REGULATING CHEMICALS: A PUBLIC POLICY QUANDARY

Report of a 1987-88 Study Group on Chemicals in the Human Food Chain: Sources, Options, and Public Policy

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Regulating Chemicals: A Public Policy Quandary

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Preface

Harold O. Carter and Carole Frank Nuckton

This is the second in a series of reports stemming from the UC Agricultural Issues Center’s major study in 1987-88:

Chemicals in the Human Food Chain: Sources, Options, and Public Policy

An interdisciplinary approach was used with the project as over 60 faculty and extension specialists applied their expertise from diverse fields—veterinary medicine, medicine and health sciences, nutrition, environmental toxicology, agricultural economics, food science and technology, agronomy, pomology, entomology, law, and others. Participants came from three UC campuses—Berkeley, Davis, and Riverside—and Stanford University. Many persons from outside the university also participated in the study as consultants, study-paper reviewers, and panelists at the Center’s June symposium.

Each of the three main topics—Sources, Options, and Public Policy—was divided into a number of subgroups. The Sources group examined five major sources of chemicals in the human food chain—animal products, crop plant products, food additives, natural toxicants, and industrial/environmental contaminants. The Options group had three study teams: animal products, plant products, and postharvest handling and processing.

The Public Policy group was concerned with society’s mechanisms for dealing with chemicals, including criteria for food safety, risk assessment and the regulatory environment. Its approach was to involve panels of experts to solicit differing perspectives on regulatory effectiveness. Participating were consumer groups, food producers-processors-retailers, chemical manufacturers, risk assessors, and regulators. This report summarizes the results of a number of workshops and interviews held with these participants in the policy process.

Key findings of the study groups were presented at a symposium on June 2-3, 1988. (The proceedings may be ordered from the Center.) The complete study group reports are now being published. In addition to this report from the public policy study group, will be three reports on Alternatives to Agricultural Chemical Use—Case Studies in Animal Production, Case Studies in Plant Production, and Case Studies in Postharvest Handling and Processing. Also, a reference book on sources of chemicals in the human food chain is being prepared. Video tapes from the symposium are being produced for classroom and extension workshop use. Additional outreach is planned, and new areas of research inquiry have been opened that may well continue for a number of years.
ACKNOWLEDGMENTS

The efforts, comments, responses and cooperation of the many experts from within and outside of the university who contributed to this study are greatly appreciated. Some participated on the panel discussions at the Center's June 1988 symposium. Many others served as consultants, interviewees, reviewers, and workshop participants. Their names are acknowledged below:

Symposium panel members:
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Panel 2—The Art of Risk Assessment: What Role Should Science Play?
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Panel 3—The Regulatory Process: How Should We Regulate?
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Steve Murrill, State Assembly Committee on Toxic Substances
Bob Olson, Food Industry Research
Peter Passoff, UC Cooperative Extension
Keith Pfeifer, California Department of Food and Agriculture
Donna Porter, Library of Congress
Linda Posati, U. S. Department of Agriculture
Len Richardson, California Farmer
Linda Russell, Office of Legislative Affairs, U. S. Department of Agriculture
Art Scarlett, UC Cooperative Extension
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Roy Sharp, Livestock Systems Management
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Peter Thor, Tri/Valley Growers
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Jim Wells, Pesticide Enforcement Division, California Department of Food and Agriculture
Barbara Wells Willis, U. S. Department of Agriculture
INTRODUCTION

Sandra O. Archibald

Economic benefits from agricultural and food use chemicals are well-known. Chemicals minimize food losses at all stages of production, processing, and distribution, increasing profits for producers, lowering product prices and increasing product quality for consumers. Chemical technology guarantees consumers year-round variety, reduces risks of microbial contamination and enhances shelf-life. Yet there are potential environmental and health risks associated with these economic benefits. As a result, a complex regulatory system—founded on scientific assessment of risks to humans from expected exposure—controls food-use chemicals at all stages of production, sales, and use.

Society’s mechanism for balancing the risks and benefits of chemical technology in the human food chain face new challenges from consumers who demand higher levels of protection, by producers and industry who believe the costs exceed the benefits, and even by regulators who find themselves overburdened under increasing pressure to provide new controls with constrained resources. The chemical industry claims that overly stringent regulations on technology are increasing costs and negatively affecting innovation. Producers and processors are uncertain and afraid of losing their competitive advantage to less regulated states and countries. They question whether we are able to identify and quantify real risks to human health and the environment and communicate them effectively.

The policy quandary that we face is determining the optimum balance between current benefits from agricultural and food-use chemicals with largely low-level, long-term and uncertain risks to consumers from this technology. How do we weigh these uncertain risks against known benefits or should we weigh economic benefits at all? How can we regulate to California standards without harming our comparative advantage? How much should we spend on regulation?

The study group on policy and regulation analyzed current mechanisms for balancing the risks and benefits of chemical technology in the human food chain. A primary objective was to explain the recent observed increase in the number of regulations governing agricultural and food-use chemicals, particularly in California. In the past several years, we have added controls on the use of agricultural chemicals that might contaminate groundwater (The Groundwater Contamination Prevention Act). We have passed a law calling for state agencies to review federal standards governing the pesticide residue level legally allowable in food (AB 2021). We have demanded that chemicals long in use be reexamined for their potential reproductive and cancer-causing effects (Birth Defects Prevention Act). At the same time, we have mandated that clear warnings be provided to persons exposed to hazardous substances, authorized banning of chemicals that foul
drinking water sources, and created a “bounty” for whistle blowers on chemical use violators (Proposition 65). New laws requiring reporting of all pesticides used and increased monitoring of chemical residues, are now under consideration. This regulatory activity indicates an obvious “gap” between desired risk levels and perceptions of current risks encountered from chemicals in the food chain. Studies have shown that these gaps are indicative of dissatisfaction with existing market and regulatory mechanisms.

A second objective then was to assess existing regulatory mechanisms. A critical question is whether these new rules are needed, in light of our existing controls. Why aren't federal policies and regulations adequate to protect us? Will we benefit in terms of reduced risk to human health and the environment from more controls? Or will the cost to industry, taxpayers, and ultimately consumers of a more complex, perhaps unwieldy regulatory system, far outweigh possible benefits? How will costs of and demand for California products be affected? The answer to these questions is critical for the future health of California.

And finally, we wanted to identify feasible regulatory changes to better meet the demands of consumers and industry. For example, can more information and education on risks and benefits lessen consumer concerns, reducing the demand for regulation? Can economic incentives, such as subsidies or tax policies, in addition to or in place of existing controls on chemicals, encourage the development of new technology, both chemical and non-chemical without negatively affecting innovation? And can scientific soundness, timeliness and efficiency of current regulation be improved with greater cooperation among all parties?

Balancing Risks and Benefits
In theory, the optimum quantity of regulation is that which equates the marginal costs of control to the marginal benefits, in this case reduced risk from exposure to chemicals in the food chain. Benefit-cost analysis is a decision tool for deciding how much regulation to provide. In this process, the benefits of regulation are quantified in monetary terms and weighed against the monetary costs. For example, the benefits from an incremental reduction in pesticide residues could be defined as an increase in public health. These benefits could be evaluated by how much consumers would be willing to pay for reducing morbidity or mortality. The economic costs of regulation are, theoretically, the resources invested in reducing chemical risks valued at their opportunity costs. The criterion for economic feasibility is that the present (discounted) value of net benefits from the policy exceeds zero.

Applying these principles depends upon our ability to measure the gains and losses that result from regulation. We have been limited in our ability to do so by both the high costs of obtaining needed information as well as by political and technical problems involved in measuring benefits. Low level risks such as those from chemicals in the human food chain are difficult to assess, and even more difficult to manage. In addition, the low probability of occurrence makes the benefits of regulation hard to demonstrate.

In practice then, society achieves this “optimum” balance between risks and benefits of technology by trial and error. Society reveals its preferences for risk through the laws and regulations it adopts. Thus, political, social, and legal processes operate to shape and
implement economic results. Key to understanding the present regulatory environment then is to understand how participants in the policy process—consumers, the food industry, regulators and chemical manufacturers—perceive risks and benefits since it is these perspectives that drive the demand for regulation and result in the differences of opinion between participants in the policy process that have led to current conflicts over appropriate levels of control.

Study Procedures

Historical benefit-risk data can be used to determine patterns of acceptable risk-benefit tradeoffs. However, empirical analysis of the costs and benefits of regulation are constrained by a paucity of research and a lack of data necessary to conduct such analyses. The uncertainty surrounding actual risk levels, lack of information on how regulation affects producers and processors costs of production and absence of observable performance criteria for regulation itself, make quantitative analysis of the costs and benefits of regulation near impossible. These deficiencies are a serious issue, leading in large part to our public policy quandary. In light of this, the study required a new approach if we were to go beyond merely chronicling existing inadequacies.

The information essential to this analysis of regulatory effectiveness was obtained from representatives of industry, consumers, and governmental agencies. After an initial contact by letter, we conducted interviews around the state and held round table discussions to obtain information needed for our analysis. Nearly 100 participated in our study over the course of the past year. (See the list of participants in the acknowledgments.)

In the course of these discussions, (1) we solicited what these experts believed to be the key problem and issues with current risk or food safety standards, risk assessment methodology, and regulatory effectiveness. And (2) we sought their recommended changes for relieving the regulatory quandary.

Participants in the Policy Process

Regulations are made in the policy arena. They are pounded out by the ongoing interaction of law, science, economics, and politics. Consumers, chemical manufacturers, the food industry, and regulators are all participants in this policy process (Figure 1)—although not always as equal partners. We chose to interview each group independently from the others to avoid postured responses—that is, to avoid having them say what they think they should say. Because they realized their views would be heard and their individual opinions would be reported as representative of their group, they were candid and eager to contribute.

Consumers' perspectives were separated into those of consumer advocates and those of consumers themselves, for we expected distinctly different levels of concern between them. Consumer advocates included knowledgeable people from organizations representing consumer groups, environmental groups, government agencies, and trade associations. They participated in interviews and a round table discussion.
For consumers' perspectives, we drew mostly from published reports and other written material. Most of this information was obtained from national and regional consumer surveys conducted between 1984 and 1987.

The food industry was disaggregated into food producers, processors, and retailers.

Individual interviews were held with these industry representatives throughout the state.

Agricultural chemical manufacturers contacted were professionals from individual companies and industry groups, including scientists and managers.

In theory, hazards should first be identified and assessed scientifically, and then the method of their control chosen in the policy process where risks and benefits are weighed. Once this degree of control is established, the most cost-effective means of achieving it should be chosen. In practice, however, these distinctions are not so clear. We decided to separate regulators into two groups—those who assess risk and those who manage it:

Risk assessors are scientists and physicians, charged with identifying and quantifying important health hazards facing society.

Risk managers implement, monitor, and enforce laws and regulation. They include scientists, economists, and lawyers; most are employed by governmental agencies.

From the results of this research critical issues in regulating chemicals in the food chain were identified. While there are some areas of agreement over broad objectives, each group approached any common ground from very different perspectives. These areas of commonality must be exploited if we are to move the dialogue to a higher level where some, at least partial solutions, can be entertained, compromise is needed. It is essential that each group must give up a little in order to reach viable solutions to the present quandary.
The Setting
To gather information on the perceptions of consumer advocates regarding the effectiveness of regulation governing chemicals in the human food chain, knowledgeable people in government agencies, trade associations and organizations representing consumer interests were interviewed. In addition, a round table discussion of representatives from consumer interests organizations was held at the University of California, Berkeley, in November 1987.

Key Problems and Issues
There was complete agreement among the consumer advocates that consumers are quite concerned about potential food safety issues resulting from chemicals in the human food chain. The present generation of consumers is more skeptical about the effectiveness of government regulation and protection and generally more sophisticated about health issues. Consumers today are better educated and have greater access to information.

