

Risk Assessment, Cost-Benefit Analysis and Knowledge Management in Food Safety Risk Analysis: An Economist's Perspective on Tools for Decision Making

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Abstract

Risk analysis is the framework for decision makers and regulators to use risk assessment, risk management, cost-benefit analysis (CBA), and risk communication in order to reduce the public impact of risks, especially, health and safety risks. The primary mission of FDA's Center for Food Safety and Applied Nutrition (CFSAN) is to protect the public health by ensuring that food is safe. Decision makers rely on a risk analysis framework to evaluate risk management options for implementing food safety programs and policies. The standard paradigm states that risk analysis is made up of three components: risk assessment, risk management and risk communication. It is also argued that components should be kept separate in the interest of scientific integrity and to make sure results are not affected by political pressure. However, it is important to maintain interaction among the different components of risk analysis so that the risk assessment along with the CBA can aid risk management in decision making. CBA needs to be part of risk analysis.

1. Risk Assessment versus Safety Assessment

Risk assessment is according to the National Academy of Science definition: "The use of factual base to define the health effects of exposure of individuals or populations to hazardous materials and situations." A risk assessment can help risk managers decide that the potential hazard is of enough significance that it needs to be managed or regulated. Thus, when conducting such analyses, some level of risk is considered acceptable.

A safety assessment is different from a risk assessment in that it estimates the amount of a particular hazard that is either safe or acceptable. Safety assessments are not useful for making decisions because these estimated levels use uncertainty factors or conservative default assumptions that swamp out uncertainty around an estimate. By making risk managers unaware of uncertainty, decisions are based on overestimated risks (Williams and Thompson, 2004). In fact, uncertainty factors can make imaginary risks appear as real risks. Risk management of imaginary risks takes away resources from managing real risks, thus leading to unnecessary dangers to public health and safety (Jaynes, 2003).

2. Risk Assessment in CFSAN

Risk managers in the FDA Center for Food Safety and Applied Nutrition (CFSAN) adopt a decision based approach to identify and select risk assessments based on several aspects, such as public health concerns, regulatory needs, resources (available/needed), and feasibility. Our framework for identifying, selecting and managing risk assessments is available on the web (FDA CFSAN, 2002).

The scope of CFSAN's risk assessments is very broad and includes all areas and products that are regulated by CFSAN, such as food, dietary supplements and cosmetics. CFSAN has been conducting risk assessments for more than 30 years. At first most risk assessments were cancer risk assessments from contaminants or chemicals in food additives. However, in the last ten years, microbial risk assessments

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have increased significantly and have played significant roles in decision making. More recently CFSAN has applied risk assessment approaches to developing a conceptual model for a risk assessment of food allergens.

Also, there is recent interest in looking at risk assessments related to nutrition. In fact, the Institute of Medicine recently hosted a two day workshop jointly sponsored by the Interagency Risk Assessment Consortium, the US Department of Health and Human Services, the US Department of Agriculture and the International Life Sciences Institute to explore current and potential uses of risk assessment methodologies to answer questions related to nutrition. Topics discussed included: The Interface Between Risk Assessment and Nutrition, Current Uses of Nutritional Risk Assessment, Risk Assessment Methods: Nutritional Recommendations and Health Outcomes, Research Gaps (IOM, 2007).

To continue the advance of the field of risk assessment, investment in building capacity is needed to provide education and training opportunities to scientists interested in risk assessment and modeling; obtain computing and analytical software; and encourage development of new technologies including better methods of using existing model components (e.g., growth models) as building blocks for new risk assessment models.

3. Integrating Risk Assessment and Economic Analyses

In the past 25 years, food safety risk analysis has been characterized by steady improvements in the risk assessment methods themselves. However, less progress has been made in combining the different parts of risk analysis to produce results relevant to health and safety policies. Risk assessments that can be integrated with economic analyses have become increasingly more important in public policy designed to protect human health.

