectiveness method would compare the estimated change in costs of a proposed action level or tolerance for a contaminant in food with the associated reduction in human health risk—i.e., the benefits of the proposed tolerance or action level. The comparison of net costs and risk reduction is performed for several alternative levels in order to select a tolerance or action level. The principal cost of regulatory action is the cost of food held off the market because it exceeds the proposed action level or tolerance. There would also be a reduction in medical costs as a result in the reduction of human risk. These costs would need to be subtracted from the cost of restricted food.

The cost in lost food would also have associated distributional effects which would need to be identified to fully weigh the impact of a regulation. These effects would include identifying the consequences for producers, change in the cost of food to consumers, and indirect impacts on such businesses as food processors, animal feed manufacturers, or bait and tackle shops,

The cost of food losses and related effects would be compared with the estimated reduction of human risk for the contaminant at the proposed action level or tolerance. The hu-

man risk data could include such information as the reduction in the estimated number of new cancer cases, the potential mutagenic and teratogenic effects, and other toxicological effects described in chapters II and V. The toxicological effects vary by substance and are stated in scientific terms. The estimated net cost and reduced human risk at various proposed action levels or tolerances are estimated and compared. The cost-effectiveness method then requires the regulatory agency to make its own judgment on what is the proper balance of net cost and reduced human risk when setting a tolerance or action level.

The Food and Drug Administration (FDA), for example, followed a similar procedure in its decision to reduce the tolerance for polychlorinated biphenyls (PCBs). In deciding on a 2 parts per million (ppm) tolerance for fish, FDA compared for 5 ppm, 2 ppm, and 1 ppm in fish the estimated reduction of human risk with the estimated increase in the amount and cost of food expected to be taken off the market. Table 16 shows the human risk from cancer and cost data on commercial fish for each of the three levels and the net changes in risk and cost for moving to a 2-ppm and 1-ppm tolerance. It is these net changes that are evaluated in the cost-effectiveness method, Though FDA reviewed other available toxicological data, it was FDA's judgment that the reduction in risk (13.3 cancers) for a l-ppm tolerance did not offset the increased cost ($10, 3 million) and that a proper balance for the net changes was established at 2 ppm. Thus, FDA has placed an implicit dollar value on life. A more thorough application of the cost-effectiveness method would attempt to identify all the net changes in the benefits (the reduction of all known risks) and all known costs,

Judgment is an important aspect to the cost-effectiveness method. It allows the decisionmaking body, in this case FDA, flexibility in interpreting health data and evaluating the implications of that data on the setting of a tolerance or action level. This flexibility can be particularly important in the assessment of insufficient or variable toxicological data. While an agency's interpretation of toxicological data might differ from others and generate disagreement about the final decision, the cost-effectiveness method does allow the complexity and shades of gray to be factored into the decisionmaking process,

The health data used in the cost-effectiveness calculations are generated by the toxicological and epidemiological procedures reviewed in the previous chapter. There are also various approaches and techniques used to estimate the costs of food likely to be taken off or restricted from the market as a result of a proposed tolerance or action level. The cost estimates will vary depending on the approaches or techniques employed. All these approaches require chemical analysis of a statistically significant number of food products known or thought to be contaminated, With such data, the amount of contaminated food that exceeds the proposed action level or tolerance can be estimated,

Table 16.— Impact of PCB Tolerance

Tolerance	Lifetime risk of cancer for heavy consumers of fish	Reduction in human risk	One year cost (1974 dollars) of commercial fish (land value)	Increasing costs
5 parts per million (ppm)	9.8 per 100,000 or 46.8 new cancers per year	Starting level	$ 06 million	Starting level
2 ppm,	7.2 per 100,000 or 343 new cancers per year	125 new cancers	$ 57 million	$51 million
1 ppm	4.4 per 100,000 or 21 new cancers per year	13,3 new cancers	$16 million	$10.3 million

SOURCE *Federal Register* VOI 44 No 127 June 29 1979 p 38333

FDA multiplies the estimated amount of food removed from commerce by the appropriate price (production, wholesale, retail, etc.) per unit (pound, bushel, ton, or animal, etc.). This method of estimating food costs is not the most accurate way of estimating costs and does not attempt to measure the indirect costs or distributional effects that result from an action level or tolerance.

There are two other approaches for estimating the costs from the reduction of the food supply: the alternative-cost approach and the opportunity-cost approach. The alternative-cost approach estimates the cost of the next best alternative method or methods, if available, for replacing food removed from the market.

For example, assume that 164,000 lbs of lake trout in Lake Superior were restricted from commerce because of the 2-ppm tolerance for PCBs. The alternative-cost approach would require cost estimates of each available method as well as various combinations of methods for producing (and thus replacing) the entire 164,000 lbs of lake trout, the amount condemned by the tolerance. In establishing the replacement cost, this approach does not consider price or supply shifts in the restricted food product nor shifts in the supply of other food products. Such shifts are likely to occur when large amounts of food in relation to the total supply are taken off the market. Consequently, this approach can lead in some instances to an overstatement of costs.