Consumer advocates believe that consumers are aware that hazardous or potentially hazardous substances may be present in some foods and beverages, despite current regulations. Surveys indicate that carcinogens are of greatest concern, followed by risks from substances that may cause birth defects or sterility. Advocates assign the highest priority in their regulatory agenda to reducing pesticide residue contamination. According to consumer surveys, adverse health effects are associated in consumers’ minds primarily with pesticide residues, followed by antibiotics used in livestock and poultry, allergens (e.g., sulfites), irradiation, and biologically transformed or genetically engineered products. Microbial contamination (e.g., salmonella) and foreign substances in food (e.g., insect parts, rodent hair) appear, rightly or wrongly, further down on the consumer’s list.

Information about food safety and quality is essential for consumers to make informed decisions. The more sophisticated and highly educated the consumer, the more information they seek about food quality and safety. Their understanding about the degree of risk associated with potential hazards is not only a function of the quantity but the quality, completeness and accuracy of the information about risks that they have access to.

Consumer advocates argue that too little unbiased information on food safety reaches the average consumer, and believe it imperative that accurate information be provided to inform consumers. Who should provide this information and how it should be presented remain open questions. What is important to convey to consumers is that the level of risk associated with potentially hazardous substances in the food supply is uncertain and
depends critically on the quantity ingested and differences in individual sensitivities. Consumer advocates believe that information about these technical complexities should be provided to all consumers who generally do not have access to this information.

Consumer advocates are dissatisfied with the existing regulatory system's capability to ensure food safety. They believe that regulators are too often influenced by well-financed lobbies and producer, distributor and retailing trade associations, whereas the voice of consumer organizations, who also have useful information, is seldom heard in the regulating process. They note that many consumers are surprised when food safety problems occur as they have taken government's ability to protect the food supply for granted. However, as more incidents occur, consumers are losing faith in their protector regulatory agencies—in the Food and Drug Administration (FDA), the U.S. Department of Agriculture (USDA), and the Environmental Protection Agency (EPA).

There are valid reasons for this, according to advocates. For example, recent reports by the Government Accounting Office (GAO) and the state of California Assembly Office of Research are critical of federal and state food monitoring programs. FDA samples only about 1 percent of the products entering the retail market and their scientific techniques are "poor," according to the advocates, raising questions concerning the agency's ability to assure safety. It is not certain that every food or beverage ingredient on FDA's Generally Recognized as Safe (GRAS) list is above suspicion merely because it has been in use for a long period of time. They believe we should submit "old" chemicals to "new" scientific standards. Advocates worry that the current sampling and testing techniques are inadequate to detect many widely used pesticides including some carcinogens and reproductive toxicants. In addition, they point to other outdated testing and monitoring procedures.

A recent National Research Council study has heightened awareness of the inadequacies of current meat and poultry inspection, monitoring, and enforcement techniques used by the FDA and other regulatory agencies. These inadequacies call into question the credibility of the information they provide these agencies as to the safety of the food supply. The advocates conclude that the current regulatory system is inadequate in view of the complex problems we now face concerning food safety. Enforcement of existing regulations is equally deficient for the task at hand.

In general, there is insufficient scientific knowledge about the relative risks of production technologies we use. We know for sure that some pesticides used in agriculture are more hazardous than others, but there is much we do not know about precise relative levels of hazard. For example, is irradiation relatively safer than the use of postharvest chemicals?

Most deficient of all are the data needed for accurate and precise risk assessment of adverse health affects. In particular, the advocates stressed the paucity of data to determine effects of pesticide residues. They note that presently data are lacking on many food-use chemicals now approved. These data are critical to such assessment. Pesticide use patterns are not known, toxicological data are unavailable for some approved materials, and legal tolerances for residues may not be health based. Recent National Research Council and governmental reports lend support to advocates' perspectives on these concerns.
A critical issue is determining what the appropriate risk standards should be. Should economic benefits be considered or only adverse health effects? Should substances or processes be banned if they cause one additional death for 10 thousand, 100 thousand, or one million people exposed? Should differing sensitivities of children, pregnant women, and other special groups be a factor? In light of these policy issues, current scientific uncertainty about long-term health effects, and regulatory inadequacies, consumer advocates actively support the zero risk standard in spite of the difficulties involved in adjusting to it and enforcing such a strict standard.

Recommended Changes

Better Information
Consumer advocates were adamant about consumers’ need for access to more unbiased, useful information about hazardous and potentially harmful substances used in the growing or processing of food. The debate on food safety and the inadequacy of the regulatory system should also be made public. Consumers, they say, have the right to make choices based on accurate information. Providing consumers with the necessary information on which to base their purchasing decisions should be viewed as the long term solution to the food safety problem. In the long run, advocates believe this will lead to a safer food supply. Consumers are entitled to “good” information but they are not getting it.

This demand for more consumer information on risks was the message of Proposition 65 which partially shifts the burden of acquiring information from the consumer to the purveyor of food. The grower or processor, not the consumer or the government, is now responsible for providing information to the consumer if a known carcinogen or reproductive toxicant that may pose “significant risk” is present in a marketed product. Foods are temporarily exempt awaiting the outcome of a lawsuit, but advocates push for their inclusion.

The agricultural industry and retailers have objected to the general information provision required by Proposition 65, in part because of increased costs, but advocates point out that producers have supported legislation that would require that fruits and vegetables be labelled to show the country of origin. Labels warning of the presence of potentially harmful substances should be no more expensive. Advocates believe that producers are often reluctant to provide such general warning for fear they will alarm consumers and reduce product sales. And consumers might find it impossible to study information provided for every food and beverage available (there are 5,000 to 15,000 items in the average supermarket in the United States). On the other hand, consumer advocates want to balance information provided. Corporate and agribusiness influence on regulation now far outweighs consumers’ influence, but this can be overcome by consumer groups who are willing to provide accurate information. A group with one thousand consumer members can make a difference, they believe.

Currently, consumers’ major sources of information about chemicals in food are the government, public interest groups, retailers, and producers. Consumer advocates believe that consumer confidence in this information supplied by both government and the food industry is eroding. They believe that the quality of consumer information will improve over
time as will methods of communicating risks, leading to greater sophistication and awareness in consumer decision making. This will come about as additional sources of information, including that provided by the private sector and consumer groups, become available. Besides better information on safety, there is a need for more consumer education on health risks and how to evaluate and respond to them.

**Increased Regulation**

Even if better information on and education about risks of chemicals were provided, this would not be sufficient. Even very knowledgeable consumers, prepared and able to choose the level of risk they prefer, should be protected against known significant health risks. Thus, government should ban the use of certain substances that pose known health risks.

Better testing for the presence of chemicals in marketed products is essential. If monitoring cannot be provided by government agencies, then it will be supplied by private industry. There was general agreement that there is a need for development of economical “quick tests” that government agencies or retailers could use to determine whether a contaminant is present in a food or beverage and whether it is above or below a safe level. Such “certification” at the retail level could assure consumers that food is “safe.”

**Nonchemical Technology**

Organically grown fruits and vegetables can be sold profitably and should be made more available. There is evidence according to consumer advocates that some consumers are willing to pay more for some foods in order to avoid risk. Sales of higher priced organically grown agricultural products are increasing. Another indication of demand for alternatives is the popular acceptance of retailer promoted “Nutraclean” fruits and vegetables certified to have no pesticide residues. Consumers should have those alternatives available.

Advocates recognize that prohibiting certain pesticides or food additives may increase prices and possibly decrease availability of some foods in the short run. However, in the longer run, consumer advocates believe that alternative technology will be able to provide high quality food without large increases in price. Advocates encourage support of Integrated Pest Management (IPM) and other technologies to reduce growers’ dependency on pesticides.
Perspectives of Consumers
Christine Bruhn, Sylvia Lane, and Laura Walton

The Setting
To gain an understanding of consumers’ perspectives as garnered from published sources, recent national and regional consumer surveys were reviewed.

Key Problems and Issues

Chemical Residues
From comparing results of consumer surveys, it appears that consumer concern about the use of chemicals in food has increased over the past 20 years. In a poll conducted in 1980 by Louis Harris, 81 percent of the respondents believe that society is exposed to more risk from chemicals in 1980 than 20 years earlier. Sachs, Blair, and Richter, (1987) found that concern among Pennsylvania consumers regarding the impact of pesticide residues on public health increased during the nearly 20 years between 1965 and 1984.

When asked to rank the issues, most consumers put pesticides first. When specifically queried about safety, 77 percent of the respondents in a 1984 survey of over 1,000 U.S. households conducted by the Food Marketing Institute (FMI) considered pesticide residues a “serious health hazard.” Thirty-two percent expressed concern over food additives and preservatives, 26 percent over coloring agents. In a similar study conducted in 1987, again two-thirds (76 percent) of the 1,000 respondents considered pesticide residues “a serious health hazard” and another 20 percent, “something of a hazard” (FMI, 1987). In this same survey, the issues of antibiotics and hormones emerged quite strongly. Sixty-one percent thought antibiotics and hormones in poultry and livestock feed “a serious hazard” and another 32 percent, “something of a hazard.” Other issues of concern included irradiated foods, nitrates, additives, and artificial colorings (see Table 1).

A 1986 survey of 200 female readers of Good Housekeeping, confirms that food safety is a major issue with American consumers (McNutt, Powers, and Sloan, 1986). On a scale of 0 to 10, consumers rated the characteristic “the food is safe” at 9.6, thereby ranking food safety higher than all other desirable characteristics including “the food is priced right.” “The food is pure” statement received a rating of 8.2, providing further evidence of the importance of a safe food supply.

It appears that even small levels of exposure to chemicals in food concern many consumers, explaining, in part, the preference for the “zero risk” policy called for by consumer advocates. The McNutt, Powers, and Sloan (1986) study found that 45 percent of respondents reported that the smallness of the exposure to a potentially unsafe ingredient
Table 1. Consumer Responses to the Following Question About Selected Food Attributes: 1984-87.

Q: How concerned are you about the following items? Would you say that (READ EACH ITEM) is/are a serious health hazard, somewhat of a hazard or not a hazard at all?

<table>
<thead>
<tr>
<th></th>
<th>1984 Serious Hazard</th>
<th>1985 Serious Hazard</th>
<th>1986 Serious Hazard</th>
<th>1987* Serious Hazard</th>
<th>Not a Hazard at All</th>
<th>Not Sure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Residues, such as pesticides and herbicides</td>
<td>77</td>
<td>73</td>
<td>75</td>
<td>76</td>
<td>20</td>
<td>3</td>
</tr>
<tr>
<td>Antiobiotics and hormones in poultry and livestock feed</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>61</td>
<td>32</td>
<td>4</td>
</tr>
<tr>
<td>Fats</td>
<td>x</td>
<td>42</td>
<td>44</td>
<td>55</td>
<td>40</td>
<td>3</td>
</tr>
<tr>
<td>Cholesterol</td>
<td>45</td>
<td>44</td>
<td>48</td>
<td>51</td>
<td>42</td>
<td>5</td>
</tr>
<tr>
<td>Salt in Food</td>
<td>37</td>
<td>39</td>
<td>40</td>
<td>43</td>
<td>49</td>
<td>6</td>
</tr>
<tr>
<td>Irradiated Foods</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>38</td>
<td>47</td>
<td>5</td>
</tr>
<tr>
<td>Nitrates in food</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>38</td>
<td>47</td>
<td>5</td>
</tr>
<tr>
<td>Additives and preservatives</td>
<td>32</td>
<td>36</td>
<td>33</td>
<td>36</td>
<td>54</td>
<td>9</td>
</tr>
<tr>
<td>Sugar in food</td>
<td>31</td>
<td>29</td>
<td>29</td>
<td>28</td>
<td>37</td>
<td>13</td>
</tr>
<tr>
<td>Artificial Coloring</td>
<td>26</td>
<td>28</td>
<td>26</td>
<td>24</td>
<td>53</td>
<td>20</td>
</tr>
</tbody>
</table>

*Split sample; bases=498 and 509

Source: Opinion Research Corporation for the Food Marketing Institute, 1987, p. 32.

did not reduce consumers' fear of that ingredient. Over one-third reported that their concern over chemicals in food resulted from fear that these chemicals were cancer-causing. Specifically, when asked what evidence was necessary to determine if dyes used in food "really cause cancer," 19 percent responded that they should "ban them just on the chance that they may cause cancer."

