

Integrated Analysis: Combining Risk and Economic Assessments While Preserving the Separation of Powers

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This article presents a process for an integrated policy analysis that combines risk assessment and benefit-cost analysis. This concept, which explicitly combines the two types of related analyses, seems to contradict the long-accepted risk analysis paradigm of separating risk assessment and risk management since benefit-cost analysis is generally considered to be a part of risk management. Yet that separation has become a problem because benefit-cost analysis uses risk assessment results as a starting point and considerable debate over the last several years focused on the incompatibility of the use of upper bounds or “safe” point estimates in many risk assessments with benefit-cost analysis. The problem with these risk assessments is that they ignore probabilistic information. As advanced probabilistic techniques for risk assessment emerge and economic analysts receive distributions of risks instead of point estimates, the artificial separation between risk analysts and the economic/decision analysts complicates the overall analysis. In addition, recent developments in countervailing risk theory suggest that combining the risk and benefit-cost analyses is required to fully understand the complexity of choices and tradeoffs faced by the decisionmaker. This article also argues that the separation of analysis and management is important, but that benefit-cost analysis has been wrongly classified into the risk management category and that the analytical effort associated with understanding the economic impacts of risk reduction actions need to be part of a broader risk assessment process.

KEY WORDS: Benefit-cost analysis; countervailing risk; economic analysis; risk assessment

1. INTRODUCTION

In 1983, a seminal report by the National Academy of Sciences on Risk Analysis, known as the “Redbook,” put forward the concept of separating risk analysis into three components, risk assessment, risk management, and risk communication.⁽¹⁾ At that time, risk assessment was directed primarily at chronic hazards and the results of risk assessments were the

de facto risk management decisions with outputs of either safe or acceptable levels using uncertainty factors, sometimes referred to “management factors.” Arguments advanced at the time suggested that the uncertainty factors were grounded with scientific defensibility such that there was very little role for risk managers to play in these decisions. Further, the use of “conservative” defaults and assumptions by risk assessors also effectively usurped risk management since managers were often never made aware of uncertainties or the potential impact of these uncertainties on the results and were essentially forced to make decisions that began with an assumed overestimate of the risk.⁽²⁾ Although the original notion of separating risk assessment from risk management was based on the idea that risk assessors might be captive to

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risk managers, it could be argued that the opposite occurred.

1.1. The Role of Economic Assessment in Risk Management

The Redbook said very little about the role of economic analyses in making risk management decisions, but suggested that it falls in the risk management category, and regulatory agencies treated it consistent with this interpretation. More recently, the Presidential/Congressional Commission's report similarly acknowledged benefit-cost analysis as part of risk management, without making clear why, although it did highlight problems that result from the lack of coordination between risk assessors and economic analysts.⁽³⁾

In spite of the apparent consistency about where benefit-cost analysis fits, some question remains as to whether or not benefit-cost analysis really belongs as a part of risk management. Definitions of risk management vary somewhat, but several prominent ones note that the distinguishing nature of risk management falls where decision-making authority rests.

Risk management is the process of weighing policy alternatives and selecting the most appropriate regulatory action, integrating the results of risk assessment with engineering data and with social, economic, and political concerns to reach a decision. (Reference 1, p. 3)

Risk management is the process of identifying, evaluating, selecting and implementing actions to reduce risk to human health and to ecosystems. The goal of risk management is scientifically sound, cost-effective, integrated actions that reduce or prevent risks while taking into account social, cultural, ethical, political and legal considerations. (Reference 3, p. 2)

Risk management is the term used to describe the process by which risk assessment results are integrated with other information to make decisions about the need for, method of, and extent of risk reduction. (Reference 4, p. 28)

All of the definitions describe a process whereby a selection or decision is made based on careful consideration of the options by a risk manager. We suspect that it is unlikely that the original placement of benefit-cost analysis in the risk management category was done such that the economist performing a benefit-cost analysis was expected to be (or should be) the risk manager empowered to make decisions. Just the opposite is typically true, economists performing benefit-cost analyses are analysts, just as are risk assessors, and they are only charged with providing input

into the decision-making process. Furthermore, the separation of risk managers from economists is desirable for exactly the early reasons that were given to separate risk assessors from risk managers, to keep the analysts insulated from pressures to develop analyses that support predetermined positions (i.e., fitting the analysis to the decision instead of using the analytical results to inform a decision).⁽¹⁾

