# Risk Assessment, Economics and Chemicals In Food

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Over the past few years, Americans have become increasingly worried about the purity and safety of the food supply. Driving these fears are concerns about chemicals such as pesticides used to prevent losses in the field, pesticides and chemical additives used in storage and processing to retard spoilage and chemicals used to enhance the attractiveness of foods. Fear about the long term health effects of consuming the growth regulator daminozide (Alar) led to huge cutbacks in consumption of apples. The same type of concerns lie behind Proposition 128, the "Big Green" initiative on the 1990 California ballot. Proposition 128 would have barred the use of all pesticides classified by the Environmental Protection Agency (EPA) as human or probable human carcinogens or reproductive toxins and would tighten tolerances for pesticide residues on foods.

What the American public wants is reassurance that its food supply is safe, with no ifs, ands or buts. Unfortunately, the science and technology now available do not permit such reassurances. Technology makes possible the detection of increasingly minute amounts of chemical and microbial contaminants. In many cases, though, the advancement of scientific knowledge is not enough to determine whether or not these contaminants pose a real threat in those amounts. This is especially true for long term health effects like cancer or birth defects. Moreover, current thinking rules out threshold exposures below which they pose no risk. Thus, many assume any exposure, no matter how minute, will increase the likelihood that one will eventually suffer some ill effects.

This state of affairs poses a dilemma for the regulatory agencies responsible for health and safety. The shaping of their mandates were in response to problems associated with short term exposure to microbial pathogens or toxic chemicals that typically exhibit threshold effects. Thus, the goal of a toxicological assessment was to determine the threshold dose. Once regulators knew that

threshold, they could mandate procedures resulting in exposures well below that dose. This would ensure that the population would experience virtually no adverse health effects.

When no threshold exists, though, it becomes impossible to guarantee safety absent the elimination of all traces of potential toxic agents. It is by no means clear that eliminating all potential toxins is technically feasible. Even if it were, the marginal cost of eliminating them tends to rise rapidly as concentrations fall. So, eliminating every trace is prohibitively expensive. As a result, the concern of regulators can no longer simply be with whether or not a food product is safe. Instead, they must determine how safe food products should be. To do this, they must evaluate tradeoffs between increases in safety (or reductions in risk) and social cost. Since the increments in safety under consideration have become increasingly small and the increments in cost correspondingly large, these tradeoffs are nontrivial, and quantitative estimates have begun to play an ever more important role in making such evaluations.

The growing need for quantitative assessments of risk has led to the emergence of a new discipline, that of risk assessment, complete with its own professional association and journals. Over time, researchers have developed protocols for conducting assessments of types of risks. These protocols govern acceptable scientific methods, for example, the specific strains of test animals, the range of doses used and the proper methods for administering them, and other procedures used in conducting a carcinogen assessment. They also govern methods or drawing inferences from incomplete information. These include extrapolating from animal doses to the corresponding human equivalents or extrapolating toxicity from the high doses seen to the low doses typical of actual exposures.

Many have emphasized distinguishing risk assessment from risk management (National Academy of Sciences 1983). They view risk assessment as the province of the natural sciences, and the development of risk assessment protocols as a task in setting scientific standards. Risk management, on the other hand, is the province of decision making and thus of economics, psychology (risk perception) and operations research.

This distinction has obvious appeal. It is clearly important to bring the most advanced scientific knowledge to bear on problems of risk estimation, regardless of potential political or economic implications. Yet scientific understanding of the basic mechanisms governing long term health damage remain limited. Without hard biomedical knowledge, judgement plays a critical role. These judgements often have policy implications and thus infringe on risk management narrowly defined. Moreover, policy considerations frequently motivate judgements. There is nothing wrong with this in and of itself. However one

must acknowledge the consequences of such judgements. This paper explores some results of frequently made judgements and suggests alternatives for meeting the same goals.

### *Efficiency Criteria and Comparability of Risk Estimates*

For the past 20 years, economists have argued that health and safety issues were as amenable to economic analysis as any other public policies (Mishan). In addition, they have argued that government should take a holistic approach that applies economic efficiency criteria to all human risks. In other words, the standard economic evaluation tools of costs, benefits and efficiency can and should be applied to life-saving public activities as different as food safety regulation, occupational safety and health regulation, traffic safety measures, drinking water standards and the provision of emergency medical response services (Bailey).