The opportunity-cost approach does include shifts in supply. But what information is included in the analysis depends on which techniques are used. The budgeting technique only includes shifts in supply for the contaminated commodity. This technique uses data on the production of the contaminated product to calculate the costs of producing and consequently replacing a particular amount of that food product that has been restricted from commerce. It is assumed that other commodities will be produced in the same amounts and at the same price that prevailed before the establishment of the tolerance or action level.

The modeling technique, however, includes not only supply shifts but also resulting price shifts in both contaminated food and other food products. With this technique, mathematical models of the relevant portion of the economy are employed to trace shifts in supply, changes in the amount and price of various commodities, and other factors affected by the restriction on the use of a contaminated product.

These models can, if properly programed, project changes in the production location of particular crops as well as changes in the use of various production factors in each region of the country. Thus modeling can more realistically describe likely reactions in food production to the change created by a tolerance level. The result is a better estimate of the potential cost of lost or restricted food.

In attempting to project replacement costs, the opportunity-cost approach (using either budgeting or modeling techniques) more accurately estimates the true costs of a tolerance or action level then either the alternative-cost or the FDA approach.

The distributional effects of a tolerance or action level can be incorporated in the cost-effectiveness method. But the opportunity-cost approach can better generate these distributional effects. With either method these effects are most easily identified when the data are initially being collected. The information is important in determining who will bear the brunt of the costs, both directly and indirectly. The distributional effects flowing from human health risks can also be identified. The available risk data can be assembled to determine who bears most of the potential and actual risks. Thus the distributional effects of the net cost and the reduction of risk from a tolerance or action level can be compared (l).

COST-BENEFIT

The cost-benefit method compares the estimated dollar costs of a proposed regulation with the estimated dollar benefits of reducing human health risks. The cost-benefit method of setting tolerance or action levels also requires the evaluation of several alternative levels. The differences in benefits and costs as one moves from one proposed regulatory level to the next are then compared. The tolerance or action level would be lowered until the costs (impact from food condemned) are greater than the benefits (reduction of human risks). When this level is reached, the economically efficient tolerance or action level will be the next higher level at which the benefits exceed the costs.

By representing the costs and benefits for a proposed action level or tolerance in dollars, cost-benefit analysis attempts to make the two sides of the ratio more comparable. This method recognizes, as does cost-effectiveness, that any proposed action level or tolerance will incur costs in terms of food taken off the market and benefits reflected in the reduction of either actual or potential health risks. As the level is lowered, costs increase and human health risks decrease.

Techniques of estimating costs are similar in the cost-benefit and cost-effectiveness methods with the exception that the reduced medical costs are included with the benefits. There are some ways of valuing benefits, though, which are unique to the cost-benefit method.

Though both methods rely on the available toxicological data, cost-benefit requires the conversion of all data into dollar values. This economic conversion is best accomplished when the data are expressed as the number of premature deaths per year avoided, the number of person-days lost to illness avoided, or the probability that some percentage of the exposed population would die prematurely or would lose a specified number of days from normal activity due to illness.

Two approaches are available for converting the risks into dollars: forgone earnings and willingness to pay. In the forgone-earnings approach the analyst places an explicit economic value on life in attempting to estimate the productivity lost as a result of illness or premature death caused by a contaminant in food. This approach, however, does not include associated health costs such as medical expenses incurred from illness. Including such costs is required in order to more accurately represent the total reduction of health costs—i.e., the benefits. The willingness-to-pay approach allows people affected by the regulation (rather than the analyst) to estimate how much they would be willing to pay to avoid a risk.

The forgone-earnings approach attempts to estimate the lost earnings of those individuals who are estimated to become ill or die prematurely because of the contaminated food (l). The estimated dollar value of the benefit will be determined by various techniques chosen or assumptions made by the analyst in converting the risk data to a dollar value. Discounting and earnings are two areas in which the analyst can influence the value of the benefit.

Since many of the benefits of a tolerance are not likely to be realized until 10, 20, or 30 years later, discounting is used to convert future dollar benefits into present dollars. Discounting is also used for estimating future costs. Discounting is required even if the future dollars are adjusted for the rate of inflation because a dollar spent now can be invested productively to yield a larger number of real dollars—i.e., inflation adjusted—in the future, For example, $100 invested at 5-percent interest becomes $105 in one year. Discounting is the reverse: $105 next year has a present value of $100 when the discount rate is 5 percent. This means that $10,000 worth of benefits that will occur 10 years from now would actually have a present value of $6,135 if a 7-percent discount rate is used,

While most economists agree that future costs or benefits need to be discounted, they do not agree on the value of the discount rate. The rate can vary from 1 percent to as high as 15 percent (z). The rate, however, has to remain constant for both the costs and the benefits. Obviously, the value of the rate will affect the estimate of benefits or costs, The lower the discount rate, the greater the dollar estimate in present dollars. Consequently, more weight would be given to the benefits and costs accrued in the future.