While we find some limited evidence in the existing published research and popular press that benefit-cost analyses currently lack needed independence,⁽⁵⁾ even a cursory examination shows great difficulty in finding any federal rules in which the costs exceed benefits. This means that either benefit-cost analysis drives regulatory decisions toward efficiency and that only rules in which the benefits truly exceed the costs get promulgated, or that at least some regulatory benefit-cost analyses may be crafted in such a way as to support inefficient decisions (i.e., those where costs truly exceed benefits) by overstating benefits or understating costs so that the decisions appear efficient. While both of these may be occurring, criticisms of "poor" economic analyses leveled at analyses provides some evidence that the latter does occur. Unfortunately, the lack of validation of analyses makes it difficult to characterize the extent.

By moving benefit-cost analysis out of risk management, this at least partially removes any incentive to adjust the analysis to fit a decision. It correctly implies that benefit-cost represents an analytical effort and an input to the decision, just like risk assessment, but it is not the sole analysis in risk management that provides "the" answer. This gives policymakers a new degree of freedom to select rules that are inefficient (presumably because other attributes of the decision drive their choice) and allows for transparency about the best estimates of the benefits and costs as well as documentation of the true rationale for their decision.

Many reasons explain why risk managers may choose an option that deviates from the output of a benefit-cost analysis, that identifies an option that maximizes net benefits (i.e., total benefits minus total costs). First, benefit-cost analysis is based on the principle of potential compensation that assumes that social welfare is maximized if the winners (who receive the benefits) *could* compensate the losers (who bear the costs). The argument is that any options that meet this criterion have the potential for everyone to be at least as well off, or better, than the current situation.⁽⁶⁾ However, the criterion only requires that the winners are able to compensate the losers; it has

no actual requirement for the compensation to occur. In fact, in situations where the costs and/or benefits are widely distributed, the transaction costs associated with making any such compensation are likely to be excessive. It is also true that some risk management decisions may factor in distributional effects that benefit-cost analyses ignore. In particular, government actions may intentionally redistribute wealth, as is usually the case when the government chooses to protect high-risk subpopulations. In most situations, those consumers who are highly exposed or highly sensitive (who may receive the benefits of risk reduction) could not in fact compensate those who bear the costs (i.e., not only are benefits not usually maximized in these situations, but total benefits may not even exceed total costs). However, the protection of sensitive subpopulations is a potentially valid social choice, despite the fact that the information from the benefit-cost analysis may completely miss differential impacts on subgroups within the population if this variability is not explicitly considered.⁽⁷⁾

Second, like risk assessment results, economic estimates often have considerable uncertainty associated with them. For example, it is difficult to predict how market participants will react to a regulation and how markets will change, particularly given the rapid evolution of science and technology. This means that the prediction of both costs and benefits are uncertain. Factoring in the uncertainty inherited from estimates of risk that often span several orders of magnitude, analysts face significant challenges in predicting the actual consequences of risk reduction actions, in addition to challenges associated with estimating what those reductions are worth. All of this uncertainty frequently makes the overall goal of determining which of the options is most efficient an exercise in comparing uncertainties. In particular, it may be the case that a sensitivity or uncertainty analysis reveals that changes in one or more parameters reorder the intervention options in terms of their effectiveness estimates. Recognizing this clearly means that the risk managers must be responsible for making decisions accounting for the uncertainties in both the risk assessment and in the benefit-cost analysis and that failure to understand the uncertainties in either may lead to an inefficient and poorly informed choice. Performing the comparisons requires that the analysts of both the risk and benefit-cost analyses assess the *same* decision options, and for this reason risk and economic analysts must work together enough to ensure that they are providing the analytical information that the risk manager needs.

Finally, risk assessment and benefit-cost analysis results are not the only information considered in public health and safety decisions. Legal considerations (including congressional intent and the explicit illegality of considering benefits and costs under some statutes), strategic considerations about whether a given action will prompt congressional action, political considerations, resource constraints, and divergent stakeholders' views often play more significant roles in effect than any of the analyses. Regulatory decisions are first and foremost the result of a law passed by Congress, some very specific as to intent and others more general in giving the regulatory agency authority to accomplish a politically derived goal.