The application of cost-benefit methods to policy decisions about health and safety has been problematic. Despite the considerable effort spent on developing proper concepts and empirical methods for estimating the benefits of the application of cost-benefit measures to situations involving human life remains doubtful (Fisher, Chestnut and Violette). Many find the idea unacceptable on ethical grounds. Moreover, we must first overcome significant empirical problems. Reducing risks of potentially fatal health problems may reduce the incidence of deaths from particular causes, but that doesn't mean that those saved live forever. Thus, one needs to estimate how much longer the people at risk will live and how much additional utility they will derive from the extra life span they receive. This will depend on their health status as well as on the additional length of time. For example, lengthening the life span of a person suffering from a painful, degenerative disease may provide that person with very little gain. The measure of additional life that takes these considerations into account is that of "quality-adjusted life-years." While the notion is conceptually precise, it hard to make empirically precise and even harder to measure with any degree of accuracy (Zeckhauser and Shepard).

Despite these difficulties, economic analysis can be an important tool for helping to improve health and safety policy. At the very least, cost efficiency criteria can be extremely useful. For example, the ethylene bisdithiocarbamate (EBDC) family of fungicides is a group of similar compounds used on dozens of crops. All of them may be carcinogenic in humans and their registration is now under review. Given estimates of residue levels and of the economic impacts of banning these chemicals for use on each crop, one can determine the least cost way to reduce risk from exposure to EBDC residues to some acceptable level.

Similarly, we can use estimates of risks and costs to help regulatory agencies set priorities. From a broader point of view, we can use cost efficiency criteria to help allocate resources across regulatory agencies and programs. Several economists have used this approach to critique current allocations of effort (Bailey; Graham and Vaupel; Broder and Morrall). Noting that the cost per life saved or year of life saved differs dramatically across health and safety programs, they have argued for a radical redistribution of effort.

The key to being able to apply cost efficiency criteria is having estimates of risk that are qualitatively and quantitatively comparable in results. Qualitative considerations may restrict the scope of cost-efficiency analysis to subsets of health and safety problems. For example, cancer risks from exposure to toxic chemicals may be comparable to each other. However they may not be comparable to occupational safety measures aimed at accident prevention or to emergency medical response units. This suggests that the sweeping critiques made by some economists are inappropriate. Nevertheless, a broad range of problems remains amenable to economic analysis and critiques of policies aimed at similar risks (like occupational safety standards for chemical exposure) remain valid.

Unfortunately, the risk assessment methods now in use give risk estimates that are quantitatively non-comparable even for health effects that are qualitatively comparable. Hence we cannot use these estimates in economic efficiency analysis. The reason is the way uncertainty is treated.

### *Uncertainty in Risk Assessment and "Creeping Conservatism"*

Uncertainty is arguably the central problem of chronic risk estimation, and plays a significant role in estimating acute risks as well. Because chronic health effects take a long time to develop, there are potentially many causes and many important contributing factors involved. Scientific understanding of the mechanisms of chronic health effects such as cancer and birth defects is now limited, so it can provide only partial guidance about which factors are or are not potentially important. Many chemicals of concern appear to have low toxicity, so detection of their effects becomes a severe problem. We cannot use controlled experiments to assess risks to human beings directly. In such a situation, we cannot use empirical methods to make up for shortfalls in scientific knowledge. Likewise, we cannot use scientific knowledge to compensate for difficulties in observation and measurement. As a result, we can explain only part of the observed variations in environmental outcomes with available data.

Compounding these difficulties is the policy goal to prevent avoidable death and disease. This preventive posture constrains policymakers to issue decisions

in a timely manner, so data collection is often not as thorough as desired. Estimation of even acute risks, like the risk of food poisoning from salmonella in poultry products, is subject to significant uncertainties. This is true because of the difficulties of measuring product contamination, exposure in human populations, and the relationship between intake of salmonella and the incidence of food poisoning.