From the evidence, it does not appear that many consumers have changed their purchasing habits as a result of concern over chemical residues, although a 1987 survey from The Packer, a trade publication for the fresh fruit and vegetable industry, found that, of those concerned about pesticide residues, 18 percent responded that they have altered their buying habits (Zind, 1988). The sixty-four percent who were concerned about residues have not altered their purchasing, and 19 percent were not concerned about chemical residues. It should be noted that limited availability of organic or laboratory-certified pesticide-free produce may have influenced the 64 percent who had not altered their purchasing.

Consumers continue to have confidence that the food they purchase is safe. It appears that the fear of pesticides, drug and hormone residues, and additives remains a latent concern. It emerges when consumers are specifically asked to rank a given set of hazards, as in the cited consumer surveys, leading experts to discount these responses somewhat. When asked an open-ended question to describe their food safety concerns, chemical additives and harmful ingredients are mentioned by only a few, 10 percent or less (FMI 1988). Cont-
sumers think about pesticides, for example, when they hear or read about them in the news (Jones, 1988). This could explain the apparent inconsistency between 76 percent who rate pesticides as a major concern (Opinion Research, 1987) and the (only) 18 percent who have changed their purchasing habits as a result of this concern.

There is only limited evidence to indicate that consumers perceive that there is misuse of pesticides. Respondents to a 1987 survey (Zind, 1988) were asked if they agreed or disagreed with the statement: “I think there is too much misuse or abuse of chemical pesticides and insecticides in relation to the production of fresh produce items.” Thirty-nine percent said they agreed strongly with the statement, 37 percent said they agreed somewhat, 16 percent neither agreed nor disagreed, 6 percent disagreed somewhat, and 2 percent strongly disagreed.

Likewise, from the same study there was no strong evidence to indicate that consumers were not satisfied with current government controls over food safety. In reply to the statement, “government agencies do a good job of making sure the fresh produce items I buy are safe to eat,” 6 percent strongly agreed government was doing a good job, 37 percent agreed somewhat, 22 percent disagreed somewhat, and 7 percent disagreed strongly with this statement. When asked the same question for producers and/or marketers, again 6 percent strongly agreed they were doing a good job, 41 percent agreed somewhat, 21 percent disagreed somewhat, and 5 percent disagreed strongly.

Respondents in the Zind study were also asked about risks from alternative nonchemical technology in food. When asked whether and under what circumstances they would buy a produce item that had been treated with irradiation (and so labeled), 54 percent said they would not buy an irradiated item “until I knew more about the process of food irradiation.” Twelve percent answered that they were indifferent between purchasing an irradiated or nonirradiated item, 11 percent said they would buy an irradiated item only if a nonirradiated item was not available, 9 percent said they would “never buy” an irradiated item, and 13 percent said “I don’t believe I would ever buy an irradiated item.” Twenty-seven percent of the men, but only nine percent of the women, questioned said they would buy an irradiated item without hesitation. Twenty-six percent of those questioned who were over 60 said they would never buy or probably would not buy an irradiated item, making this the least likely age group to accept irradiated produce.

In contrast to this study, 70 percent of consumers from a national sample survey of U.S. households (Brand Group, 1986) said they would buy irradiated food. In actual market behavior, irradiated foods have been well received when educational material on the technology was available. The products were sold at significantly higher prices than their non-irradiated counterparts (Bruhn and Noell, 1987). In the above-mentioned 1987 FMI survey, food irradiation ranked significantly lower in consumer concern than pesticide and antibiotic residues.

**Sources of Information**

Consumer perceptions of risks associated with chemicals in the human food chain are shaped, in part, by the information available to them. Consumers report that government agencies are the foremost source of information regarding food additives, animal drugs or
hormones, and pesticides. The government was relied on for information on food additives by 34.1 percent of consumers, on animal drugs or hormones by 25.4 percent, and on pesticides by 20.1 percent (Kramer and Penner, 1986). (See Table 2.)

The second most frequently used source of information reported varied depending on the subject matter. For food additives, 19.4 percent used food industry sources. For animal drugs or hormones, 10.9 percent reported that a popular media personality was their source of information. For pesticides, consumers also used an extension agent or home economist for information. One may surmise that pesticides are more familiar to the rural population who is also more acquainted with extension agents. Note that one quarter of the sample reported receiving no information on pesticides, animal drugs, or hormones, areas where food safety concern is highest.

A great deal of confidence is placed on information provided by extension agents or home economists with 63 percent responding that they had “a lot” or a “high” level of confidence in these sources (Table 3). Universities ranked placed second, with 38.1 percent. Consumer groups, with 36.6 percent, were third. Consumers expressed a greater tendency to believe sources claiming that food was unsafe, than the opposite. The sources receiving the highest credibility ratings (ratings on a scale from 0 to 10) if they said a food was not safe, were the American Medical Association (8.5), physicians (8.5), nutrition experts (7.9), the Surgeon General of the United States (7.9), and the Food and Drug Administration (7.7). These ratings may be compared with those received for food advertising on television: 5.0 if the advertisement claimed a food was unsafe; 3.3 if it claimed a food was safe.

In short, many consumers indicate they have serious concerns about chemicals in the human food chain and some methods of food processing. Their concerns are about pesticide residues on agricultural products, food additives and preservatives used in food processing, antibiotics and hormones used in poultry and livestock feed, nitrates in food, artificial colors and irradiation. Moreover, in every case except that of artificial coloring, the levels of serious concern seem to be increasing. It is clear that information is critical to shaping their risk perceptions.

References

Table 2. What Sources of Information Are Used?

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<th>Environmental contaminants</th>
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<td>20.1</td>
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<td>14.5</td>
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<td>2.9</td>
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<tr>
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<td>9.2</td>
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<tr>
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<td>7.7</td>
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<tr>
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Table 3. How Much Confidence is There in Information Sources?

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<th>Some</th>
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The Setting
Individual interviews were conducted with agricultural producers, processors, and retailers throughout the state to determine the key issues and problems in regulating chemicals in the food chain and what changes they would recommend.

PRODUCERS' PERCEPTIONS

Key Problems and Issues
Producers perceive that there is a proliferation of regulations governing chemical use. Many producers do not see a need for these regulations. They are well aware of the potential hazards from agricultural chemicals. They manage them very carefully and have many incentives to use as few as possible because of their costliness. Producers believe they are already highly regulated and want the public to understand better the current regulatory system and thereby reduce its level of concern. The current system is more than adequate to protect the food supply, already among the safest in the world.

They see a number of reasons behind the demand for new restrictions that producers face. Consumer advocates and environmentalists have escalated food safety to a top priority issue, often for political reasons. Similarly, the press focuses on the rare incidents of misuse, aware of the food safety issue as a marketable concern, yet this raises consumer fears unnecessarily. Often, well intended but uninformed (about agriculture) policy makers call for higher standards without knowing the feasibility or costs of implementing them and without establishing any mechanism for determining added benefits. The result is that demand for regulations is more emotionally than factually driven.

In some cases government agencies support the demand for more regulation because it enhances their bureaucratic position. A real problem for producers is that regulations are written and enforced by those with little knowledge of agriculture. The result is "busy work" that uses scarce government and grower resources and may not accomplish intended goals.

A related problem is that detailed scientific standards are being written into the law by those without scientific training leading to controls on production agriculture that are not likely to solve the problems but are very costly. The result is a constant threat of litigation which is a foreboding atmosphere in which to farm.
Producers believe real risks from chemical use are overstated. First of all, there has been a tendency to generalize about hazards associated with agricultural chemicals, when only a few are dangerous. This has tended to generate an overall fear of chemicals. The ability to measure the presence of chemicals in food far exceeds our understanding of the health risks involved. As our measurement technology improves, we tend to narrow the definition of food safety. What used to be perfectly safe, no longer is considered so, as our power to detect the presence of chemicals escalates. Just because we can measure chemicals in parts per billion or even per trillion, doesn’t necessarily mean these are harmful levels. The whole focus is now on measurement—not on health.

We are regulating the wrong thing by focusing on the presence of chemicals, when we should be looking for health effects. But we don’t know enough in this area. We do not have credible information about health effects. We tend to overstate the risks involved whenever we rely on animal studies and extrapolate those effects to humans. As a consequence, risks to humans are based too much on highly conservative conclusions from tests on mice and rats.

The result of this whole system is higher costs of production without any perceived benefits. We should put the food safety issue in proper perspective alongside the other things we do in our life—smoking, driving, for example.

Meanwhile, our strict standards may put California at a competitive disadvantage. Other states and other countries can produce at lower cost under less stringent regulations. Low-cost traditional methods of pest control are being eliminated in California without adequate evidence of harm. (For example, other states allow the ear tag method of fly control; California doesn’t.) And at the same time, imports are not regulated on the same basis.

Costs of production are escalating as producers seek to comply with an increased number of regulations and to deal with increased liability. Also, the greater uncertainty about the future direction of forthcoming regulations discourages new investment in agriculture. Another problem is constantly changing standards that hamper farmers’ ability to comply and make it difficult to evaluate benefits associated with having standards.

Recommended Changes

Provide More Information About Current Regulations

Producers believe that the public is basically unaware that they are already highly regulated. The regulatory procedures should be discussed with the public, including the methods used in scientific testing, to provide assurance of the safety precautions being taken. When dealing with pesticides, farmers realize they are handling poisons. They do take extreme precautions and are legally liable if they don’t. They train those who will be handling the materials and pay close attention to postharvest intervals to assure residues are minimized. The kinds and amounts of chemicals they use are closely controlled by permit including the requirement to notify the county prior to using restricted chemicals. Producers would like the public to be better informed about the controls in place and how well they comply.
Farmers are convinced that their credibility would be enhanced if their compliance performance were better known.

**Develop More Effective and Better Enforced Regulations**
Food safety standards should have more input from the scientific community. And those affected by the regulations should also be heavily involved in formulating them. Regulations should be realistic—not idealistic.

One problem, however, is a laxity of enforcement. There are a few violations. Incidents, accidents, misuses are rare—but highly publicized. Any violators should be immediately prosecuted. Efficient prosecution of violators would help the credibility of the rest of the farming community.

Imported foods must be required to meet the same standards. FDA data show a higher incidence of residue violations. California and U.S. produce growers are put at a competitive disadvantage when differing standards are applied or when products in violation are allowed to be marketed here.

**Seek More Self Regulation**
Agriculture should be pro-active, not reactive. Farmers want more power to self regulate. They are very willing to take on this responsibility. More self regulation could allow the heavy labyrinth of the present regulatory system to be lifted from the state’s production agriculture.

**Develop Cost-Effective Alternatives to Chemical Use**
Many producers also realize that in the face of the public’s growing concern about pesticides and the increasing restrictions on chemical use, they need to find some alternatives. For one thing, farming with chemicals is costing more. "In rice and almond weed control, it seemed that I was selecting for the weed that was hardest to kill, and invariably that last weed required the highest-priced herbicide to control it. Then, often that didn’t work anyway, so I got the feeling that the system wasn’t viable in the long run for us."