If the results from benefit-cost analysis are not "the" answer and the results are used only to inform decisions, then just as risk assessments were intended to separate the analysts from decisionmakers, the same should hold true for the economic assessments. Risk assessment has been described as "primarily a process of gathering and evaluating extant data and imposing science-policy choices" (Reference 4, p. 27). As well known in policy analysis, the same statement applies to benefit-cost analysis, with the simple replacement of "economic-policy choices" for "science-policy choices." Another way of viewing this is that neither is "science," in the sense of testing hypotheses being a central tenet, but both analyses combine and integrate scientific data in a way that is useful to decisionmakers. Thus, if the original reasons for separating risk assessment from risk management are still valid, it should be equally true that the conduct of benefit-cost analysis should be separate from risk management.

1.2. The Arguments for Combining Risk and Economic Assessments

Given our arguments that (1) an artificial separation exists between risk assessment and benefit-cost analysis and (2) that benefit-cost analysis should not be a part of risk management, we now suggest combining them into one integrated analytical assessment process for regulatory decisions. In this regard, we can identify several reasons for combining these two assessments:

- *Most* benefit analyses currently use the results of risk assessments as the starting point. To be useful with estimates of cost, risk assessments need to estimate actual risks and to factor in the probabilistic information when possible in

order to properly characterize the expected and net risks.⁽²⁾ Using upper bound estimates of risk is not consistent with the general goal of benefit-cost analysis since it provides an intentionally distorted estimate of the risks, which may significantly bias the estimate of the benefits. Economists often receive risk assessment results as an input to benefit-cost analysis and find that they require modification to address “the scenario most likely to occur.”⁽⁸⁾ Risk estimates must reflect the most likely values to allow fair comparisons of benefits against costs. Merging the analytical tasks with the expectation that the integrated analysis must produce estimates of the risks, benefits, and costs for all of the decision options will facilitate improved communications. It should also promote faster iteration and greater efficiency in the analytical process since this creates some opportunity to avoid the need for sequential adjustments. In addition, where there are different kinds of morbidity or mixtures of morbidity and mortality, economic valuation techniques can provide a consistent scale for presenting risk assessment results^(9,10) and direct interaction between the risk assessors and the economic analysts will promote improved understanding by the economists about the key risk assessment assumptions used.

- In some areas, notably in the assessment of microbial risks, probabilistic analyses produce estimates of the risk reduction associated with various interventions.^(11,12) Branches of probability-based decision trees for the risk assessment can, with input from economists, also be used to establish baseline practices and risk reduction for estimating marginal costs and benefits, and using probabilistic information is the only way to assess the value of obtaining additional information.^(13,14) In addition, by integrating the analytical efforts, the analysts may collectively improve their abilities to identify any highly impacted groups and develop a means to better characterize the implications of any decision on these groups. If the risk assessors do not present information about these groups to the economists, then the economists cannot evaluate any significant distributional impacts. Similarly, if the economists do not discuss how consumers may respond to the different decisions, then risk assessors cannot evaluate the changes in behavior and exposure that may lead to countervailing risks and impact the risk estimates.⁽¹⁵⁾
- Changes in exposure, both decreases in target hazards and increases in countervailing risks, ultimately result from reactions by market participants in their roles as consumers, managers, and workers. Estimating those market reactions, such as relative price changes, represents the role of economists, while estimating the change in risk represents the role of risk assessors. As both benefit-cost analysis and risk assessment proceed, new information and analysis raise both market and risk questions that depend on input from each other. Further, each public health problem generates questions at different points in the process of analysis. Because of this, even working concurrently and separately represents a less efficient approach, although we acknowledge that it represents a big improvement over working sequentially.
- Combining risk assessment and benefit-cost analysis to address the variability and uncertainty analyzed together should make the use of this information easier for risk managers, who often face a bewildering array of conflicting information and who will need to understand the “bottom-line” economic impacts of variability and uncertainty.^(2,7) We emphasize that by integrating the risk and benefit-cost analyses the analysts can directly share mathematical models and discuss the characterization of any particular high-risk groups in addition to focusing on the net impact. This will promote greater understanding between the analysts related to what otherwise might emerge as apparent conflicts (i.e., risk analysts focusing on a particular subpopulation because they feel that the risks experienced by this group represent an important consideration for the decisionmaker while benefit-cost analysts focus on the net benefits).
- Finally, the last argument is one of increased transparency, both between analysts and for the public. Lutter argues that benefit-cost analysis should play a role as a public accounting device, “Good benefit-cost analysis can help to keep risks in perspective and ensure more balanced policymaking in Congress and Regulatory Agencies.”⁽¹⁶⁾ Clearly, good analyses also help synthesize the information and inform democratic deliberation about the