Limited scientific knowledge and the need for timeliness create a situation where the risk assessments used in quantitative policy analysis contain substantial uncertainty. This is due to errors in estimating risk and to the variability in risk across populations. The public is sensitive to these uncertainties. Psychologists have noted that the public perceives as more hazardous effects that have greater uncertainty associated with them (Slovic, Fischoff and Lichtenstein). The recent furor over Alar on apples bears this notion out. Data available suggest that about 85 percent of fresh produce in the marketplace have no detectable residues. Further, most of the remaining cases involve residue levels that are extremely small and well below those the EPA considers the maximum safe levels (Food and Drug Administration Pesticide Program). Yet much of the U.S. public believes that pesticide residues on foods pose a serious threat to public health. Policymakers are also sensitive to these uncertainties, in part because of public demand for assured safety, and because mistakes are the most visible indicator of poor performance.

The desire to prevent avoidable health problems means that government agencies have asymmetric preferences with respect to uncertainty. Avoiding false negatives weighs more heavily than avoiding false positives. The public health profession, for example, views the proper response to uncertainty as providing an adequate margin of safety in protective measures. Much of the legislation governing food safety contains this point of view, especially that concerning chemicals in food.

One way that regulatory agencies have responded to this requirement is by basing regulatory action on risk estimates that have margins of safety built into them. In deciding about pesticides or other residues on foods and noncarcinogenic food additives, the EPA and the Food and Drug Administration (FDA) must balance risks against benefits. By inflating the estimates of risk, these agencies try to be sure that any actions taken will incorporate a margin of safety.

This is a reasonable way to tackle uncertainty, even if it differs somewhat from the approaches to uncertainty most common in economics. It corresponds to the application of classical statistical methods to adjust for uncertainty. In formal statistical terms, incorporating a margin of safety corresponds to using the upper bound of a confidence interval (Lichtenberg and Zilberman). It is common in engineering, where the application of safety factors is widespread.

While the principle may not be objectionable, regulatory practice in this regard leaves much to be desired. In particular, the way in which agencies like the EPA and the FDA use margins of safety to construct conservative estimates renders the resulting estimates noncomparable. Specifically, they add a margin of safety by combining conservative estimates of each parameter entering a risk assessment model to get an overall estimate of risk. When we give conservatism a formal statistical meaning, the estimate used will be the upper limit of a 95 or 99 percent confidence interval (Anderson et al.). For example, suppose that the incremental risk of cancer from ingesting residues of a pesticide residues on foods, R, is expressed as a multiplicative combination of parameters describing the residue level, $X_1$, the ingestion rate, $X_2$, the breakdown of the residue into toxic metabolites, $X_3$, and the toxicity of the pesticide and its metabolites, $X_4$:

$$R = X_1 X_2 X_3 X_4.$$

The standard regulatory procedure would involve estimating the upper limit of a 95 percent confidence interval for each parameter and then multiplying these limits to get an overall risk estimate.[1]

This practice typically results in creeping conservatism: The final risk estimate is associated with a confidence limit much greater than any of the individual parameter estimates (Bogen). The following hypothetical example shows how this occurs. Suppose that the additional risk of contracting cancer from exposure to residues of a pesticide on food can reasonably be modeled using a multiplicative model and that all the parameters of that model are random variables with lognormal distributions. The natural logarithm of the excess cancer risk is normally distributed. Further suppose that the mean and standard deviation of the estimated log risk are −13.82 and 1.46, respectively, while the standard deviations of the parameters sum to 2.35. Making no adjustment for uncertainty, the estimated risk will be about one in a million. If the upper bound of a one-tailed 95 percent confidence interval is used, the estimated log risk will be −11.4, corresponding to a risk of about 1.1 in 100,000. If the regulatory agency constructs its risk assessment using the upper limits of one-tailed 95 percent confidence intervals as its estimates for each of the parameters in the model, it will arrive at a figure of −9.95, or about 4.8 in 100,000. This is over four times as large as the actual upper bound. In this example, the estimate of the logarithm of the incremental cancer risk will correspond to the upper bound of a 99.92 percent confidence interval.