Some are turning to organic farming. Others look to low-input agriculture: "I think that more important than organic farming and very useable by mainstream agriculture is the concept of low-input or regenerative agriculture. This, I think, is really more appropriate for reducing chemical use and making farms more profitable." Many are using or are interested in trying integrated pest management approaches. "As research continues, I think alternatives are going to be used. The majority of us want to use the most economical system. We are concerned about chemicals and want to minimize their use, and still provide a very cost-competitive product to the consumer . . ."

**PROCESSORS’ PERCEPTIONS**

**Key Issues and Problems**
Processors are also basically very supportive of food safety regulation, but have some problems with the current system. They agree with many of the problems and issues iden-
tified by the producers. They too are convinced that demands for increased food safety regulation are too often based more on fear than on fact—and that these fears are often not well grounded. Rather, they stem from a public mis-perception about the degree to which chemicals are already regulated. And, processors note that they are regulated perhaps even more at the processing than at the production level.

Along with producers they face high costs associated with an overly inflexible and constantly changing regulatory system. While it is clear regulations can be improved, we should recognize that we probably will never be able to legislate chemicals away entirely, for they constitute a critical component in the state's agricultural dominance.

Among the many facets of the current regulatory quandary is the difficult problem of deficient coordination between government agencies, such as the USDA, FDA, EPA, and between different levels of government, federal, state, local. This lack of meshing among regulatory bodies leads to inconsistent directives which they are obligated to try to meet.

Processors comment on the amount of time spent on reporting requirements and aren't sure that it always produces the intended results. They ask: Are the reports being used by anybody? Is reporting an effective use of their time? Or is it simply satisfying bureaucratic requirements? They frequently see no follow-through. They see the cost, but little or no benefit in this additional work. Generating more paper and more forms isn't the answer to the regulatory quandary!

A fundamental problem is the lack of public confidence in government's ability to deal with many of critical issues facing society. One reason for lack of performance is that the bureaucracy is over specialized. Each agency or individual sees only a small part and defends that turf. No one oversees the entire system so no one sees the whole picture.

They believe there is increasingly no voice from the food industry when the regulations are written. Also, there is too much detailed regulation written without enough scientific input.

It is difficult to establish an acceptable level of safety. Surely, scientists don't always agree on what is safe. However, a zero risk standard no longer makes any operational sense. Once the impossibility of a no risk standard is realized, much of the debate about food safety standards would evaporate.

Overly bureaucratic regulations constrain their flexibility to be sensitive to changing consumer demands. Processors' economic vitality depends on flexibility and responsiveness to consumers, but the heavy hand of regulation can easily squelch this fragile effort.

Changes Recommended
Processors believe that chemicals for the most part are here to stay—we have to devise a better way to live with those we simply cannot live without. Because we need to restore credibility within the entire system—industry, government, and consumers—a set of solutions is needed, not just a single one.
Specify Food Safety Standards
Processors want precise standards spelled out for them—standards that don’t change very much or very often. And when change is necessary, it should be gradually phased in, not suddenly forced upon the industry. Abrupt regulatory changes are extremely costly. Processors could and would willingly live with a solid set of consistent standards. Compliance to such standards would increase their credibility—and decrease their liability.

Improve Monitoring
But even under the present system of regulation, processors call for more frequent inspections so to enhance public confidence in the system. They want to demonstrate that they are complying with the regulations. But processors call for help in achieving compliance. For example, Proposition 65 is vague and difficult. Like producers, they would like more self-regulation, but could use clear guidelines as they attempt to implement new rules.

Regulatory Oversight
Most consumers are not equipped to deal with the food safety issue. What is needed is an official panel of experts—a advisory body (one with clout) composed of agricultural industry personnel (input, production, processing, marketing), scientists, regulators, and consumer representatives. This body would oversee food safety standards. It could solve the bureaucratic specialization problem cited by processors and achieve the coordination needed to put consistency back into the regulatory system. It could move the whole food safety issue to a higher plane where compromise among conflicting parties becomes possible and workable solutions are reached. Members’ terms should overlap to minimize political influence. As a first step we could have a state-level task force as a prototype for what is needed at the national level.

Retailers’ Perceptions

Key Issues and Problems
Retailers are prominent in the food safety issue in that they interface directly with consumers. Therefore, they feel that a large part of the food safety responsibility rests on their shoulders, at least in the consumers’ minds. They are the ones first and most directly affected whenever consumers question their food supply. Retailers know that their reputation is on the line. Their business is built on maintaining the public’s trust. Yet, much of the control is with producers and processors. Therefore, they feel they are in an in-between position.

They have recently had to deal with another serious food safety problem—tampering. (They did successfully shift much of the cost of the changes needed back to processors in the form of new packaging.)

They don’t know what will be required ultimately under Proposition 65 and the Clean Drinking Water Act. They may be asked to bear much of the cost of informing consumers about hazards. If various warnings about certain chemicals must be displayed, they fear such warnings might adversely affect sales, or change the mix of what is sold.
Recommended Changes
Retailers would like to assure that responsibility for food safety is shared appropriately in the marketing chain—near to where the problems occur. One way would be to have products certified before they reach the retail level. Another would be to allow more self regulation by producers and processors. This approach, plus more efficient prosecution of violators, could help assure that products arrive at the retail level with safety guarantees.

At any rate, the responsibility for presenting the public with a safe, high quality food supply should be balanced between producers, processors, and retailers.

Perspectives of Chemical Manufacturers
Sandra O. Archibald, Brian Hurd and Robin Marsh

The Setting
Regulations relating to food-use chemicals directly affect the agricultural chemical manufacturing system. In February 1988, a round table discussion of professionals involved with the manufacturing and distribution of agricultural chemicals was held at the University of California, Davis. The discussion addressed many issues and concerns from the perspective of the industry.

Key Problems and Issues

Regulation Slowing Introduction of New Technology
A key issue for chemical manufacturers is the growing delays in the approval process for registering chemicals in California. No new chemical active ingredient has been registered in California for two and one-half years, due largely to increased demands on regulatory staff from added legislation. In addition, agricultural chemicals already registered for use in California face new re-registration requirements under the Birth Defects and Prevention Act (SB 950) increasing regulatory lags.

Consequences of these delays will be felt throughout the food production system from growers and processors to retailers and consumers. For example, the chemical industry has products in development that are more "environmentally friendly" than some of those currently registered for use; however, the negative regulatory environment, evidenced by the lack of any new agricultural chemical registration in California, is inhibiting their introduction. Consumers may be faced with lower quality, higher priced products at the market if increasingly stringent controls on pesticides reduce the availability of cost-effective pest control for growers.
Increased Costs of Doing Business in California
The process of developing, testing, registering, producing and marketing agricultural chemicals is a costly undertaking. It generally requires $30-50 million and 8-10 years of testing, registration, construction and manufacturing to bring the chemical to market. Current patent laws which provide 17 years of exclusive use-rights to the developing company are severely restricting to chemical manufacturers. If eight years are spent in the registration process, there are only nine effective protected years on the market.

This current regulatory environment already severely constrains the economic conditions that make chemical manufacturing feasible. Since the costs of manufacturing and registering new agricultural chemicals is so high, initial research is restricted to high value crops for which there is a large market, such as corn, soybeans and wheat. Once a chemical has been registered for use on a major crop, the decision may be made to broaden its use to include lower volume or lower value crops.

New regulatory requirements are adding to these already high costs. It is estimated that the battery of environmental tests required to re-register agricultural chemicals under AB 2021, the Pesticide Groundwater Contamination Act, will cost, on average, $600,000 per chemical. The toxicology tests required under SB 950, the Birth Defects Prevention Act, cost $2.8 million, on average, for each active ingredient registered. In light of these growing and costly data requirements mandated by California for both old and new chemicals, manufacturers may decide in certain cases not to register or re-register some products for use in California. As a result, growers are facing tremendous uncertainties for protecting their crops from damaging pest infestations. Minor crop producers are likely to be hardest hit since their crops represent a significantly smaller market for agricultural chemicals and the rising fixed costs of chemical registration make expenditures for these agricultural chemical markets difficult to justify economically.

Multiple-Non-Uniform Regulatory Standards
Like representatives from the food industry, chemical manufacturers view multiple nonuniform regulations between agencies and the state and federal governments as a major issue. The increase in the number of regulatory standards specific to California creates a serious problem for the industry. California’s Proposition 65, the Safe Drinking Water Act, is one clear example. Similar legislation is emerging in other states, and all have slightly different regulatory requirements.

Much of this state-sponsored regulation is in response to frustrations with the long delays in the re-registration of pesticides at the federal level. Yet the result is that multiple, nonuniform requirements must be met. In addition to added costs, questions of pre-emption of federal authority arise. California’s AB 2848 is a direct example: This legislation requires the state Department of Health Services (DHS) evaluate existing federal food tolerances for pesticide residues to determine if they adequately protect the public health. DHS is authorized to notify the Environmental Protection Agency (EPA) that a particular chemical’s tolerance level is considered unacceptable. If EPA fails to respond within one year, the state will establish its own tolerances.

Inconsistencies in requirements frequently extend to different scientific protocols for basic
toxicological studies. These differences not only increase registration costs but may also significantly alter the risk assessments associated with the chemical, depending on the interpretation of the toxicologist.

This multiplicity of nonuniform laws and standards required by state and federal agencies creates confusion, increases costs to manufacturers and ultimately to users, and may not serve the public’s best interest, if for no other reason than the tremendous duplication of effort and resulting inefficiencies.

"Data Gaps" Changing Standards
The issue of multiple, nonuniform requirements is compounded by the retroactive nature of many of the new laws that effectively change the rules of doing business midstream. A primary point of contention surrounds the issue of “data gaps.” Data gaps are deficiencies in the information required by legislative “guidelines” to register a chemical for use on particular crops. New regulation often requires extensive and costly additional research on the health or environmental effects of currently approved chemicals that have met prior approval and may still meet EPA requirements. For example, recent legislation passed in California now mandates information on the likely environmental fate of chemicals (AB 2021, the Groundwater Contamination Prevention Act). Companies are required to provide original lab notes and data on an array of facts about currently registered material, such as water solubility and persistence. Much of these original data may no longer be available and will need to be redone.

When a manufacturer is notified by either the state or EPA that a “data gap” exists and the chemical’s continued registration is in jeopardy, the company must then decide to perform the necessary studies (or to pay the state to do so) or withdraw the chemical from the market. Companies will decide either to provide the information or to abandon the chemical based on the economics. This decision will depend on how much longer the patent is effective, the current and projected profitability of the chemical’s market, and the associated costs of acquiring the information needed to satisfy data requirements. If a company decides not to complete the studies necessary to re-register the material under the new standards, it will do so most often for economic reasons, yet frequently such a decision is interpreted as implying that the chemical is unsafe.

Regulation Ahead of Scientific Feasibility
Political judgements, intended to protect and enhance public health, drive the development of laws and set policy objectives and expected levels of enforcement; the result is that regulations are not always in step with the scientific ability to define and detect potential hazards. As one example, the pesticide monitoring or environmental fate studies required under AB 2021, the Groundwater Contamination Prevention Act, are subject to considerable scientific uncertainty related to the ability to map and predict the underlying hydrology and geochemistry. Yet, as indicated above, these studies will cost well in excess of $500,000. This law implicitly assumes that science can adequately define the path of a chemical’s movement through soil and groundwater; however, the variability of geologic formations and the presence of dry wells, cracks and fissures make it a predictive process rather than one which can be calculated precisely. Too often political expediency dominates without sufficient regard to science.
Recommended Changes

Consider Both Benefits and Risks
The chemical manufacturing industry, despite its commitment to public health and the environment, will likely continue to be seen as wearing “black hats” and placing profit before people and the environment. It is this image that has allowed the political system to rally support to increase regulation and control often beyond the limits of real risk, enforcement feasibility, and scientific reasoning. Protection of the environment and public health is an essential concern of us all, and can only be enhanced by a reasoned approach that balances the social costs and social benefits of alternatives.