issues. We suggest that combining the two types of analysis will help to ensure that they each respond to issues raised by the other and this offers the opportunity for significant improvement in developing communication tools that will help the public assess the efficiency of risk-related rules.

Given our arguments that risk and economic assessments should be combined, we focus the remainder of this article on a “straw-man” process for accomplishing this integrated policy analysis and we address some important differences between types of actions that can be taken to reduce risks.

2. PROPOSED PROCESS

Fig. 1 provides an overall schematic for the proposed process for integration of risk and economic assessment. In the following sections, we specifically address the public health problem, issues of hazard and market failure identification, preliminary control options, baselines, and iteration.

2.1. Public Health Problem

The first step in the analysis is to define the public health problem that may require a decision to intervene in the market. Defining the public health problem is the job of the risk manager, although other stakeholders clearly play a role in shaping the definition⁽³⁾ and analysts should help to clarify it. Defining the problem establishes the boundaries of potential solutions. If the problem is defined too narrowly, the set of solutions may miss out on broader societal improvements. For example, if the problem is defined

as finding an acceptable level of *Salmonella* in shrimp at the docks, it leaves out a solution outside of the boundaries such as requiring the placement of minimum cooking times on information labels that might be a more efficient way to control the risk. Alternatively, if the problem is phrased too broadly, the solution set may become unwieldy. This critical step of defining the question is too often neglected or poorly thought out, but it should form the basis for all subsequent analysis.

2.2. Hazard and Market Failure Identification

The next step explores the extent and nature of the problem, its relative importance and whether or not the problem is appropriate to consider as a problem that should be remedied by government. Specifically, the three initial tasks following the public health problem formulation are: (1) identifying the hazard; (2) identifying the hazard’s relative importance (compared to other, similar hazards); and (3) determining whether the public health risk is the result of a market failure. (We note here that some regulatory actions may arise from specific statutes that require action independent of economic merit and in the absence of market failure, but that these are not the focus of this article.) The first part of this step, hazard identification, is a common first step in all risk assessments.⁽¹⁾ The next step, identifying the hazard’s relative importance, is similar to risk comparison. In this step, the analyst places the hazard in context compared to other risks so that risk managers can determine if the risk is sufficiently large enough to warrant consideration for action, both on an absolute and a relative basis. If the hazard is considered insignificant, either absolutely or relatively, this might be considered a stopping point for the analysis, unless other factors (i.e., legal or political requirements) dictate. Similarly, the assessment of market failure, a common first step in benefit-cost analysis that determines whether the hazard is excessive because markets have failed to adequately “price” risk reduction, can also be a stopping point if no market failure is found. (Where risk is incorporated into price such that both consumers and producers are aware of the risk and the price of the product reflects the risk, no market failure exists and intervention is generally considered unnecessary from an economic efficiency perspective.)

2.3. Preliminary Control Options

At this stage, analysts and managers should establish a preliminary set of control options to focus the

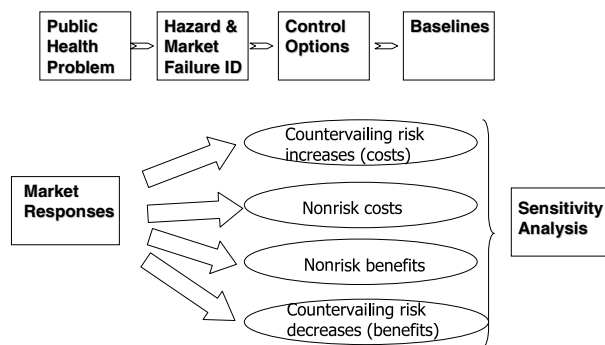


Fig. 1. Overall schematic of the proposed process for integrating risk and economic assessments.

