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RISK ASSESSMENT, ECONOMICS AND CHEMICALS IN FOOD

by

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Over the past few years, Americans have become increasingly worried about the purity and safety of the food supply. Driving their 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, a food virtually synonymous with healthy eating, in homes and schools across the country. The same type of concerns lie behind the "Big Green" initiative in California, which would bar the use of all pesticides classified by the Environmental Protection Agency (EPA) as human or probable human carcinogens or reproductive toxins and would tighten substantially 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 currently available do not permit such reassurances. Technology makes possible the detection of increasingly minute amounts of chemical and microbial contaminants, but scientific knowledge is not advanced enough to determine whether or not these contaminants pose a real threat in those amounts. This gap between ability to observe and ability to comprehend is especially pronounced for long term health effects like cancer or birth defects: Current thinking rules out threshold exposures below which they pose no risk, so that any exposure, no matter how minute, is thought to increase the likelihood of eventually contracting them.

This state of affairs poses a dilemma for the regulatory agencies responsible for health and safety. Their mandates were shaped largely 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 that threshold dose was known, regulators could mandate procedures resulting in exposures well below it, ensuring that the population would experience virtually no adverse health effects.

When no threshold exists, though, it becomes impossible to guarantee safety unless all traces of potential toxic agents can be eliminated. 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 that eliminating every trace is prohibitively expensive. As a result, regulators can no longer be concerned simply 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 the social costs of achieving those increases. 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, protocols have been developed for conducting assessments of different kinds of risks. These protocols govern acceptable scientific methods, for example, the specific strains of test animals (usually rats or mice), the range of doses to be used and appropriate methods for administering them and other procedures to be used in conducting a carcinogen assessment. They also govern methods for drawing inferences in the absence of scientific information, such as extrapolating from animal doses to the corresponding human equivalents or

extrapolating toxicity from the high doses observed to the low doses typical of actual exposures.

A great deal of emphasis has been placed on distinguishing risk assessment from risk management (see for example National Academy of Sciences). Risk assessment is viewed as the province of the natural sciences, and risk the development of risk assessment protocols is seen as a task in setting scientific standards. Risk management, on the other hand, is viewed as 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 it has a certain artificiality. Scientific understanding of the fundamental mechanisms governing long term health damage is limited. In the absence of hard biomedical knowledge, judgement plays a critical role. These judgements often have policy implications and thus infringe on risk management narrowly defined. Moreover, they are frequently motivated by policy considerations. There is nothing wrong with this in and of itself, but it is important to be explicit about the motives and the consequences of the judgements made. This paper explores some of the impacts that current risk assessment procedures have on policy analysis for food safety problems and suggests ways in which the goals motivating them can be better served.

Efficiency Criteria and Comparability of Risk Estimates

For the past 20 years or more, 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 risks to life and limb. In other words, the standard economic evaluation tools of costs, benefits and efficiency could and should be applied to life-saving public activities as disparate as food safety regulation, occupational safety and health regulation, traffic safety measures such as speed limits and passive restraint requirements, drinking water standards and provision of emergency medical response services (see for example Bailey).

To what extent this is true has been hotly debated. Despite the considerable effort expended on developing appropriate concepts and empirical methods for estimating the benefits of increased safety (for a survey see Fisher, Chestnut and Violette), it remains doubtful that cost-benefit measures will ever be applied strictly to situations involving human life. Many find the idea unacceptable on ethical grounds. Moreover, there are significant empirical problems yet to be overcome. 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, which 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 appropriate measure in this context is that of "quality-adjusted life-years" (QALYs), which are hard to define in an empirically precise way and even harder to measure with any degree of accuracy (for a discussion of these issues see 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 EBDC fungicides are used on dozens of crops. 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 whatever level is deemed acceptable. Similarly, estimates of risks and costs can be used to help increasingly overburdened regulatory agencies set priorities. From a broader point of view, cost efficiency criteria can be used to assist governments facing increasingly tight budgetary constraints 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 terms of outcomes. 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, but not 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 (occupational safety standards for chemical exposure, for example) remain valid.

Unfortunately, the risk assessment methods currently in use ensure that risk estimates even for qualitatively comparable health effects are quantitatively noncomparable, so that they cannot be used in economic efficiency analysis. The underlying reason is the way that 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 currently limited, so that it cannot provide guidance about which factors are potentially important and which are not. Many chemicals of concern appear to have low toxicity, so that detection becomes a severe problem. The fact that human beings are concerned rules out the use of well controlled experiments. In such a situation, empirical methods cannot be used to make up for shortfalls in scientific knowledge, and scientific knowledge cannot be used to compensate for difficulties in observation and measurement. As a result, only part of observed variations in environmental outcomes can be explained by available data.