As a result of recent regulation, California agriculture is likely to face some critical changes in the way it does business as constraints on the availability and use of agricultural chemicals increase. Greater consideration of the consequences for agriculture should be high on the list of political priorities because of the very large economic stakes involved. These costs affect not only Californians, but those throughout the world who benefit from its agricultural system.

We should assure that high standards governing the safe use of toxic chemicals do not run contrary to other policy goals such as effective management of disease and maintenance of sanitary health standards. Neither should ignore the benefits of chemical use in reducing and eliminating naturally occurring contaminants and assuring high quality, food products. The chemical manufacturing industry would like to raise the public discussion of the benefit-risk tradeoffs based upon reasonable scientific criteria in the hope that a balanced perspective on the nature of risks and benefits to public health can be realized.

An Agreed-To Set of Operating Rules
The chemical manufacturing industry is extremely committed to maintaining high standards for public health and environmental quality. In order to do so it desires to reach a consensus with regulating agencies, scientists and consumer groups as to a consistent and scientifically based set of rules and conditions under which the industry can reasonably expect to operate its business.

It was suggested that the regulatory system could be improved by bringing together all of the interested parties to reach a consensus on the best way to regulate chemical use to protect public health and the environment, and to settle on a set of operating rules that would hold for a set period of time (i.e., five years), barring any unforeseen significant development.

Consider Scientific Feasibility
Science should be given greater weight and should be “up front” in the regulatory process. Sensitivity to scientific and regulatory feasibility should be a primary component in the drafting of good laws. When laws are written, adequate involvement of the agencies or industries that will be charged with implementing them should be sought.

Determining Regulatory Cost-Effectiveness
Manufacturers maintain that regulation often lacks feasible criteria for assessing its effec-
tiveness in meeting its stated objectives. The result could be that costs are increased without any way to measure benefits. Requirements for the registration of pesticides in California could result in significant cost increases. We should move to determine ways to measure the effectiveness of these programs.

PERSPECTIVES OF THE RISK ASSESSMENT COMMUNITY

Noreen Dowling, Sandra O. Archibald, Brian Hurd, and Anna Fan

The Setting
Risk assessment, as distinguished from risk management, concerns the identification, quantification and characterization of health hazards facing society. A roundtable discussion was held at the University of California, Davis, in February 1988 with selected representatives of the risk assessment community. The agenda included discussion of the scientific and regulatory problems involved in assessing risks from chemicals in the food chain, as perceived by professionals.

Key Problems and Issues

The Risk Assessment Process and its Limitations
The process of assessing risks involves four fundamental steps. The first is identification of a hazard, e.g., potential carcinogenicity. The quantitative analytic stage obtains evidence from epidemiological studies, long-term animal bioassays, short-term lab culture tests, and chemical structure-activity relationships to validate that hazard. Generally, positive evidence from the first two categories is sufficient to conclude carcinogenicity, while evidence from the latter two categories is usually regarded as supportive. The next two steps in the risk assessment process quantify the risk identified. Toxicological dose-response data are assembled and potential exposure of human populations estimated. These data are then "characterized" quantitatively as, for example, the additional risk of cancer from a lifetime exposure to a specific material.

As with much scientific inquiry, there are numerous sources of uncertainties and limitations with these methods. One of the most well known is the uncertainty involved in extrapolation of risks obtained by administering high chemical doses to animals. Scientists must rely upon the use of animal bioassays to determine acute toxicity and estimate the dose-response relationship that relates degree of exposure to the incidence of harm. There are several critical components in estimating the dose-response function, i.e., the doses used to generate a response and converting responses from rats and mice to the human response from expected exposure. Although in most cases the protocols within agencies for performing these operations have been established, discrepancies can arise between agencies and among researchers on several important issues. These differences include the choice of mathematical model to represent the underlying mechanisms, interpretation of negative studies, classification of tumor types, route of administration, use of maximum
tolerated doses, converting animal doses to human doses relying on weight versus body surface area, statistical models (maximum likelihood versus upper bound estimates), pharmacokinetic models (relating administered doses to effective doses), and carcinogenic mechanisms (initiator, promoter, or progressor). The complexities of risk assessment magnify with the uncertainties of these numerous issues.

Participants generally agree that the science underlying the toxicology of carcinogenesis continues to evolve. Toxicological studies are moving away from simple dose/mortality analyses into changes produced by chemicals at the organ, cellular and molecular levels. The EPA is continuing to research the use of nonlinear extrapolation models that allow dose-response relationships to be more accurately represented (which is an improvement over linear models that may unnecessarily overstate the magnitude of risks at low exposure levels). Research into the distinction between chemicals that act as initiators and those that act as promoters in the development of cancer, can guide the choice of appropriate statistical models. Recent studies have shown that in contrast to the prevailing "one-hit" models of carcinogenesis, some chemicals such as dioxin act as a catalyst and promote the development of cancer. As will be discussed later, the development of better information resulting in more accurate risk assessments can result in a communication problem with the public as risk figures are revised downwards (i.e., the public may misinterpret the motives of the revision as not being health based). Nonetheless, disagreements among scientists can arise from different approaches as well as from the complexities and inherent uncertainties in the scientific evidence itself.

**Laws, Regulations, and Risk Assessment**

Risk assessment involves analysis of residue toxicology and proposed tolerances, yet risk standards themselves are often set by law. The risk assessment process thus is shaped by and must respond to the legislative mandates of Congress and state legislatures. This fact is central to understanding the framework in which risk assessment is performed. The Federal Insecticide, Fungicide, and Rodenticide Act of 1972 (FIFRA), for example, establishes risk standards and guidelines that must be met before a pesticide can be registered for food use.

Specifically, the 1958 Delaney Clause to section 409 of the Food and Drug Act (1954) prohibits the use of potential carcinogens as food additives, reflecting the scientific assumption that even minute exposures have the potential to initiate or promote cancer. It mandates a "zero" risk standard by prohibiting any exposure. In 1972, Congress further mandated that all pesticides previously registered under FIFRA be reregistered against current protocols, implying that all materials formerly approved will have to be evaluated against the Delaney zero carcinogenic risk standard. Recently, California's Birth Defects Prevention Act (SB 950) sets a minimum risk standard (one additional cancer death for one million population) for materials shown to be reproductive toxins. The point is that risk assessment standards are determined in large part in the policy process. Within these legal guidelines, scientists interpret toxicological and epidemiological data relying on their knowledge of biological pathways and assessments of the likelihood of human exposure. Risk assessment depends a great deal on scientific judgement, requiring knowledge of both the analytical methods and their sensitivities. Regulatory agencies establish the scientific protocols for assessing toxicological data, determining exposure levels and setting tolerance levels for safe use, considering the above. However, new laws increasingly specify detailed stan-
dards, often without consideration of scientific capabilities, complicating risk assessments.

**Inconsistent Risk Standards and Regulations**
When laws and/or regulations are duplicative, inconsistent, or specified at an inappropriate level of detail, risk analysis is made more difficult. Such inconsistencies in risk frameworks exist within and between state and federal laws. For example, FIFRA allows the EPA to balance economic benefits of pesticide use with potential health risks. On the other hand, the Food and Drug Administration (FDA), under the Food Additives (Section 408, 1954) and the Delaney (Section 409, 1958) amendments, governing chemical food additives in processed foods, has less flexibility in the balancing of risks and benefits associated with carcinogens. Only health risks are considered in granting use of nonpesticide chemicals in processed food. Recognizing that “zero-risk” is not optimal, and may not be feasible, the FDA, as a result of the court opinion in Monsanto vs. Kennedy, has applied the *de minimus* doctrine in some cases, specifically in feed additives and some food additives. This doctrine holds that the law does not concern itself with trifling matters, and has been used to establish a threshold concept or to develop the notion of “significant risk.” (FDA considers this to be an excess cancer risk of one in one million.) However, recent attempts to extend this concept to food additives have been rejected by a federal court.

**Incomplete Data (Data Gaps)**
The accuracy and completeness of the risk estimates that result also depends critically on the accuracy of the toxicological and exposure data. Risk assessment professionals voice concern about a lack of accurate data on actual human exposure to chemicals in food. This lack leads directly to reliance on “worst-case” assumptions. There is a shortage of information relating to the actual exposure levels faced by workers and consumers. Participants agree that improved residue information is both feasible and essential for increased reliability of risk assessments. Improved exposure information is needed on several fronts, including: residue levels on produce and dietary information for different segments of the population. (Some segments like infants and the elderly may be more sensitive than others and ethnic differences may imply different food consumption patterns.)

Under FIFRA, pesticide companies petition the federal government for the establishment of a food tolerance. Companies propose a tolerance based on crop residue data and toxicological data. The government (EPA) establishes an acceptable daily intake (ADI) or a risk reference dose (RFD) based on a review of the data submitted. The identification and quantification of the health hazards from agriculture and food-use chemicals are complicated by incomplete toxicological data provided by industry, particularly with respect to older chemicals. New state regulations (e.g., the Birth Defects Prevention Act) require that these data gaps be filled, as does reregistration under FIFRA.

As regulators determine the sufficiency of data being supplied by industry to meet these demands, what the state considers valid, complete and adequate may differ from federal requirements. The result is apparent inconsistencies between what is acceptable by the state and the EPA, resulting in confusion and creating misunderstanding between regulators, industry and the public. Coordinating risk information has been undertaken by the EPA; however, inconsistencies between federal and state agencies still prevail and can undermine the credibility of risk assessment.
New California Regulations

Pesticides are registered in California after they are registered by the EPA. The data base required is identical, but California has historically requested additional data (dermal absorption studies, field exposure studies, etc.) which are now required by the federal government as well. However, state laws continue to add new mandates. For example, the Department of Health Services (DHS) under AB 2848 is required to evaluate federal tolerances (legal limits) established for pesticide residues in food to determine if they protect public health adequately. Tolerances (legal limits at which chemical residues may be present in food) have traditionally been set on the basis of “good agricultural practices,” not on the basis of the health standards (ADI or RFD). These current tolerances can both understate and overstate actual risk. The real issue is how to establish health-based tolerances that consider agricultural practices.

The new state-mandated tolerance review is currently underway. It instructs DHS to notify EPA of existing pesticide tolerances that it judges result in inappropriate risks to the public health. In the absence of federal action on the pesticide in question within one year of notification, the state is to establish its own appropriately justified tolerance. This requires that the state judge whether federal toxicological information is “adequate, complete and valid.” This task is confounded by the dearth of accurate exposure data—on actual residues and on consumers’ dietary patterns. Uncertainties over pesticide residues will greatly inhibit the ability of the state to execute this task. Furthermore, it is likely that differences will arise among regulatory scientists regarding what is to be considered “adequate, complete and valid.” Interpretation of data gaps, study protocols, and analysis of results can be expected to lead to differing regulatory opinions between state and federal agencies.

Pesticide Reregistration

Pesticide reregistration has emerged as a major concern. Congress has required that pesticides approved for use prior to 1972 be reevaluated under current standards and information requirements. This presents a problem for scientists because the required toxicological data to conduct risk assessments are often not available on these older materials. The work load and lack of data have delayed reregistration. Of the nearly 600 agricultural chemicals registered for use prior to 1970, some 390 are used on foods, and of that number only one has fully completed the reregistration process that was initially meant to have been completed by 1976. It is not expected that reregistration will be completed before the end of the decade. Approximately 10 percent of these chemicals have been voluntarily withdrawn from the market, often because the costs of reregistration are so high. The costs of performing the necessary animal studies are estimated at $1-2 million dollars per chemical and can take up to five years to complete. The reluctance of industry to incur these expenses is evidenced by the slowness of the response to reregistration and the withdrawal of many of these chemicals from the application process. It is partly in response to this inactivity that the state has given the DHS authority to act and evaluate tolerances under AB 2848. The difficulties of performing reliable and reasonable risk assessment under such a large degree of uncertainty and lack of information are significant.