The problem is not that combining conservative parameter estimates effectively increases the conservatism of the final risk estimate. The proper level of conservatism is within the scope of regulatory and scientific judgement. Instead the problem is the arbitrary way that it adjusts the margin of safety. The

confidence level of the estimate varies in an unpredictable way across risks. Because there is no systematic way in which the conservatism is altered, there is no way to correct the resulting estimates to put them on the same statistical basis. Risk estimates are non-comparable since they are associated with different confidence levels. So, this practice makes it impossible to impose or even check for consistency in regulation across risks.

The implications for the use of economic analysis are straightforward. We can use economic efficiency criteria to improve regulatory efficiency only in cases where the outcomes considered are comparable. As the situation stands, health risk estimates are noncomparable, limiting the scope for economic analysis. Also, the need to apply economic criteria is growing more acute, as detection limits fall and the tradeoffs involved in food safety regulation get larger.

### *Monitoring versus Enforcement*

Much of the uncertainty associated with risks from chemicals in food is due to limits on knowledge about the physiological mechanisms involved in cancer and other long and short term health risks. However, we can observe the source of a significant share of food risks. One such source is variability in exposure. We can measure levels of chemicals in foods and resolve some of the uncertainty about risk through more aggressive data collection and monitoring.

Take the case of pesticide residues on foods. Producers treat different crops with different amounts of pest control chemicals. The rates at which these chemicals degrade into harmless substances varies because of differences in weather conditions and other environmental factors. Time to market differs for crops produced in different regions, leading to further differences in residue levels. As a result of these processes, residue levels, and thus exposure levels, can differ widely even for a single agricultural commodity.

The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) governs registration and therefore legal use of pesticides. The Federal Food, Drug and Cosmetic Act (FFDCA) governs the use of food additives and pesticide residues on foods. For most cases, both statutes require regulatory agencies to balance risks against benefits in determining regulatory action.[2] In virtually all cases, benefits will outweigh risks for at least some low exposure levels. Even if a substance is quite toxic, there will be exposure levels sufficiently low that the increased risk does not outweigh the benefits. Moreover, most of the chemicals of concern are not extremely toxic. Much of the uncertainty about the risk they pose is, in fact, due to low toxicity.

One can conceive of two approaches to risk reduction. The first involves usage restrictions, which may range from banning the use of a chemical to

changes in formulation or in labeled application rates to changes in handling procedures. The second involves increased monitoring and seizure of any commodity found to have excessive levels of residues, additives or microbial agents. The extent to which we should use each of these approaches depends on their costs relative to the risk reduction achieved. Their relative cost of risk reduction depends, in turn, on; (1) the toxicity of the substance or organism, (2) the distribution of contamination levels present in the commodity, (3) the effectiveness of each possible strategy in reducing exposure and (4) the monetary and non-monetary costs of the different strategies.

Let us focus on the second of these factors. Consider a case where contamination levels vary randomly and it is not possible to distinguish differences in contamination levels by observing characteristics of the commodity such as growing location, color or time of year. In such cases regulators cannot apply usage restrictions selectively to high residue portions of the crop and will thus be more costly relative to the actual reduction in risk achieved. As the fraction of the commodity thought to pose a significant risk decreases, the attractiveness of monitoring relative to usage restrictions increases. This occurs because usage restrictions affect the entire crop. As the fraction of the crop that actually poses a risk falls, the cost of risk reduction through usage restrictions increases. At the same time the cost of risk reduction through monitoring falls. As a result, when a commodity presents food safety concerns only in rare cases, monitoring is likely to be preferable to usage restrictions.

The problem of pesticide residues on foods may provide a case in point. These residues pose a significant risk only in a small number of instances. Increased monitoring could conceivably reduce the incidence of high residues to an acceptably low level at moderate cost, while usage restrictions are likely to impose higher costs. Failure to consider enhanced monitoring as a potential policy response is thus likely to increase social cost without a corresponding increase in the marginal benefits of risk reduction.