The estimate of the benefits also depends on whether gross or net earnings are used. Gross earning estimates include an individual's or a group's total wages or salaries. Net earnings consist of total wages or salaries minus the individual's or group's consumption. Obviously the gross earnings estimate will be greater than the net earnings estimate.

The willingness-to-pay approach is conceptually a more correct approach in that it asks the individual to place a dollar value on the reduction of associated risks from an environmental contaminant. This value is then used for placing a value on life itself. While conceptually correct, this approach does have some inherent problems, such as: 1) the capability of the questioned person to accurately understand the ramifications of the risk and 2) the individual's economic position. For example, an economically disadvantaged person might place a small value on risk not because the person feels the risk is of little or no concern but because that person cannot afford an increase in food prices. This approach is affected by the assumptions made by the public being surveyed.

APPLICATION OF METHODS FOR REGULATION

The use of the cost-benefit and cost-effectiveness methods for regulatory purposes is affected by the following factors: 1) FDA's interpretation of the Food, Drug, and Cosmetic Act, 2) the approaches and techniques for estimating the economic value of the costs and benefits, and 3) the inherent difference between the two methods.

As noted earlier, FDA interprets the *Act* as requiring it to weigh only the impact of the cost and the amount of food removed from commerce in the setting of the proposed tolerance or action level. FDA's approach for estimating this cost can be applied in either the cost-effectiveness or the cost-benefit method, but both of these methods can rely on alternative-cost or opportunity-cost techniques which more accurately estimate the cost incurred from condemned food. These other techniques also more accurately estimate the tolerance or action level's impact on availability y of food than the approach used by FDA.

Whichever technique is employed to estimate the costs, adequate information is needed on the amount of food likely to be contaminated. Such information was available for PCBs in fish, but it is not available for PCBs in milk, poultry, and eggs. This is because contamination of milk, poultry, and eggs is likely to occur as a result of industrial accidents. Such accidents are sporadic and therefore difficult to predict (e.g., the July 1979 PCB contamination of poultry and eggs in Idaho) (3). Consequently, the estimates for costs incurred because of food removed from commerce cannot be determined for such contamination incidents, and thus neither method can be employed. Both methods could be used to set a tolerance or action level for mercury and kepone in fish.

The approach and techniques used by the cost-effectiveness methods for generating necessary data can take considerable resources and time, 2 months to over a year to gather the data just for the costs alone. The amount of time needed depends on the approaches and techniques used. The more accurate the information being generated, the more time and resources are required.

FDA, however, often has to make an initial decision in the form of an action level in 2 months or less for a newly identified environmental contaminant. A sufficient amount of time is usually available for utilization of the various approaches or techniques if a follow-up decision is involved. For example, 6 years expired from the time an initial PCB action level was proposed until a final tolerance for PCB was proposed this year. Either method is more likely to be used in setting a formal tolerance than an initial action level for an environmental contaminant.

The substantive difference between the cost-benefit method and the cost-effectiveness method is that the cost-benefit method places an explicit value on life by converting the health data to dollars while the cost-effectiveness method places an implicit value on life by weighing the health data in its scientific form with the costs. As a result, a significant amount of judgment is exercised by the analyst using the cost-benefit method when selecting the different approaches and techniques for estimating the benefits. As discussed earlier, the selection of these approaches and techniques has a strong bearing on the outcome of the ratio and consequently the tolerance established by this method.

The cost-effectiveness method places a greater judgment burden on the agency and less on the analyst. While the analyst does affect the outcome, judgment is primarily exercised by the agency in weighing the net cost with the reduction in human risk (benefits). The agency exercises less judgment in the cost-benefit method, which only requires a comparison of the numbers for each side of the ratio to establish the appropriate tolerance.

The cost-effectiveness method has the potential to reveal more of an agency's thinking in the decision than cost-benefit does. This was demonstrated with the earlier discussion of FDA's setting of a 2-ppm tolerance for PCBs in fish. In addition, because it recognizes the uncertainties inherent in the estimates of the health risks, the cost-effectiveness method allows FDA the flexibility to adjust the weight given to the benefits or the costs in its decision. For these reasons, the cost-effectiveness method is the more appropriate method at this time for weighing the costs in the setting of a tolerance.

Neither method can evaluate all the information required by FDA in setting a tolerance. For example, FDA requires for enforcement purposes analytical methodologies that can detect, measure, and confirm the identity of the contaminant at the level being proposed in food. This means that the tolerance cannot be set at a level below the available analytical capabilities for detecting the contaminant in food. While the analytical capability is an important factor in setting a tolerance, it cannot be evaluated within the decisionmaking framework by either method. Consequently, these two methods should be viewed as decision-assisting aids that allow the regulator the means to weigh many of the relevant costs and benefits in the setting of a tolerance.

CHAPTER VI REFERENCES

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