analytical efforts. While we expect that these will continue to change throughout the process, identifying the options that exist to reduce the risk will help determine the information that needs to be examined to establish baselines. For example, if information provision is a possible option, then the current state of producer and/or consumer knowledge must be determined in the baseline analysis. The options generated here include legal requirements in the form of either laws or regulations. Legal options establish new conditions that market participants react to, although there are likely to be multiple responses to those options. For example, if a warning label is required, firms may choose to comply and add the warning label, reformulate, stop producing the product altogether, go out of business, lobby to reverse the ruling, not comply and hope not to be caught, or challenge the ruling in court. These types of responses will be determined in the market analysis phase. Every step in the analysis from this point on should be done for each of the regulatory options studied and for any other options later identified (see Fig. 1).

2.4. Determining the Baselines

The next step is to determine the market's baseline activities and exposure to hazards caused by those activities, inherent in the combination of economic analysis and risk assessment. The initial step in this section is an assessment of consumer and producer practices and any underlying knowledge that gives rise to the risk under consideration. These practices result from the set of choices that market participants currently face (and that they are assumed to be likely to make in the future in the absence of an intervention) in their roles as workers, managers, and consumers. These baselines will be used to determine the costs and benefits that result from the intervention. Producer practices include activities that either allow hazards to enter (or prevent hazards from entering) the market, or control or fail to control the hazards once they enter the production and distribution chain. In addition to assessing current practices, the state of knowledge that producers have about relevant hazards and how they believe they should be controlled also serves as an important contributing factor for exposure assessment. For example, farmers may have some knowledge of the risk associated with pesticide residues and take steps to ensure that they are within tolerance limits before moving crops into the distribution chain. On the other hand, knowledge may not be sufficient to induce action. Similarly, restaurant man-

agers may have both the knowledge and the will to take steps to refrigerate soft cheese to control *Listeria monocytogenes*. Both practices and knowledge will vary from producer to producer and this variability is important to consider and characterize explicitly as part of the baseline analyses.

Similarly, consumer practices also contribute to exposure to hazards (e.g., poor food handling practices, poor dietary choices, or failure to read or act on safety information on labels). Similar to producers, consumers also have variable knowledge about the risks in their environment and their incentives to act. Important sources of variation among consumers include their eating patterns and food choices, their sensitivities to hazards, and their levels of food safety knowledge and practices. Both producer and consumer baseline knowledge and activities may be explored as part of a decision analysis with accompanying probabilities for introduction or control of hazards. At the same time, the risk assessment should characterize the *status quo* to make very clear the magnitude of the risks given no action and to provide context for any changes that might occur as a result of regulation. The risk assessment should clearly characterize the weight of the scientific evidence that supports the estimates of the adverse health outcomes (which the economists will use in estimating the potential benefits of regulation).

These concepts apply broadly across regulatory regimes, and specific cases may help to provide additional context. For example, food consumption is determined by the interaction of consumer (demand) and producer (supply) behavior. Consumption must be estimated for both the baseline and to predict changes in exposure due to possible interventions. Food contamination rates are typically estimated by sampling a representative portion of food, and in the case of microbiological hazards, using predictive models to extrapolate these results. These models include production, storage, and transportation practices, both by food manufacturers and retailers, as well as consideration of the actions of consumers. Models of future changes (for baselines) may factor in both practices and knowledge to determine if market failures are a result of ignorance (i.e., due to imperfect or asymmetric information) or insufficient market incentives. In cases where these models indicate likely changes of technologies or processes, this information clearly must feed back into the risk assessment so that the risk estimates reflect such changes. In sum, consumer and producer practices will determine current exposures and risks that provide the baseline

from which to estimate both the efficacy of proposed changes and the impacts of those changes (both risk and economic).

Given the fact that risks often change rapidly, analysts must be cautious about assuming that practices and risks will remain constant in the absence of an intervention,⁽¹⁷⁾ which can lead to significant impacts on the results.⁽¹⁸⁾ The same forces that prompt regulatory agencies to consider taking action also provide incentives for changes in private markets with pressure on both firms and consumers (e.g., consider that the same high-profile food poisoning cases that motivates regulatory action may also be likely to change consumption patterns of the potentially contaminated food in question and also how those who choose to consume the food prepare it). If the pressure is sufficient, the problem that regulatory agencies are trying to solve may actually take care of itself (e.g., in the extreme case, if the producer leaves the market then regulation of its product becomes moot). These incentives and their likely effects on markets clearly should be a part of the baseline analysis. Baseline consumer and producer knowledge and practices can enrich the exposure estimates that are used to estimate the existing risk.