These difficulties are compounded by the fact that the aim of policy is to prevent avoidable deaths. This preventive posture constrains policy makers to issue decisions in a timely manner, so that data collection is often not as thorough as might be desired. Estimation of even acute risks, for example, the risk of food poisoning from salmonella in poultry products, is subject to significant uncertainties 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.

In sum, limited scientific knowledge and the need for timeliness create a situation where

the risk assessments used in quantitative policy analysis are characterized by substantial uncertainty owing to error in estimating risk and to variability in risk across populations that cannot be taken into account in risk estimates. The public appears to be sensitive to these uncertainties. Psychologists have noted that the public perceives as more hazardous effects that have greater uncertainty associated with them (for a summary see Slovic, Fischoff and Lichtenstein). The recent furor over pesticide residues on foods (e.g., Alar on apples) bears this notion out. The best data available suggest that roughly 85 percent of fresh produce in the marketplace have no detectable residues and that almost all 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. Policy makers also appear to be quite sensitive to these uncertainties, in part because the public seems to demand it, and in part (perhaps) because mistakes are the most visible indicator of poor performance.

The desire to prevent avoidable health problems means that government agencies tend to 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 appropriate response to uncertainty as providing an adequate margin of safety in protective measures, much as engineers build in safety factors when constructing dams or buildings. This point of view is incorporated into much of the legislation governing food safety, especially that concerning chemicals in food. Both the Federal Insecticide, Rodenticide and Fungicide Act (FIFRA), which governs pesticide use and the Federal Food, Drug and Cosmetic Act (FFDCA), which governs food additives and pesticide residue tolerances, require such a margin of safety.

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, that is, that are set "conservatively" high. In making decisions about pesticide or other residues on foods and noncarcinogenic food additives, EPA and the Food and Drug Administration (FDA) are required to balance risks against benefits. By inflating the estimates of risk, these agencies try to ensure 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, rather than Bayesian, 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, rather than a loss function such as expected utility (see Lichtenberg and Zilberman for a discussion of the implications of this approach). It is common in engineering, where the application of safety factors is widespread.

While the principle may be unobjectionable, regulatory practice in this regard leaves much to be desired. In particular, the way in which agencies like EPA and FDA utilize margins of safety to construct "conservative" estimates makes the resulting estimates noncomparable. Specifically, they add a margin of safety by combining "conservative" estimates of each parameter entering a risk assessment model to obtain an overall estimate of risk. When "conservatism" is given formal statistical meaning, the estimate used will be the upper limit of a 95 or 99 percent confidence interval (see Anderson et al. for a description of EPA procedures). For example, suppose that the incremental risk of cancer from ingesting residues of a pesticide residues on foods R can be 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,

$$R = X_1X_2X_3X_4.$$

(Given the narrow range of actual exposures, such a specification will provide a reasonable approximation regardless of the true functional relationships.) The standard regulatory procedure would involve estimating the upper limit of a (say) 95 percent confidence interval for each parameter and then multiplying these limits to obtain an overall risk estimate.

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 (see for example Bogen). The following hypothetical example demonstrates 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 of the parameters of that model are random variables with lognormal distributions. The natural logarithm of the excess cancer risk will be distributed normally, which makes it easy to work with. 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. If no adjustment for uncertainty is made, the estimated risk will be about one in a million. If the upper bound of a 95 percent confidence interval is used, the estimated log risk will be -11.06, corresponding to a risk of almost 2 in 100,000. If the regulatory agency constructs its risk assessment using the upper limits of 95 percent confidence intervals as its estimates for each of the parameters in the model, it will arrive at a figure of -9.21, or about one in ten thousand, six 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 in this regard is not that combining "conservative" parameter estimates effectively increases the "conservatism" of the final risk estimate; the appropriate level of "conservatism" is within the scope of regulatory and scientific judgement. Rather, 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 because they are associated with different confidence levels. In other words, 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. As noted above, economic efficiency criteria can be used to improve regulatory efficiency only in cases where the outcomes considered are comparable. As the situation stands, health risk estimates are generally noncomparable, so that the scope for economic analysis is severely limited. At the same time, 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

While 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, a significant share comes from sources that can be observed. One such source is variability in exposure. Levels of chemicals in foods can be measured, and some of

the uncertainty about risk can thus be resolved through more aggressive data collection and monitoring.

Take the case of pesticide residues on foods. Different crops are treated 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.