Recommended Changes

Achieve Consistent, Uniform Regulations

Since risk assessment responds to legislative decisions, the risk assessment community
would like to promote the enactment of "consistent" and scientifically uniform laws at both the state and federal levels. Laws and the resulting regulations should be developed within a framework that is scientifically feasible for risk assessors recognizing scientific limitations, uncertainties and constraints on data.

A workable balance between rigidity and reasonableness of interpretation is necessary for a smoothly functioning regulatory framework. The EPA, recognizing the need for a consistent approach to addressing risk problems, has recently undergone some restructuring to achieve internal consistency in addressing risk issues. One of the results has been the development of the Integrated Risk Information Service (IRIS) which is a synthesis of available risk information on particular chemicals and represents a consensus of a variety of scientists. The IRIS has been completed for approximately 260 chemicals and provides a consolidated information source for risk assessment professionals around the country. As such, IRIS is an attempt on the part of EPA to promote external consistency and its success in this direction will depend on its acceptance and use by state and local risk assessment officials. Better coordination between and among researchers in both the state and federal agencies will foster consistency and reduce conflicting information and confusion; however, consistency must not be at the expense of losing individual scientific judgment.

Enhance Risk Assessment Capability
Chemicals in food production are likely to be affected by additional California laws pertaining to drinking water (Proposition 65), groundwater contamination (the Groundwater Contamination Prevention Act), and birth defects (the Birth Defects Prevention Act). These laws require that state regulatory agencies broaden the health criteria on which registration and use decisions are made. The risk assessment and thus the pesticide registration process are affected if required resources (including data) are not available. Emerging state legislation increases demands for consistent and informative risk assessment processes but could easily overextend the human and economic resources available to perform the tasks. Lawmakers need to allocate sufficient resources for implementing agencies to gather information and perform risk assessment.

Consider Cost and Benefits of Increased Information
Better information produces better risk assessment. However, information is costly to obtain. Often resources are not provided to meet mandates. The value of additional information in terms of improved health versus the cost of acquiring it is another essential question that needs to be addressed. The State of California has never addressed the entire problem of regulating pesticides or the costs involved in doing so. A "tire-patching" approach has been used as laws are passed to meet local or high priority issues. The costs and benefits of obtaining more complete information are confronting regulators in the process of many commonly used pesticides approved prior to the 1972 FIFRA regulations.

Enhance Government's Credibility
Maintenance of the government's credibility with respect to the safety of the public's food supply is essential. Recent trends of some food retailers to subscribe to private testing for chemical residues can serve to undermine the public's confidence in government food safety programs. Confronting public fears and risk perception is a challenge, and to adequately face that challenge, the use of "good" science to establish and communicate useful assessments of real risks is fundamental.
The Setting
A roundtable discussion with representatives of state regulatory agencies was held at the University of California, Davis on February 18, 1988.

Introduction
Regulating chemicals in the food chain is difficult. The benefits of chemicals are manifest; the dangers of chemical use—though theoretically quite real—are often elusive to document. Statistical inference must be employed to quantify exposure to health hazards and monitor risks; margins of error become a matter of debate amongst reasonable persons. Regulators see clearly that avoidance of health hazards simply cannot conform to the zero-risk solution called for by some. Zero-risk as a standard for synthetic chemicals is unrealistic in light of everyday encounters we have with naturally occurring chemicals and microorganisms in our lives. If we begin with the trustworthy economic maxim—"there's no such thing as a free lunch"—we will start to appreciate the regulator's dilemma: All policies have social, economic and health costs. Even the pursuit of health itself.

At the heart of regulators' frustration is the fact that those who pass the laws are not reliably constrained to consider (1) the match with regulatory staff capabilities, (2) the time frame necessary to carry out the requirements, (3) the funding needed for enforcement, (4) the impacts on California's competitive position, (5) the opportunity costs to taxpayers and consumers. Moreover, these regulators see a lack of public confidence as extremely troublesome, believing that the politicization of food safety standards leads to confusion and less effective health standards at a higher cost to the consumer.

Key Problems and Issues

Conflicting and Inconsistent Standards
Perhaps the greatest public sector problem in regulating chemical risks is the lack of coordination: Policy is set by policy-makers (in Sacramento and Washington), but is implemented by frontline regulators. Often, there is insufficiently effective feedback, and policies are put in place that fail to maximize our regulatory capabilities. The legislature, for example, may mandate new regulations in a highly visible area, but in so doing, may impose large costs on a strapped agency in exchange for minimal health benefits. State enforcement personnel are keenly aware that, while legislators live abstractly in a zero-risk world of abundance, they operate in the very real dimension of scarcity. Agencies must continually choose between devoting attention to areas of (probabilistically) higher or lesser hazard factors. For instance, farmworkers sustain far higher pesticide risks than virtually any California consumer. Yet, study and monitoring of these health problems are
made difficult by the migratory nature of such workers (making longitudinal studies extremely difficult) and by political disinterest in a relatively narrow, uninfluential group of (largely) non-voters. Recent concern over pesticide residues in the food supply has diverted public resources to create better controls for consumers. But the relatively more critical health needs of farmworkers may go under-monitored, it is suspected, because agency resources are being diverted to an area of broader concern but of much lower individual risk.

Another source of inefficiency stems from problems arising when different government bodies set directly conflicting standards. This is seen where U.S. Food and Drug Administration (FDA) sanitation regulations limit insect parts on fresh or frozen fruits and vegetables, in essence forcing pesticide use to meet these standards. Aphids in broccoli are a case in point, and the total number of commodities thusly affected is significant. It is difficult in this situation for regulators to reconcile standards when it is believed that a “cockroach in the spaghetti” would lead to a far greater public outcry than the discovery of pesticide traces. Policies which run at cross-purposes span a wide spectrum, involving non-health issues. Federal price supports for cotton, for example, indirectly encourage the use of pesticides by promoting cotton growing in regions where it would otherwise not be found.

Measurement Drives the System
A further, more fundamental, problem emerges in the choice of standards. As technology progresses in a dynamic world, techniques for detection improve in quantum leaps. Such advances should enable us to craft finer and more efficient rules regarding chemical residues; instead, we encounter a certain regulatory paralysis. In the political world, a “zero tolerance” standard is compelling, but the workability of such standards in years past has depended upon our inability to detect infinitesimally small traces of most elements. The constraint of technology provided, in effect, a de minimus standard—the “limits of detection.” Rapid improvements in our scientific capabilities, however, have forced upon the regulatory system a need for an explicit de minimus standard if beneficial chemicals are to be allowed. It appears clear that the politics of an explicit non-zero standard, though, are far more complicated than the “politics” of an implicit one.

California’s Unique Circumstances
California generally has more stringent standards than the federal government; the state uses a risk-only standard, without allowing for consideration of economic benefits of the chemical use (unlike the Federal Insecticide, Fungicide, and Rodenticide Act). Any chemical with a significant adverse health risk that cannot be mitigated is denied use under state law. Further, California has a tremendously diverse agriculture producing over 250 commodities. Many of these are “minor” crops, and in some cases no tolerances have been established.

Recent legislation may have important implications for the spectrum of crops grown in the state. The issue is that some of the materials we currently have registered for use on minor crops may not be available, as they may turn out to be “bad actors” either toxicologically or environmentally under new requirements. With certainty, minor crops will be affected if many of these pesticides are withdrawn from the market. The state will have to address
the issue of how to maintain the diversity of our agricultural economy. These costs are not being accounted for; environmental and human health issues are currently the only considerations.

The problem is that the large costs of reregistering certain chemicals may mean that some of them will not be reregistered for use in California. SB 950 mandates health effects data (specifically chronic toxicological and reproductive effects studies). A manufacturer of an "old" chemical probably has little of the required data available, and the expected price tag to meet the data gaps is about $2.7 million per chemical. The environmental chemistry data required under AB 2021 are estimated by industry to cost in the vicinity of $150,000-$180,000 per chemical, with the final sum depending on how the studies are designed. Materials that were registered in the 1940s, 1950s, 1960s, have no active patent protection. They are manufactured by several companies, each of which is likely to believe that they have little interest in providing the data, due to a classic free rider problem. Even those with a smaller price tag may not be willing to pay these costs. If an older material is eliminated from the market, a pesticide, for example, that sells for $1.20/lb. may be replaced by a patented one, made by the same company, selling for $75/lb. So, the company would be better off economically not to reregister the older ones.

If the companies are not willing to pay the price of reregistering, the state may have to do so. The question is whether the taxpayers of California are willing to fill all the data gaps for nearly 800 pesticides. Currently the cost estimates of doing so range between $160 and $170 million. In contrast, the annual budget for state and county programs is currently in the vicinity of $40 to $45 million.

The situation becomes especially problematic for many of California's specialty crops. When a product like dill begins increasing in popularity, farmers adjust to changing consumer tastes by adding some rows of dill next to their celery or other vegetables. A pesticide with a set tolerance level may well be applied to the celery, while small quantities drift to the dill. What are legal levels of a given pesticide used on the former, however, are illegal—even in minuscule "drift" quantities—on the latter, largely because dill is a low volume crop and no chemical firm has yet spent the necessary sums to underwrite the required regulatory tests. The end result is that legal residue limits on various crops are set at vastly different levels, unrelated to health concerns.

Residues discovered at "illegal levels" are frequently on crops for which no legal tolerance limits have been established—California employs a zero-residue standard when there is no established tolerance. (A zero-residue standard is not consistent with FDA policy which allows "action levels" or regulatory analytical limits on crops where no formal tolerance has been set.) Minor crop use generally does not justify a chemical company going through the expensive tolerance-setting process. Because producers may need to use pesticides on these crops, they occasionally are pushed into using materials not registered for use at all. Then, if any residue is found, anywhere, it is illegal. At the detection limits now available, we can find parts per billion on these crops. "We have such an extensive monitoring system in place that we find non-problems and make problems out of them," according to one California regulator. When found in violation, the user is prosecuted.
The Demand to Regulate is Not Squared With its Cost

The decision to create new regulations is a political one, with the result that key players—legislators, legislative staff, lobbyists, news reporters, activists, and judges—can impose burdens without shouldering the associated costs. Moreover, these agents do not generally have scientific knowledge of either chemicals or farming to discern the likely effects of legislation; measures often tend to have only a loose correspondence with announced objectives.

The effect of regulations that are unduly costly is not only to raise the price of food to the consumer. When uncertainty about regulatory standards increases, many chemical companies (and even farmers) act very conservatively, and simply exit that particular market altogether. In markets where they choose to stay involved, however, large companies tend to prosper under a tight regulatory system relative to small farmers because fixed regulatory costs are spread over a larger base. Hence, the stringent regulatory climate is seen as leading to further agribusiness concentration. And, of course, the general toughness embodied in California standards raises costs for producers relative to other regions, all else equal. The bottom line is that the current set of California standards may well make California agriculture less diversified, less competitive, and relatively large-scale, compared to what it would otherwise be.

Regulators See Private Certification as a Perilous Solution

Regulators worry about potential problems associated with private certification of food safety. For one, there is a lack of standardization in testing methodology. A private lab can run a test any way it wants. Consumers have no expertise to judge the validity of the results. Example: In one recent case, when residues were found on sweet corn in excess of the legal tolerance, the state was asked to recheck the samples. They discovered that the private lab was using the whole ear (husk and all), whereas the standard is based only on the edible portion. The test method was wrong, but the grower lost thousands of dollars and a lot more in his reputation. The test facility is being sued by the grower. When using a private testing system, there will be more flexibility, but that very flexibility creates many different standards to deal with unless protocols are regularized and labs are certified.

