Humans in the Chemical Decision Chain

by Donald Kennedy

Americans decide as a matter of public policy how much risk they are prepared to tolerate, but they do not do it in the same way at all times in all places and in all contexts.

The small package of sweetener in my morning coffee contains a known carcinogen. In March 1977 an excellent animal study demonstrating this fact was delivered to the Food and Drug Administration (FDA). Ten days afterwards I took office as commissioner. An extraordinary outcry followed—generating more mail in Senator Kennedy's office, he told me, than the U.S. bombing of Cambodia in the spring of 1970.

Nevertheless, I had to tell the world, because it was the truth, that not only the notorious Delaney Clause but the older, statelier and less controversial 1938 safety provisions of the Food, Drug and Cosmetic Act required the removal of this food additive from the marketplace.

To state the outcome plainly, I was run over by a train. The substance was saccharine. The soft drink industry ably orchestrated, but by no means exclusively caused, a protest that drew support from diabetologists, freedom of choice advocates (that was also the summer of Laetrile, a substance that didn't cause cancer but didn't cure it either), parents of obese children, and adolescent "TABaholics." They kept those cards and letters coming, and, in the end, Congress exempted saccharine from all the provisions of the Food, Drug, and Cosmetic Act.

To be sure, Congress substituted a warning label—which, with some difficulty, you can actually find on the package. But the fact remains that Congress went to extraordinary pains, even passing special legislation, to be sure that saccharine remained in the food supply. They said it would be temporary, but its availability is being transformed into eternity.

From this experience we may conclude, as one cartoonist put it, that cancer-causing products should be taken off the market except when people enjoy them.

Politics Balance Risks and Benefits

The saccharine experience does not constitute an argument for or against the stringent regulation of chemicals in the human food chain. It merely illustrates a guiding principle: Even where laws fail to permit the balancing of risks and benefits, our political process will find a way to strike the balance when the issue seems important enough.

Indeed, such considerations have always played a role in the development of consumer-protection policies. In framing our nation's food safety laws during the 1930s, Congress was careful to discriminate between the kinds of consumer hazards posed by natural constituents of fresh produce and those added during food processing. With fresh produce, the burden is on the government to show lack of safety; with processed foods, the burden is on the manufacturer/processor to demonstrate safety.

FDA sets tolerances on naturally occurring carcinogens like aflatoxin in grain; whereas equivalent amounts of an equally potent carcinogen would not be tolerated in processed foods, either under the Delaney Clause or under the general provisions of the 1938 Food Safety Amendments. From the perspective of consumers, this is surely inconsistent treatment; they are exposed to significantly different risk levels (though in each instance rather small ones) in the two cases. To the Congress, the concept of avoidability was important; the farmer and the fisherman could not, after all, be expected to pay the economic price of contamination they could not avoid. In contrast, the food processor, who might be tempted to add substances to processed food in order to increase profits, should be required to minimize the risk.

The point is simply that the regulation of chemicals in the human food chain is a human activity carried out through a process we call politics. This activity is aimed at balancing an array of factors including, but by no means limited to, the protection of consumers.

Deciding on Standards

As we approach policy choices about chemicals in food, we should consider a number of intersections between the policies and the players—producers, harvesters, processors, distributors, and consumers.

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Important complexities are at work here, and they have been made more complex by recent events. For example, Proposition 65 in California adopted a "no significant risk" standard for carcinogens, which requires the determination of maximum response levels equivalent to those recognized in current scientific risk assessments. These, of course, often involve extrapolations from animal studies with assumptions about the shape of the dose-response curve at low doses, and they are likely to be quite conservative judgments. The eventual impact on agriculture is as yet uncertain, but is likely to be significant. As the Food and Drug Administration has had frequent occasion to find out, deciding on acceptable levels of risk is very difficult.

Data Gaps

The problem is made much worse by what some have called the "data gap," a term that refers to the lack of information we have on the toxicology of a number of important compounds—including many pesticides. This problem has been around for a long time. We have made remarkable progress over the past three or four decades in our ability to detect things; modern chromatographic separation and purification techniques, coupled with high resolution mass spectroscopy, have brought us to the parts per trillion level for almost anything. And yet our ways of determining risk are just about as primitive as they were in analytical chemistry at the beginning of this revolution. In most cases we still have to do chronic studies on laboratory mammals, feeding them for several years before undertaking exhaustive pathological analysis.

As a result, we live in a world full of suspicion but woefully short on verification. Even in the universe of the relatively well-known food additives, there is confusion: The Canadians don't like one kind of red dye, we don't like the other!