Suppose that a fungicide used on, say, grapes, leaves residues that are probable human carcinogens. Suppose that exposure to high residue levels could cause an additional 125 cancer cases a year in the U.S. population. Actually, only about five percent of the grapes on the market have high residues, though, so the expected number of additional cancer cases is 6.25 annually. Suppose that restricting the usage of the fungicide would eliminate all of these cancer deaths at a cost to consumers and producers of grapes amounting to $1.2 million annually, so that the annual cost per expected cancer case avoided is $192,000. An alternative policy is an enhanced monitoring program. Assume that it would detect these residues 99 percent of the time. Assuming that high residues and detection are independent, the expected number of additional cancer deaths

under enhanced monitoring would be 0.0625, an annual reduction of 6.1875 cancer deaths. Under the monitoring plan, one would expect 0.0625 additional cancer deaths on average, one case every 16 years. If only expected values mattered, the monitoring program will be preferable as long as its direct cost plus the cost of those 0.0625 additional cancer deaths would be no more than $1,188.00.

Yet stepped-up monitoring is typically not a response to concerns about pesticide residues on foods. We usually address concerns about residue levels by imposing stricter usage limitations. One reason is risk assessment methodology; a second important one is organizational fragmentation..

Risk assessment plays a role in this case because of the way we treat uncertainty. The standard response to uncertainty is to construct conservative estimates of risk that have a margin of safety. Yet, we then see the risk estimates produced as certainty-equivalent point estimates. We assume that regulatory action cannot affect the uncertainty associated with the risks. This assumption introduces a bias against monitoring, in that it artificially inflates the cost of risk reduction for a monitoring strategy relative to usage restrictions. As a result, monitoring is an undesirable option.

Consider again the example of pesticide residues on grapes. The conservative assumption typically used is that the high residue level is on the entire crop. So the estimated number of additional cancer cases per year is 125. The estimated annual cost per case avoided under usage restrictions is artificially lowered to $9,600. The monitoring program will eliminate only 99 percent of these cases, resulting in an additional 1.25 cancer cases annually. Thus we would prefer usage restrictions as long as the cost of the monitoring program plus the cost of those additional expected cancer deaths exceeds $9,600. The conservatism of the risk assessment inflates the expected number of additional cancer deaths by a factor of 20. This increases the estimated cost of the monitoring program substantially and will thus make usage restrictions relatively more attractive.

Suppose that the social cost of an additional cancer death costs $2.5 million.[3] When the true exposure estimate of five percent of the crop issued, we would prefer usage restrictions whenever the direct cost of the monitoring program exceeds $1,031,750. When we use the conservative exposure estimate, we will always prefer usage restrictions because of the excessive cost of the estimated additional cancer deaths.

This bias is actually more severe than appears at first glance, because of EPA's reliance on chemical by chemical assessments of pesticides. An enhanced monitoring program would be able to detect residues from a wide variety of chemicals at little additional cost. So, monitoring exhibits economies of scope: the cost of a monitoring program for residues of many chemicals costs less than

the sum of the costs of individual monitoring programs for each chemical. If producers use the chemicals under regulatory scrutiny for different pests on different crops, one needs only to add the costs of the usage restrictions of each chemical. Producers use many chemicals of special concern regarding residues on foods for similar pests on the same crops. In these cases, the costs of simultaneous usage restrictions are likely to be larger than the costs of usage restrictions on each chemical separately, exhibiting diseconomies of scope (for empirical evidence, see Osteen and Kuchler). Once we incorporate these economies of scope into cost efficiency calculations, the advantages of monitoring can be seen even more clearly.

Organizational fragmentation may present as much of a problem as risk assessment methodology in this regard. FIFRA and FFDCA confer on the EPA the authority to set residue tolerances and to establish pesticide usage restrictions. Only the FDA however, has the authority to monitor foods for pesticide residues, insect parts, undesired additives or contaminants and impurities in general. The EPA has neither the statutory mandate nor the bureaucratic authority to substitute enhanced monitoring for usage restrictions. Moreover, there exists no mechanism, formal or otherwise, for coordinating regulatory policy between these agencies. To provide adequate protection for public health, the EPA must key its policies to the most at-risk individuals, in this case, the individuals purchasing high-residue grapes. Lacking a mechanism to enforce reductions in exposure selectively by removing high-residue grapes from the market chain, the EPA may enact usage restrictions that are more stringent than the data warrant.

## *Conclusions*

Over the past few years, food safety regulation has become more complex. The public has begun to express a high level of concern about items like pesticide residues, food additives and other chemicals that are typically present in small amounts, have low toxicity and typically have high economic benefits. As a result, the tradeoffs regulators must make are larger, and therefore more difficult, and economic analysis plays an increasingly central role.