In fact, in 2006, The Executive Office of the President, Office of Management and Budget (OMB) issued a draft bulletin on how risk assessment should be performed in the federal government (OMB, 2006). This guidance required the following of risk assessors: *“Every risk assessment should provide a characterization of risk, qualitatively and, whenever possible, quantitatively. When a quantitative characterization of risk is provided, a range of plausible risk estimates should be provided. Expressing multiple estimates of risk (and the limitations associated with these estimates) is necessary in order to convey the precision associated with these estimates.”* Characterizing risk in this way would be extremely helpful for use in CBA.

Although guidance for the past two Executive Orders (E.O. 12291 and E.O. 12866) have stressed that risk assessments must be performed in a certain way to help properly characterize economic benefits, this document is the first directed at risk assessors to clearly address this need. It does so directly for cases in which a risk assessment is being performed to “support or aid” regulatory analysis – although most risk assessments in the federal government are not done for that express purpose. As with the previous section, the bulletin requires among other things that: *“... a quantitative characterization of risk ... should include a range of plausible risk estimates, including central estimates. A “central estimate” of risk is the mean or average of the distribution; or a number which contains multiple estimates of risk based on different assumptions, weighted by their relative plausibility; or any estimate judged to be most representative of the distribution.”*

The OMB guidance calls for better efforts that will allow integrating risk assessments with CBA, yet there is still considerable debate regarding the desirability of combining these two entities. The debate might stem from the long-accepted paradigm of keeping risk assessment separate from risk management, which typically was thought to include CBA. Even though it is appropriate to keep risk assessment separate from risk management, CBA has been wrongly categorized as a part of risk management. Considerable attention is now placed on designing risk assessments that can be integrated into CBA, with an emphasis on the advantages of this combination, and also considering how unforeseen market or consumer behaviors may lead to offsetting risks (Williams and Thompson, 2004).

This presentation will illustrate methods that can help risk management interpret health outcomes estimated in risk assessments, see how those outcomes are used in CBA, and use that information to make risk-based decisions. In particular, techniques that are currently being used to integrate risk assessment into CBA, and how they can be used to arrive at a decision will be highlighted.

In addition to addressing examples of some well-known hazards for which health risks are assessed, obstacles facing decision makers when multiple options and multiple hazards must be analyzed will be considered. Decision making can be complicated, for example, because it is difficult to balance the interests of the different stake holders affected by the decision.

Economics provides methods to characterize trade-offs and – if not necessarily pointing to a single optimal decision – provides decision makers with better information when making difficult choices among options. That information may show when it is better to use self-interest or mixed incentives in serving the public interest, and when more prescriptive measures are needed. This particular way of thinking is referred to as public economics. Alternatively, when a risk analysis must incorporate the effects of private incentives and group pressures that can influence the adoption of the preferred regulation or policy, then it is related to public choice economics (Buchanan and Tullock, 1992). This is particularly evident when trade or consumer groups routinely lobby Congress to adopt or change regulations for economic advantage.

Risk assessment provides methods to show how to use probability distributions instead of deterministic calculations when deciding among options. They also calculate the combined effect of a model's various uncertainties in order to calculate an outcome distribution (Vose, 1996). The advantages and disadvantages of different models for estimating public or private actions that affect food safety will be discussed and different quantitative risk assessment models and techniques will be presented with examples on how they are incorporated in a cost-benefit analysis. Bayesian methods appear to be more appropriate in conducting risk assessments because they take note of important prior information (Jaynes, 2003).

While advances in risk assessment methods continue, inherent data limitations and especially public perceptions have also affected the use of combined risk assessment and economic analyses to set policy. A key factor is that many tools in economic analysis are often misrepresented as a means to prevent regulation. For example CBA is often criticized for promoting de-regulation because the costs are not measured in a way that is comparable with the benefits. Another criticism is that it doesn't yield a "fair" result. Finally, CBA is criticized for discounting effects because it is believed to "de-value" human life and health (AU CSR, 2006).