By setting up competition in testing, regulators believe unfounded fears about the food supply are being fed. So, the regulators seem very cautious about private testing and about trusting health standards to the marketplace. However, a private testing system, with proper monitoring, could greatly relieve the busy work load of the regulatory agencies, freeing such resources to investigate more substantive concerns. And, if public fears are generally unfounded, the key output of private lab testing is not “safety” (which is already achieved) but “assurance.” Apparently, consumers are willing to pay for the privilege of being assured, and the marketplace is responding.

The Press and Risk Communication

The press performs a vital role in informing the public, but the market for bringing the risks and benefits of technology to the public appears critically infected with a bias towards the easy headline. Regulators testify that “zingers” are the stuff of newspaper and television reports; complex analysis is considered death on the front page or in prime time. This is an especially problematic fact in this area, where science, statistics, and economic trade-offs are crucial, if subtle, considerations.

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Rather than inform the public about these important public policy choices, however, the news media tend to be used by special interests. When spokespersons holding ideological positions that preclude them from adopting "reasonable" standards are given widespread attention, the public's food safety (and other) concerns are fueled. Regulators are frustrated by reporters who are attracted only to the sensational, and who portray technology as the enemy. One regulator expresses frustration in noting "We cannot escape one fact: We are living older, healthier and more mentally acute than we have ever lived in the history of mankind. You just can't discount that because it's convenient for television."

Recommended Changes

Risk-Benefit, Not Zero-Risk
When zero-risk standards are imposed and cannot be met in reality, they still produce important institutional effects—as when measurable or regulateable risks of a low level are exchanged for significant but non-quantifiable, unregulateable health risks elsewhere. Bringing all interested parties to the table to consider risks and benefits could greatly facilitate discussion and clarify actual disagreements.

The most pressing specific needs of California regulators are tools giving them the ability to rationally allocate scarce health monitoring resources, including:

- the creation of de minimus standards
- employment of a process whereby new regulatory burdens are justified on their associated costs and benefits

Without de minimus standards, regulators are forced to spend valuable enforcement time on tiny risks in areas where detection technology is very good. This lessens competing commitments, where the impact of health regulation is likely to be much greater. (Indeed, the inevitable progression of scientific abilities makes de minimus standards virtually imperative.) The alternative is to expend all regulator energies pursuing more and more stringent health risks to the neglect of more significant risks, with lower margins of safety the global result.

Regulators Should Move Closer to Legislation
Ill-formed regulatory requirements can impose great costs and carry relatively small payoffs. Regulators need a need to become louder voices in the legislative process, giving better feedback as to the effectiveness of politically-determined rules. Seemingly simple laws can force the expenditure of enormous amounts of agency personnel time, creating "a black hole of regulatory activities." Where paperwork, data collection, or administrative procedures impose significant agency costs, legislative proposals should be carefully assessed by experienced agency staff to determine whether an appropriate level of health benefits is likely to result. Their recommendations should be afforded greater weight. Elsewise, the net health effect of new health laws has the potential to be negative.

Improve the Quality of Risk Communication
Finally, the press is overwhelmingly important in risk communication. Reporters assigned to health stories reflexively depend upon well-established precepts, often pitting industry
interests against consumer groups, or playing up a major health scare. The road to progress involves stimulating effective, on-going cross-links between news personnel and all layers of the health establishment, and particularly state regulators. As public servants charged explicitly with maintaining healthful conditions, a continuing dialogue on the problems and subtleties of risk assessment and management in the food chain is essential. For discourse to be effective, press and regulatory officials must communicate when no deadline beckons.

Consistent, Cost-Effective Regulations
Devising regulations for chemicals in the food chain dictates that many hard choices must be made. While noting the inherent difficulty in fixing standards we can all live with (taken literally, of course, no such standard is available), a worthy goal in reforming the regulatory process is to push the set of demands we make on regulators to be internally consistent and more globally efficient. In the first case, eliminating regulatory Catch-22's will coordinate public policy, forcing actual trade-offs to be evaluated. In the latter, allowing regulators to deploy resources where they are likely to deliver the highest health benefits will rationalize regulation in the general interests of the consuming public. In this pursuit, public health is not well served by absolute standards of performance.

FOCUSING THE POLICY DEBATE

Sandra O. Archibald and Robin Marsh

What did we find from this investigation? Not surprisingly, we found that there are significantly different perspectives not only on the efficiency and effectiveness of current regulation in managing the risks and benefits from chemicals in the food chain but also on the degree of risk involved. Because our over-riding goal is to provide information for the current policy debate, it is helpful to identify areas of common ground. There are several clear important areas of mutual concern: First, all expressed concern about the current food safety standards. Second, everyone believes there is a need to improve the scientific data base used in both assessing and managing benefits and risks from chemical technology. And finally, everyone wants more effective and less costly regulations.

Underlying these common objectives, however, we found that there are very different, often conflicting, perspectives among the participants in the policy process as to the source of the problems and the possible solutions. It is valuable to present these differing but equally important perspectives as a means of informing the policy debate. A better understanding of each other's assessments can help us to identify opportunities for action, not just chronicle the problems. The process can help us to set priorities in allocating our scarce regulatory resources. And we may find new insights into how compromise can be achieved.

Food Safety Standards
Consumers' greatest food safety concern is that suspected or known cancer-causing chemicals are being used in food production and processing, with unknown long-run health risks. Pesticide residues on foods
are of most concern according to our review of consumer surveys. These studies on consumer attitudes indicate that concern over chemicals has increased over the past 20 years, and that some consumers are bothered enough to change their purchasing habits. Interestingly, the small degree of exposure does not seem to reduce consumers’ negative reaction to chemicals in food, obviously complicating risk-benefit balancing.

Consumer advocates believe that uncertainty justifies consumers doubts about the risks they face under our current system. Advocates take the position that scientific uncertainty about the health effects of chemicals in the food chain, especially from chronic low level exposure, justifies concern about the adequacy of present standards governing chemical use. As long as the health risks from exposure to pesticide residues, naturally occurring toxins, and chemically contaminated ground water are unknown or uncertain, and exposure is not voluntary, they strongly believe regulation should err on the side of being conservative in order to assure public health is protected.

How about producers? Producers believe that current safety standards are adequate, even more than adequate. They believe that we have the highest food safety and highest quality food available anywhere. However, they insist that the same safety and quality standards should be applied to imported foods with an equal or even greater level of monitoring and enforcement since regulations or use are not as stringent in many importing countries.

Processors’ perspective on the issue of food safety standards is that a zero risk goal for public policy is really unattainable—zero tolerance as a food safety standard makes no operational sense. It is a moving target: The better measurement we have, the better we can define zero. Producers think that the U.S. Food and Drug Administration’s concept of de minimus, or minimal risk, that is presently applied to some feed and food additives should be extended to all food products to insure a cost-effective regulatory system and preserve the economic benefits from chemical use.

Retailers tell us that they believe consumers are losing trust in current food safety standards. Retailers are affected daily by consumers’ attitudes and concerns over food safety. The retail level is the point at which the interface consumers interface with the food industry. Because they sense that consumers are raising questions, retailers strongly desire to understand the proper balance between chemical use and health effects. And they want to know whether a compromise can be made that satisfies both consumer and industry concerns.

Current food safety standards pose serious concerns for chemical manufacturers. They believe there is undue emphasis on regulating synthetic chemicals. By emphasizing synthetics, we ignore regulation of other food safety risks that are probably more hazardous to health:
naturally occurring toxins; disease-causing pests; insects and fungus, otherwise controlled by pesticides; and personal lifestyles that include smoking, drinking, and driving cars.

What about risk assessors? Risk assessors think that the credibility of existing risk standards is being called into question. They remind us that risk standards are set in law, determined by the political process, so they reflect different policy objectives established at different times. Such differences in standards tend to be confusing to the public. For instance, a risk-benefit framework is used for regulating raw agricultural produce, while a zero risk standard is applied for carcinogens in processed food. It is this inconsistency that risk assessors believe often undermines their credibility in working with the food safety issue.

Regulators are concerned that real risks are clouded in the debate over adequacy of current standards. Regulators assert that Californians are protected by the most extensive and stringent food safety regulatory system in the nation. Current standards already adequately protect the public against illegal chemical residues on domestic and imported food. The current push to allocate scarce regulatory resources to very minimal risk from chemicals residues clouds other more serious risks; it also forces a reallocation of resources from regulating greater known risks: sanitation standards, for example; natural toxins; ground water contamination; farm worker and applicator health and safety.

Everybody wants our food supply to be clean, wholesome, nutritious, and of high quality. Yet there are differing perspectives on what the risk standards should be.

The Scientific Data Base
The second area of common concern identified is the adequacy of the scientific data base used in setting risk standards and monitoring regulations. Again, perspectives differed.

Consumers expressed great trust in scientific opinion—opinion coming from universities, extension agents, physicians, and consumer groups. Yet most of their information on risks and benefits, they tell us, comes from government, industry (including advertisements), and the media. Studies show that consumers want more accurate, scientific information on the real risks and benefits of chemicals in the food chain to make better purchasing decisions.

Consumer advocates assert that bad data underlie any guarantees we presently have about the safety of our food supply. Data on health effects used to determine risks are missing in too many instances, particularly data about the effects of older pesticides. They also argue that current tolerances—the legal limits at which chemical residues may be present in food—are missing or based on out-of-date detection limits, when they should be based on actual or potential health effects. Furthermore, current tolerances do not account for differences in dietary patterns among various population subgroups and for changes in these patterns over time.
What’s more, monitoring for residues in foods is incomplete. Therefore, they believe that any residue may be potentially dangerous, especially for known or suspected carcinogens, thus justifying their efforts to achieve a residue-free food supply. Inconsistencies in residue data provided by federal and state agencies and consumer groups reaffirm suspicions about bad data.

Producers and processors point out that risk assessments are often based on “worst case” or overly conservative assumptions about the quantity and range of chemicals actually used in food production and processing, instead of real exposure based on actual quantities used. This approach overstates risk and generates unfounded fears. Furthermore, extrapolation from high dose exposure in laboratory test animals to the low dose exposures actually received by humans, may lead to false conclusions about risk. These extrapolations substitute for reliable data and epidemiological evidence. “Poor” science, they conclude, leads to false outcomes. Producers and processors state that consumers need to be educated about real risks from exposure, not invented risk.

Retailers have found that consumers want better information about chemicals used on foods and the health risks involved. The retailer’s reputation is at stake. Retailers want to be able to provide reliable information to consumers and are increasingly open to alternative sources of information—private laboratory testing, more government information, and even analyses from consumer groups.

How about chemical manufacturers? They believe that overly stringent regulations could have serious economic repercussions for California agriculture. Updating the data base to re-register chemicals in California is slow and expensive and may not be economical for the chemical industry. They have responsibilities to meet both state and federal laws, yet these regulatory requirements often differ, adding to costs. For example, data requirements under California’s Birth Defects Prevention Act (SB 950) and the U.S. Environmental Protection Agency’s re-registration requirements under the Federal Insecticide and Rodenticide Act differ, making it very difficult for the chemical industry to make planning and production decisions. One of their most fervent desires is to have consistent data requirements that do not change so rapidly over time.

Risk assessors tell us their science is a dynamic one, that risk assessment is an evolving science. We constantly are learning more about health effects and are improving our measurement techniques. Better scientific information and technology permit increasingly refined risk assessments. But keeping the risk assessment and regulatory procedures up to date is costly and time consuming. Ironically, when greater information is available that lowers the calculated risk as, for example, most recently with Dioxin,
consumers become suspicious and concerned about the validity of the new information and revised risk standards.