2.5. Iteration

Having established the baseline practices and risks, the next step is to refine the control options and the risk, benefit, and cost estimates. Estimating baseline behavior and knowledge typically lead to the generation of additional ideas about ways to control the risk, and in particular may lead to targeted interventions for high-risk groups. Interventions for food safety may include, for example, consumer information provisions, required changes in safety practices, installation of equipment, testing, safety (performance) standards, record keeping, training, public statements, or strengthening liability laws. The ultimate effects of control options are determined by examining the likely reactions by consumers and producers. In this context, it may be useful to distinguish between market responses, how market participants actually change their behavior, and legal control options. Market responses to legal requirements reflect predictable changes in behavior by market participants in response to a government intervention. These changes, by producers and consumers, are defined as the predicted deviations from the baseline behavior. Prediction of these deviations requires taking into account individual (firms or consumers) costs

and benefits (incentives) that depend on the individuals' own set of decision options.

In addition to the reactions from the participants with direct impacts, indirect impacts or "ripple" effects may also result from new requirements (e.g., an increase in production and sale of hamburgers might result from an increase in the price of hotdogs resulting from increased regulation on nitrites in hotdogs). For each predicted change in private behavior, both the direct and indirect responses may lead to changes in the social benefits and social costs, which include private benefits and costs.

Analysts trying to predict private responses face both analytical uncertainty and consumer and producer variability in the responses to legal requirements. Manufacturers' responses to laws or regulations depend on, among other things (1) the stringency of the requirement; (2) how the requirement is interpreted; (3) the probability of detecting noncompliance; (4) the costs of compliance; (5) the structure of the industry; and (6) changes in demand and relative prices. Consumers' responses depend on their existing knowledge base and changes in relative prices. For example, suppose a firm is required to place a label on its product warning consumers of a hazard inherent in the product. Consumers' responses to such a label might include stopping their purchases of the product, seeking more information about similar hazards, lobbying to have the product banned, petitioning for a requirement that firms take more protective steps, reducing risk in other areas of their lives, totally ignoring the information, or failing to notice or understand it. As difficult as these reactions are to predict, they form the basis for estimating social benefits (from reduced risks) and costs.

2.6. Marginal Costs and Benefits

Estimating marginal costs and benefits of regulatory options should flow from the analysis completed up to this point. In general, we aggregate individual costs and benefits of private changes to estimate changes of "intervention margins." Intervention margins can be defined as the components of the regulatory options that can be manipulated to increase or decrease marginal benefits and costs. These margins include:

- Different provisions: labeling, standards
- Coverage: producers, transporters, farms, retailers

- Different time periods for compliance: one or two years
- Hazards addressed: chemical, physical, biological, radiological
- Stringency: allowable exposure

Evaluation of regulatory options may consist of one, all, or some of these margins. Marginal costs reflect the costs of making a decision between options. When faced with a new legal option, people affected often must change what they would have done otherwise (the baseline) that would have been their preferred course of action. The costs of actions are normally estimated by the cost of time spent on the new activity or the cost of new capital. Presumably, this new activity also has a benefit associated with it, normally the reduction in the target risk for a health and safety rule. However, other changes in the risks (in addition to changes in the level of the target risk) may have implications for costs and benefits.⁽¹⁵⁾

2.7. Risk Changes Affecting Benefits and Costs

Both costs and benefits are likely to be subject to changes in both directions (i.e., increases and decreases) in the risk profiles of the affected actors. This follows from the fact that every human action has some risk associated with it so that any change in activity changes the risk that people face.⁽¹⁵⁾

Reductions in the target risk (i.e., the public health goal of the intervention specified in the first part of the analysis), is the primary benefit that all options will address. However, there may be other non-risk related benefits as well. Reducing the presence of a carcinogenic chemical in foods with high saturated fat contents will raise the price of those foods and reduce their consumption. If the increased price led consumers to decrease their consumption of these foods then this would have an added benefit of reducing the risks of coronary heart disease. Similarly, pasteurizing or irradiating foods to reduce the presence of one pathogen would also have the beneficial effect of reducing other pathogens.