Regulatory agencies like the EPA have developed tools for risk assessment to provide quantitative guidance in dealing with these tradeoffs. Risk assessment methods blend scientific understanding with inference based on judgement. An emphasis on preventing avoidable deaths influences to a considerable extent the ways in which inference is employed. In particular, we treat uncertainties due to limits to scientific understanding and to unobservable variability in exposure and susceptibility through the use of conservative estimates of risk.

Conservatism in risk assessment is not a problem by itself; there are good reasons for incorporating adjustments for uncertainty into risk assessment and into regulatory decision making. However, the arbitrary way in which we construct conservative risk assessments presents significant problems when it comes to decision making. The practice of combining conservative parameter estimates makes the resulting risk estimated noncomparable, which in turn rules out application of economic efficiency criteria. Treating risk estimates as fixed leads to a failure to recognize the possibility of uncertainty reductions through policies such as monitoring and biases regulators toward excessive use of usage restrictions.

We can remedy these problems by altering the risk assessment methods used in regulatory decision making. Instead of estimating risk in an arbitrarily conservative way, we can model uncertainties and population variabilities explicitly (Bogen). Explicit modeling of uncertainty can also incorporate policies like monitoring or data collection into the policy determination process. We can accomplish the goal of preventing avoidable death and disease, or of providing adequate protection of public health with a sufficient margin of safety, by using a statistically defined upper bound risk estimate. We can use the estimate corresponding to the upper limit of a 95 percent confidence interval. Such a procedure corresponds to extending the Baumol and Oates standards and charges approach to incorporate uncertainty (Lichtenberg and Zilberman). Empirical studies have shown that adjustment for uncertainty can alter policy significantly (Lichtenberg, Zilberman and Bogen), suggesting that this approach will preserve the preventive posture of regulation. As the tradeoffs involved in food safety regulation continue to get larger, the costs imposed by arbitrariness in risk assessment will continue to grow. Consequently the returns to adopting to such a more sophisticated approach to risk assessment will increase.

Organizational reform is needed as well. The agencies responsible for food safety, EPA, FDA and the U.S. Department of Agriculture, have in the past taken regulatory action without regard of the consequences on each other. One example is that of the interaction between monitoring and usage restrictions. The EPA cannot substitute monitoring and seizure of high residue produce for usage restrictions because it has jurisdiction only over the latter, while the FDA has jurisdiction over the former. Another example is how food purity standards affect pesticide use and therefore residues on foods. The threat of FDA seizure of produce because of excessive amounts of insect parts or pest damage gives farmers a significant incentive to apply more pesticides (Pimentel and Pimentel). FDA food purity standards may thus lead to greater residue problems and, in turn, to a threat of more stringent usage restrictions because of elevated residues.

In this case, lack of coordination between regulatory agencies leads to a sort of regulatory arms race.

### *Notes*

This research was supported by the Maryland Agricultural Experiment Station Competitive Grants Program and by the Economic Research Service, U.S. Department of Agriculture, under Cooperative Agreement 58-3AEM-8-0065. The views expressed are solely those of the author. Scientific Article No. A-6173, Contribution No. 8342 of the Maryland Agricultural Experiment Station.

1. Given the narrow range of actual exposures, such a specification will provide a reasonable approximation regardless of the true functional relationships.
2. The principal exception is the case of food additives known to be carcinogenic in humans or animals Section 409 of the FFDCA, the so-called Delaney Clause governs these cases. The Delaney Clause forbids the using lot substances of this kind as food additives. Pesticide residues on foods are not considered food additives unless their concentration increases after processing. An example would be residues on hops: Because the volume of hops shrinks during drying, pesticide residues are often found in greater concentrations even though the absolute volume of residues may have decreased. Unless concentration during processing occurs, pesticide residues are covered by Section 408 of the FFDCA and are subject to risk-benefit balancing criteria. For further discussion, see National Academy of Sciences (1987).
3. This is typical of the estimated values of saving a life obtained from econometric studies (see Fisher, Chestnut and Violette).

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