While I was commissioner of the FDA, several of us banded together to begin the National Toxicology Program, an effort to get various agencies to work together in prioritizing research needs in risk assessment. That entity is still alive and well, and it has proven useful in eliminating duplication and helping to make better decisions about what tasks to tackle next. Unfortunately, significant gaps in our knowledge remain; and the extremely uncertain character of the risk assessment process itself makes for uncertainties even for the more thoroughly investigated compounds. A regulatory approach that emphasizes the best-known compounds of highest risk, as recommended (for example) in the 1985 National Academy of Sciences (NAS) study, is probably the most prudent approach.

But regulators inevitably have to face a reality with respect to risk assessment: It is well-summarized in a cartoon poster that the American Chemical Society once made using a quotation from, of all people, me. In the poster, a rat approaches two alternative doors, behind which the viewer can see—but the rat cannot—on the left a cat even nastier and more hostile than Garfield, and on the right a piece of delicious, smelly looking cheese. The legend is taken from a moment of unaccustomed frankness that occurred in a piece of my congressional testimony. It reads: "Sometimes you have to decide, even when the data are not as good as you would like."

This article is based on Dr. Kennedy's presentation at the University of California, Agriculture Issues Center's symposium on *Chemicals in the Human Food Chain: Sources, Options, and Public Policy,* June 1988. Proceedings of the syposium are available from the Center for $15.00. Several other reports from the year-long study have also been published; request a list from the Agricultural Issues Center at UC Davis, CA 95616, (916)752-2320.

Same Policy, Different Purposes

Beyond contending with the data gap, we also have to worry about some important contests between different public policy objectives. Nowhere is human decision-making about chemicals in the food chain more difficult than when different objectives get tangled up. One area in which different objectives lay claim to the same policy has to do with the protection of workers and of consumers. There is no question that serious occupational health hazards are associated with the use of pesticides, particularly insecticides. But a careful look at the problems of occupational health and the problems of consumer health reveals that they are not the same. Persistence is an important feature of pesticide risk to consumers; but the occupational threats to production workers, applicators, and agricultural field workers relate much more to immediate toxicity. Thus the organophosphate insecticides, if proper reentry times are not observed, constitute major occupational hazards—but owing to their rather quick degradation— they are not the major problems for consumers.

Concerns about occupational health frequently have the effect of making consumer safety a proxy for worker safety. Thus, in

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arguing for boycotts against agricultural products in the interests of farm workers, hazards of insecticide spraying to consumers are sometimes noted. In that way, a political tangle—and thus a public policy dilemma—is created between the two legitimate objectives of occupational health and consumer protection.

A second example of disparity in objectives has to do with the application of pesticide residue tolerances. When I was at FDA—and I'm sure things haven't changed much since in this respect—there was considerable pressure from domestic agricultural interests to concentrate monitoring and enforcement activities on imported produce. That argument is based upon some federal findings that imported produce has about twice the incidence of illegal pesticide residues as does domestic. But California figures for produce imported from Mexico are not significantly different from that grown in the state, and much of the enforcement pressure—at least in the old days—was related to produce being brought across that border that was in direct competition with domestic produce. I can't state in any authoritative way what the present situation is, but I would emphasize that the use of regulatory requirements to provide a surrogate barrier to entry is an old story in food regulation.

An experience with ice cream also illustrates how food regulations can be used as a trade barrier. Early on in my stay at FDA, the agency, at the request of the Ice Cream Manufacturers Association, published a proposal to allow somewhat more casein in ice cream at the expense of nonfat dry milk solids.

I soon discovered that we had strayed into the politics of protectionism. Most casein is imported from Europe, where it is a major byproduct of cheese manufacture. Nonfat dry milk solids, on the contrary, are a domestic dairy surplus commodity, then subsidized by a rather cushy support price. Before I knew it, I was in a meeting with Pat Healy, head of the National Milk Producers Federation and unquestionably the most sinister-looking lobbyist I encountered during my time in Washington. His proposition was simple: Get off the dairy industry's back, or else.

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Later that week, I received notice that I was to be the witness at a hearing held jointly by the two agriculture subcommittees of the House. The invitation made it clear that I had everything to fear: The co-chairmen, Congressman Charlie Rose of North Carolina and Congressman Fred Richmond of New York, proposed to query me about the dastardly act FDA proposed to carry out against America's favorite dessert. (Congressman Richmond gave all the regulatory agencies so much trouble that several of us were much relieved when he was later convicted on criminal charges and left the Congress.)