Estimating the amount of risk reduced is a complex undertaking, particularly in the case where the “mechanism” by which risk will be reduced must be determined. The benefits “mechanism” is the link between the legal requirements, the changes in market behavior, and the resulting reductions in the target risk. This means that analysts must estimate the likely change in behavior due to the intervention and how much risk will be reduced as a result. This becomes

particularly difficult when the requirement is a performance standard where the behavior change is purposely left up to market participants and a wide variety of responses is possible. In these cases, risk analysts will need to analyze all of the possibilities to ensure that any of the outcomes that could occur still meet any risk-criteria that must be addressed. For example, if the best economic strategy is one that creates a market for permits (e.g., sulfur dioxide trading), risk analysts will need to ensure that this still accomplishes the health risk reduction objectives and does not create any unacceptable countervailing risks. Where marginal benefits cannot be quantified for every particular intervention, it will be extremely useful to qualitatively discuss how and how well a particular mechanism is likely to work, and for both risk and economic analysts to comment on the implications of violations of assumptions made by the other.

There are three types of countervailing risks that should be considered in a risk analysis:

1. *Consumption risks* arise from changes in the relative prices of final products or changes in consumer information. They cause consumers to reevaluate their sets of consumption choices, making changes in the set of final goods they purchase. For example, an intervention that makes food safer normally increases the price of that food, leading some consumers to choose a less-expensive substitute. Establishing a lower tolerance (i.e., stricter regulation) on tuna containing methyl mercury would raise the price of tuna, causing less to be purchased and possibly leading to increased consumption of a higher saturated fat flesh food. Similarly, banning low cost pesticides on fruits and vegetables would raise their prices and may cause substitute consumption of foods with a worse nutritional profile. One final example would be warnings on fresh fruit juices about microbial risks potentially causing consumers to substitute less nutritious drinks, such as sweetened sodas.
2. *Production risks* are the most complicated types of countervailing risks to predict. These risks can arise because of changes made by the target firms (defined as those directly addressed by the intervention) as well as other firms that are related to the target firms through market mechanisms. These include firms that are upstream or downstream in the production or distribution chain, or

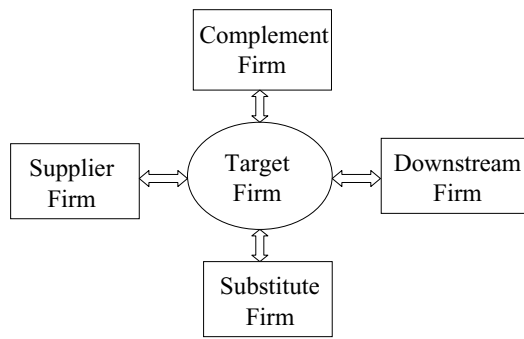


Fig. 2. Interactions between firms that may influence production risks.

those firms that produce substitutes or complements (see Fig. 2). Elements of production risk changes that should be investigated include: risk changes that occur to people in those firms (in their capacities as workers, stock owners, or consumers); risks that arise from either starting or stopping a production activity, where both may be associated with increases or decreases in risk; risk changes realized because of behavior changes that are either directly mandated or because of changes in relative prices or quality; and risks that may arise due to “crowding out,” where firms are forced to spend less on safety because of mandated expenditures. One example of a production risk is the case where water was no longer allowed to be chlorinated (because of potential cancer risks) with less effective methods employed to clean the water, which may allow waterborne disease risks to increase. Another production risk would arise if firms were mandated to reduce the shelf life of foods because of concerns about microbial growth. This would happen, for instance, if there were rules that specified a “sell by” date that was earlier than that currently in practice, which would cause more frequent deliveries of these products and hence more truck miles and increased risks of truck accidents. Another countervailing risk arises with the requirement to add folic acid to grain products to reduce the risk of neural tube defects in children, which increased the risk of masked pernicious anemia in the elderly. Finally, the ban on the pesticide EDB, because of carcinogenic concerns, allowed increased amounts of

carcinogenic aflatoxins produced by a fungus to grow on nuts and grains.