Recall that both FIFRA and the FFDCA require regulatory agencies to balance risks against benefits in determining regulatory action. 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 currently of concern are not extremely toxic; much of the uncertainty about the risk they pose is, in fact, due to relatively low toxicity.

One can conceive of two approaches to risk reduction. The first involves (1) 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 (2) increased monitoring and seizure of any commodity found to have excessive levels of residues, additives or microbial agents. The extent to which each of these approaches should be used depends, of course, 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, that is, where 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, usage restrictions cannot be applied 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, while 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 well provide a case in point. As noted above, the best data available suggest that roughly 85 percent of fresh produce in the marketplace have no detectable residues and that almost all of the remaining cases involve residue levels that are extremely small and well below EPA tolerances, which are set conservatively (Food and Drug Administration Pesticide Program). 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 much greater 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.

An example may help clarify this point. Suppose that a fungicide used on, say, grapes, leaves residues that are probable human carcinogens. Suppose that if the U.S. population were exposed to high residue levels, an additional 125 cancer cases a year would occur. In reality, only about 5 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 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. If only expected values matter, the monitoring program will be preferable as long as it costs no more than $1,188,000.

Yet stepped-up monitoring is typically not a response to concerns about pesticide residues on foods. The opposite tends to happen: Concerns about residue levels are usually addressed 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 uncertainty is treated. It was noted above that the standard response to uncertainty is to construct "conservative" estimates of risk that have a margin of safety built into them. This is a valid method for treating uncertainty. However, the risk estimates produced in this way are taken as certainty-equivalent point estimates. In particular, it is assumed that the uncertainty associated with the risks cannot be affected by regulatory action. 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 appears to be an undesirable option.

To see how the decision process is affected by "conservatism" in risk assessment, consider once again the example of pesticide residues on grapes. The "conservative" assumption typically used is that the high residue level is found on the entire crop, so that the estimated number of additional cancer cases per year is 125. The estimated annual cost per case avoided under usage restrictions will be artificially lowered to $9,600, while the estimated cost per case avoided under the monitoring program will be unchanged. As a result, usage restrictions will be preferred as long as the cost of the monitoring program exceeds $59,000, and they will be preferred erroneously whenever the cost of the monitoring program lies between $59,000 and $1,118,000.

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. In other words, 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 the chemicals under regulatory scrutiny are used for different pests on different crops, one needs only to add the costs of the usage restrictions of each chemical. Many chemicals of special concern regarding residues on foods, though, are used for similar pests on the same crops. In these cases, the costs of simultaneous usage restrictions are likely to be larger than the sum of the costs of usage restrictions on each chemical separately, that is, they exhibit diseconomies of scope (for some empirical evidence see Osteen and Kuchler). Once these

economies of scope are incorporated 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 EPA the authority to set residue tolerances and to establish pesticide usage restrictions. Only FDA, however, has the authority to monitor foods for pesticide residues, insect parts, undesired additives or contaminants and impurities in general. 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, 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, EPA may be forced to 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 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 in employed. In particular, uncertainties due to limits to scientific understanding and to unobservable variability in exposure and susceptibility are treated through the use of "conservative" estimates of risk.

"Conservatism" in risk assessment is not a problem per se; there are good reasons for incorporating adjustments for uncertainty into risk assessment and into regulatory decision making. However, the arbitrary way in which "conservative" risk assessments are constructed 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 biases regulators toward excessive use of usage restrictions.

These problems can be remedied by altering the risk assessment methods used in regulatory decision making. Instead of estimating risk in an arbitrarily "conservative" way, uncertainties and population variabilities can be modeled explicitly (see for example Bogen). Explicit modeling of uncertainty can also incorporate potential uncertainty reducing policies like monitoring or data collection. The goal of preventing avoidable deaths, or of providing adequate protection of public health with a sufficient margin of safety, can be accomplished by using a statistically defined upper bound risk estimate, i.e., 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 and has been shown to generate reasonable decisions (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, and the returns to adopting to such a more sophisticated approach to risk assessment will increase.

Organizational reform will be 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 given above: EPA cannot substitute monitoring and seizure of high residue produce for usage restrictions because it has jurisdiction only over the latter, while 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 (see Pimentel and Pimentel for a discussion of this problem). 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".

These three agencies have recently initiated mechanisms to coordinate responses to potential food safety problems. While this move is positive, more is needed; greater coordination must be made possible for routine regulatory decisions like those involved in pesticide regulation. It is possible that statutory changes will be needed. Yet as the costs of meeting rising standards for food safety escalate, the importance of making such changes can only grow.

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