For two hours at the hearing, I thought I gave as good as I got, and answered all their questions perfectly satisfactorily. You can understand, then, with what eagerness I opened the paper the next morning to read its account of the proceedings. There it was, right at the bottom of the first page of the *Washington Post*. The headlines read: "FDA PLAN WOULD PUT FOREIGN CHEMICALS IN ICE CREAM."

States' Rights

Another area I want to discuss has to do with the contest between federal and state authority in regulating chemicals in food. This is a historic battleground for the very most fundamental of reasons. The states argue that the protection of their citizens' health is a fundamental state responsibility, and assert that if they wish to set standards more stringent than federal ones they should be allowed to do so. On the other hand, interstate commerce is an activity of crucial importance to the public, and the courts have been wary of state efforts on behalf of consumer protection that present serious impediments to it.

Here the most significant contests have always been between California and the United States. California has a large and active state government, and a treasured tradition of independence. California agriculture is an important activity, and the state approaches a kind of self-sufficiency in this regard that makes state regulation seem much more plausible. On the other side, there is every reason to want California consumers to have a fair chance at purchasing food grown here and elsewhere at reasonable prices; and California risks decreasing the competitiveness of its agricultural economy if the costs imposed by regulation are too high.

The past two decades have seen a considerable struggle between the states and the federal government over this important issue of preemption. So far the states have won most of the battles, with strong support from the National Governors' Association and many environmental, labor and consumer groups. In the future, the balance will probably depend upon how much legislative and judicial interest in the status of interstate commerce is balanced against the arguments of the states that climatological and other conditions dictate a state rather than a national approach to these problems.

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Risk and Public Confidence

All these issues, important though they are, are dwarfed by two overarching problems. The first of these is the primitive nature of the science of risk assessment in combination with widely different public attitudes about different risks. Until these situations change, we will continue to find ourselves in a highly unstable political climate with respect to chemical decisionmaking.

The second overarching problem is the lack of confidence in government decisionmaking. For example, a recent administrator of the Environmental Protection Agency pointed out that surveys show that 90 percent of our citizens believe that we should be doing more with respect to environmental protection—but that, at the same time, 90 percent of our citizens don't trust the EPA, the federal agency in which that function is vested. That is, I suggest, a political crises of the gravest proportions.

And it is not new. At the end of my time in government, the then administrator of the EPA, Douglas Costle, saw that his agency was completely stymied on another significant environmental health issue, that of the health risks posed by mobile source emissions. The situation was a familiar one: Neither industry nor the general public trusted the quality of EPA's scientific risk assessment; yet industry-supported research was not deemed to be credible either. In the meantime, suspicion about the carcinogenicity of diesel admissions was mounting.

New Institutions

Costle and the chief executive officers of several engine companies realized that a new kind of institution was needed, and they set about to plan one. The idea was simple: Find a nonprofit corporation with a nationally credible board of directors, and use it to support first-rate research with funds supplied partly by government and partly by industry. The idea was so simple some of us began to wonder why the organization we were planning didn't already exist. What we brought into being was called the Health Effects Institute (HEI), and I am pleased to say that it is alive and well eight years later.

Archibald Cox, professor of law at Harvard and former solicitor-general of the United States, William O. Baker, former director of Bell Labs, and I served as the founding board of directors, and we were fortunate enough to get Charles Powers as the first executive director. We put together two committees of scientists, one to direct and select research programs, and the other to peer review the results rigorously. EPA provided half the funding, and the motor vehicle industry the other half. The organization has grown, it supports excellent and well-respected research, and internationally renowned scientists have been willing to come forward and serve on the committees. Walter Rosenblith, former provost at MIT and foreign secretary of the NAS, has chaired the Research Committee since its inception; Robert Levy, former director of the National Heart, Lung and Blood Institute and former dean of the School of Medicine at Columbia, first chaired the Review Committee and he has been succeeded by Professor Arthur Upton of New York University, the former Director at the National Cancer Institute.

The idea of an independent nonprofit organization filling this niche between government and regulated industry has already been applied to another problem, that of toxic wastes: In many respects the organization called Clean Sites, Incorporated, is a spin-off from HEI.

I focus on the HEI experience in order to emphasize the importance of institutions and the critical nature of trust, for whenever we talk about risk we necessarily talk about trust. There is an obvious need for organizations that can be trusted by producers, environmentalists, agribusinesses, and consumers alike—supported by all and captured by none.

Every difficult risk assessment problem I have encountered has been profoundly shaped in its politics by the degree to which people were prepared to repose confidence in those who were doing the estimating. Indeed, in the real world of politics, trust enters the very definition of risk, in such a fundamental way that it is part of the calculation. We may not be able to improve toxicology as quickly as we would like, but surely we have the means at hand to improve trust.