3. *Public/private crowding risks* focus on those changes in risk that arise when private safety purchases are reduced because of reduced income due to government taxation or regulation. An example of this would be a regulation that reduced harvesting of Gulf of Mexico oysters because of concerns about *Vibrio vulnificus*, leading to reduced incomes of oyster harvesters.⁽¹⁹⁾ At least part of the reduced income of oyster harvesters would have been spent on private risk reduction, such as safer cars and smoke detectors (and maybe something as basic as food for their children). Thus, the risk to oyster harvesters goes up as the risk to oyster eaters goes down. This example also demonstrates that while risk assessors might identify people who frequently eat raw oysters and their children as a high-risk population, the economists might identify the oyster harvesters and their children as a high-risk population. Clearly identifying early any options that address the concerns of both high-risk populations (where possible) represents opportunities for decisions where the benefits may outweigh the costs not only on net, but also for the groups most impacted. This will occur only if risk and economic analysts recognize opportunities to work together.

2.8. Sensitivity Analysis

Finally, a sensitivity analysis should be performed on all of the parameters of the risk analysis. The value of this type of analysis, particularly when done on the combined risk/benefit-cost analysis, is that all parts of it can work together and give decisionmakers a quick and comprehensive look at all aspects of risk analysis. This is critical in the context of identifying key uncertainties and in ensuring that the assessment results get communicated to the risk manager with transparency and with complete disclosure by the risk and economic assessors about the impacts of important assumptions.

3. DISCUSSION AND CONCLUSIONS

The original reason for separating risk assessment and risk management was primarily to keep the assessment “pure,” probably a worthy goal. By “pure,” we mean preventing risk assessment results from being corrupted or driven by *a priori* preferred

management results. But as the practice evolved, risk assessors actually usurped the role of risk management more than the reverse. In general, it appears that little serious consideration of the role of benefit-cost analysis has led to its mischaracterization as part of risk management. But, just like the results of the risk assessment, the results of a benefit-cost analysis are not and should not determine “the” decision. Instead, the results of both analyses should inform risk management without usurping the responsibility of the decisionmaker. In addition, a number of good reasons support combining risk assessment and economic assessments into one analysis, which should make it easier for decisionmakers to understand all of the different kinds of data considered in the two analyses and should ultimately ensure that the separation of risk assessment and risk management doesn’t mean divorce.⁽²⁰⁾

This article has presented a process that encourages the interaction between risk assessors and economists as they assess how risks, benefits, and costs will change in response to interventions in the market that lead producers and consumers to reevaluate their market choices. The principal elements of the process are that it starts with carefully defining the public health problem (including the type of risk and market failure leading to the risk) and options to solve that problem. Each option has a baseline of current consumer and producer behavior that must be estimated along with the current risk. Following that, changes in the baseline behavior in response to potential solutions must be estimated, including changes in both the target and the countervailing risks. Countervailing risks include those that affect consumption, production, and crowding out of private expenditures to reduce risk. From those behavior changes, costs and benefits, including increased and reduced risk, can be estimated.

We recognize that the concepts proposed here represent a significant change from the *status quo* and that numerous criticisms can be lobbied against our approach. First, those who oppose either risk assessment or benefit-cost analysis will certainly object to their combination. Second, some who might agree that the benefit-cost analysis should be separated from risk management may not see the benefits of combining the benefit-cost analysis with the risk assessment. As experienced risk and economic analysts, we emphasize that sequential analyses are not nearly as efficient as concurrent ones, and that the interaction between risk assessors and economists with the shared mission of performing analysis that informs

the policymaker promises to increase the utility of all of the analyses for the risk manager and the public. Third, some risk managers may object if this approach creates greater accountability for them. We believe that this should represent a minor issue since risk managers are responsible for making the decision considering all of the information. The benefit-cost analysis should not be forced to support a decision because the benefit-cost analysis should not be synonymous with risk management. Instead, benefit-cost analysts should be encouraged to provide their best estimates and characterizations as is expected of the risk assessors. Finally, this creates the need for greater communication and interaction of different disciplines, and this may create some new management challenges. We believe that risk assessment and economics are inherently interdisciplinary and that this increased interaction between the analysts can significantly improve the risk management process and the ultimate decisions.

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