CBA is also criticized because it can be easily manipulated to fit political interests. However, this problem is not caused by the CBA itself, but by those who use – or rather – misuse it. This problem does not relate to CBA alone but to other types of analysis, including statistical analysis, risk assessments, and others.

CBA is perceived as unfair because most often those who bear the costs of a rule or program are not the same who receive the benefits. However, a decision made without CBA is actually more unfair because CBA informs decision makers of who bears the costs and who receives the benefits.

The objection of quantification of benefits is also very common. By measuring morbidity or mortality in monetary units, there is a perception that the value is reduced. A common statement is that people say they don't value health the same way they value money and that monetizing benefits trivializes health. The concept of trading risk or health for cash sounds unappealing to many people, but in practice it happens every day. Otherwise, all parents would buy Volvos to provide the purported additional protection to children from accidents, but that is not the case. At the same time no one expresses that they are willing to increase risk of injury to their children just to save a few thousand dollars by buying a "less safe" car.

It is important to understand and be able to explain common misperceptions as to what CBA can and cannot do. For example, discounting (often mistaken as "devaluing" human life) actually helps evaluate costs and benefits of policies whose effects will happen in the very distant future or extend over a long

period of time. Discounting helps recognize the difference between time preference and uncertainty about the future.

For all the reasons above, transparency in policy formulation and the peer review process in CBA and other studies such as risk assessment are very important. Increasing the transparency of analyses and more explicitly addressing uncertainty and the quality of the information that underlies them may be part of the process for improving public acceptability.

4. Efforts in Building Capacity and Increasing Transparency: Tapping the Internet to Promote Education, Collaboration and Acceptability

As recently as 15 years ago, the Internet was practically in diapers, and using it to find information that would help address critical risk analysis issues was a daunting task. The evolution of information technology presented a clear opportunity for enhancing educational outreach and scientific collaboration. Toward this end, nearly ten years ago a group of food safety professionals specializing in risk analysis took a first step toward banding together to build an Internet community.

The Food Safety Risk Analysis Clearinghouse was created in 1997 in response to a report to the President on the National Food Safety Initiative. The Joint Institute for Food Safety and Applied Nutrition (a collaboration between FDA and the University of Maryland) is responsible for the Clearinghouse. The Clearinghouse is operated and directed by collaborators from CFSAN, FDA's Center for Veterinary Medicine and the University of Maryland. The mission of the Clearinghouse is to collect and catalogue available data and methodology on food safety risk analysis offered by the private sector, trade associations, federal and state agencies, and international sources.

5. Looking Ahead: Information Technology and Knowledge Management

The overall goal of the Clearinghouse initiative was to bring together representatives of various groups that have or are developing Internet resources for food safety risk analysts, to strengthen the knowledge base, as well as enhance communication and professional interactions regarding food safety. This activity continues to uncover new data sources and new methods to help integrate risk assessments into cost benefit analyses of FDA food safety regulations.

Things are much different today than in the early days of the Internet, as terabytes of public and private information can be accessed through the Internet. However, with so much information available, analysts can spend a large amount of time “deep web harvesting”, assessing the quality of the information found, and organizing it.

This situation calls for the consideration of a programmatic taxonomy to help facilitate access to content relevant to food safety risk analysis, and to enhance knowledge management approaches. Through such approaches, the relationships among the basic categories and entities that make up the organizational framework for food safety risk analyses can be identified, so that key content can be accessed more quickly, and the bases of the technical analyses can be more readily understood. Information and communication technologies present significant opportunities for better integrating risk assessment and CBA to guide policies for food safety, including strengthening information access and sharing knowledge that supports these analyses and to further the understanding and implementation of effective decisions for public health protection. For more information on food safety risk analysis efforts visit www.Foodrisk.org (JIFSAN, 2007).

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