Risk managers argue that to achieve the higher levels of food safety being demanded requires more resources. The current pesticide monitoring program is effective at what it was designed to do—enforce pesticide use laws, not provide comprehensive pesticide monitoring. They know that current regulatory efforts to update the data base and re-register older chemicals is proving to be slow and expensive; data are costly. Yet new legislation mandates more regulation, too often without providing new funding. Regulators have encountered reluctance from affected parties when seeking compliance with increasingly strict standards, especially when the costs of compliance are high and the benefits are not clear. The problem is compounded when the interpretation of valid, complete, and adequate scientific information to meet registration or re-registration standards not only differs at the state and federal levels but also changes over time.

So here again we have our multiple perspectives on the adequacy of scientific data base undergirding regulation: trust in scientific opinion, perceptions of "bad" data, "poor" science, a demand for more data, inconsistency of data requirements, the need for additional resources, and a call for recognition of the dynamics of the regulatory process.

**Regulatory Effectiveness**
The third area of common concern identified is the need to enhance the effectiveness of our current regulation.

Consumers believe that antibiotics and chemicals are dangerous and very heavily relied on in the production process, leading them to the conclusion that current regulatory resources may be inadequate to assure safety. Hence, they believe that more vigilant monitoring and enforcement of regulations are necessary.

Consumer advocates’ perspective is that legislation and regulatory processes have traditionally largely been influenced by agriculture and industry, biasing the risk-benefit balance. Too little accurate unbiased information reaches consumers; providing them with accurate information on their exposure to hazardous substances is critical. Objective, unbiased information about the risks from exposure to chemicals in the human food chain should be a primary goal of the regulatory process. This goal was expressed in the risk warnings component of California’s Proposition 65, the Clean Drinking Water Act.

Producers and processors are convinced that more self-regulation and better incentives for self-policing are needed instead of more legislation and government control. The regulatory system is already too strict and complex. Further regulation could actually make the market unworkable, whereas the goal
of regulation is to correct for market failure, not to create it. Of paramount concern is that California's regulatory environment may adversely affect California's competitive position in the future.

Retailers believe that regulation has to be balanced to make sense—for everybody involved. The regulatory system is fundamentally based on trust. With greater self-regulation by producers, processors, and retailers, government regulation would become less critical. Balanced means learning to share the responsibility among consumers, the food industry, and regulators, for providing the public with the safest food supply possible.

Again, chemical manufacturers are faced with multiple and nonuniform regulatory requirements. Chemical manufacturers argue that regulations, to be effective, must be uniform at the federal and state levels and stable over time to facilitate planning and compliance. Nonuniformity can complicate interstate commerce. Chemical manufacturers also believe that the proliferation of chemical-use related laws and regulations is often based more on political expediency than on scientific foundation and the public good. And they assert that the unfavorable regulatory climate in California could potentially make it uneconomical to register new pesticides for minor uses with implications for both California agriculture and consumers.

Risk assessors find that legislation too often gets ahead of science. Increasingly they are asked to make risk assessments that are infeasible given current toxicological information and data. For example, re-examination of existing federally set tolerances is very difficult to carry out in the absence of more complete and accurate residue and exposure data. They are also asked to predict ground water contamination risks when they do not have the needed geological surveys or the existing capability to make required determinations.

Risk managers also face an uncoordinated policy environment. They see a lack of coordination between those making the policy, those who draft the laws, and those who have to implement them. Regulators are then confronted with considerable uncertainty in interpretation of the laws and encounter scientific, technical, and political difficulties with their implementation. To complicate matters, they are often given unreasonable time frames. With the proliferation of new laws and constraints on resources, risk managers believe it is essential to set priorities. We must decide if we are more concerned about pesticide residues, antibiotics, farm worker safety, sanitation standards, or monitoring of food imports.

So here again we have a wide range of perceptions to be accommodated. There is a common goal—more effective regulation—but each group comes to the common goal with its own set of issues, problems, and priorities. We are going to have to work our way through these differences before we move to a workable consensus.
Next Steps: Looking for Compromise

Sandra O. Archibald

From our study it is evident that we do hold some common objectives on which to build. But we also continue to hold strong opinions about key elements in the regulatory process—how large risks really are, how we should control them and how much we should spend doing so. And we differ about what compromises must occur before progress toward resolution can be made. Some possible compromises to reach desired objectives based on solutions proposed by participants in this study are explored here as a means of moving the policy debate forward.

How Safe is Safe: What Criteria Should Guide Our Food Safety Standards?
Resolution of any important policy issue is founded on legislative compromise. No exception to this rule, food safety is governed by a patchwork of safety standards defined in a multitude of laws that have evolved over time to meet a variety of needs. These laws are criticized for their inconsistencies which, many believe, have led to costly, and perhaps, ineffective regulation.

Examination of just four of the major pieces of legislation governing risk standards for chemicals in food, highlights these inconsistencies and reveals existing differences of opinion about appropriate risk standards. On the left side of the figure, the 1958 Delaney amendment to the Food and Drug Act establishes a zero or no risk standard for carcinogenic chemicals in processed foods. On the far right side is the risk-benefit balancing framework mandated by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) that regulates pesticide residues on raw agricultural products. FIFRA establishes a regulatory framework that balances environmental and health risks from pesticides with economic benefits.

These differences in risk standards for raw and processed products were originally justified on the premise that naturally occurring carcinogenic chemicals were unavoidable, and thus

Reasonable Risk Standards?

<table>
<thead>
<tr>
<th>Zero Risk</th>
<th>De minimus Risk (1 in 1 million)</th>
<th>No Significant Risk (1 in 100,000)</th>
<th>Risk/Benefit</th>
</tr>
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<tbody>
<tr>
<td>Delaney</td>
<td>SB 950</td>
<td>Proposition 65</td>
<td>FIFRA</td>
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excluded from regulation. Pesticides, on the other hand, though not naturally occurring were essential to guarantee an adequate, inexpensive food supply. If they were to be used, some residues were to be expected in raw products as a tradeoff. Nonetheless, the thinking continued, processors could avoid deliberate addition of carcinogenic substances to foods, so processed foods were banned from using chemicals known to cause cancer.

In the middle of the figure, is the de minimus concept that is utilized by the Food and Drug Administration to regulate some feed and food additives, and is the standard underlying the recent California Birth Defects Prevention Act (SB 950), controlling known reproductive toxicants. The U.S. Environmental Protection Agency has just announced its intention to apply the de minimus principle to register pesticides with low level cancer risks as well (Norman, 1988). This standard is generally accepted as a “one in a million” risk from a lifetime of exposure to residues in food. Also shown in the figure is the recent standard adopted by California for chemicals in drinking water. Under Proposition 65, the initial definition of no significant risk is one additional cancer in 100,000 people.

As a chemical manufacturer, as a producer, as a consumer, as a regulator, what can be said about safety? Which standard is appropriate? Do we want consistency among all the laws? Or do we want them to be different, reflecting implicit risk-benefit decisions achieved in the legislative process which vary for different activities? In the present case, we assume that it matters more if a carcinogenic chemical is used in processed food than if it is present in ground water. And we have decided that we are less willing to assume cancer risks from chemicals in food than we are adverse reproductive consequences. In practice, since many of the same chemicals are likely involved in drinking water, raw food products, and processed foods, the lowest risk level adopted will probably drive the system.

Most of those involved in this study believe that chemicals used in food be should guided by a common statutory framework. But here the agreement ends. Many consumer advocate groups and some health scientists believe that standard should be strictly health based, expressing preference for a no risk standard. Many producers, processors, chemical manufacturers and scientists believe no risk to be an economically and scientifically infeasible goal, preferring to recognize unavoidable low levels of risk. Furthermore, there are differences of opinion as to whether health risks alone should drive regulations. Others argue that benefits must be considered in the balancing equation.

The consequence of this policy stalemate is that “no risk” statutes remain on the books, in part because consumers perceive them as “insurance.” Yet the Delaney amendment has never been invoked to withdraw an old pesticide, although it has been used to deny registration to new pesticides (National Research Council, 1987). Expectations that many older materials currently registered for use cannot meet the stringent zero risk standard of Delaney, has probably contributed to the delay in re-registering economically important older pesticides. As a consequence, older materials with perhaps greater health risks remain in use. Here is a clear case where over-regulation—a zero risk standard—has led to under-regulation.

If a de minimus risk standard were recognized, many consumers are concerned about where
the new level would be set. Would it be one in 1,000,000, one in 100,000, or one in 10,000? What role would consumers have in deciding the appropriate level? If risks were balanced with economic benefits, wouldn’t they always overwhelm risks? This then is our public policy quandary. How can we move toward a consistent, economically and scientifically feasible, mutually agreeable risk standard?

Enhancing Risk Assessment Capabilities: What Role Should Science Play?
There was general agreement that risk analysis capabilities must be strengthened if we are to rely on such assessments to guide policy. Standards we set, whether technology or health related, must have a sound scientific base or risks will be over- or under-regulated at a potentially high cost to consumers, producers or both.

Current risk standards emerged from the policy process. And when we make these risk-benefit decisions in the policy process, to a large degree without full benefit of scientific and economic assessment, we can expect to produce such inconsistencies. The level of risk that society is willing to tolerate will remain a question to be decided by policy. Yet determination of these risks is a question for science. The problem is separating science from policy. The dissonance between science and the creation of public policy is well recognized as being especially troublesome in formal risk assessment (Ruckelshaus, 1983). A major problem currently is that neither the science nor the public attitudes about risk are well developed (Kennedy, 1988).

Presently, risk assessment must rely on conservative assumptions about chemical exposure, largely for lack of better data. Risk assessors state that if data on the actual quantity of pesticides used, likely residue levels and realistic food consumption data were available, risk analysis could be based more on “expected” exposure in contrast to “worst case” assumptions.

Since we found that better data were called for by most groups surveyed, could cooperation produce the data necessary to improve risk assessments? Chemical companies have toxicological data and, with producers, could generate pesticide use data. Detailed computer-based retail inventory and accounting systems could provide needed information on food consumption as well. Could these data be made available to regulators in a timely fashion in exchange for a uniform consistent regulatory framework? Consumers would gain in the quality of information regarding true risks of chemicals, industry would have the facts to demonstrate that current assumptions overstate risk and risk assessors would have better data to conduct their analysis. Would consumers be more willing to accept minimal risks if they had access to reliable information on the actual risks involved?

Everyone has said that better communication about risks must be available to consumers. Risk assessment remains an uncertain process. And this uncertainty must be communicated to policy makers, regulations and consumers in an understandable way. Scientists have a high degree of credibility, according to our study, and could take a larger role in explaining risks. Science will be challenged to communicate risks and the uncertainties surrounding risk analysis in an understandable way, taking care to keep separate their own policy recommendations from the scientific analysis itself (Ruckelshaus, 1983).
This problem is complicated by laws that establish a degree of certainty which science and technology cannot deliver. Regulators and scientists themselves imply certainty when they represent risks precisely, for example when risks from a given chemical are reported as 7.65 x 10^{-7}. When uncertainty over such precise numbers is debated between industry and regulatory agencies, the public often sees it as a question of industry trying to expose consumers to higher risk levels.

Consumer advocates want consumers to know exactly what they are exposed to, and what the risks truly are. They want to know what we know and what we don’t know and how sure we are of our science. One means of improving understanding and acceptance of risk analysis is to bring the process more out in the open, following perhaps the example of the automobile industry where a non-profit organization has been organized to share responsibility for risk assessment between regulators, industry, scientists, and consumer and environmental groups who direct research programs and peer review research results (Kennedy, 1988).

The Regulatory Process: How Should We Regulate?
Chemical companies argue that present regulatory requirements are not uniform across agencies or between state and federal governments, they are constantly changing, costly to comply with, and often lacking in scientific foundation. Would more rapid, cost-effective development of relatively more benign, environmentally friendly alternatives be facilitated under a more consistent and efficient regulatory system that could guarantee relatively unchanging standards? Consumers would gain with access to less toxic materials. Chemical companies would have more planning certainty and regulators a more realistic mandate.

Consumer advocates do not have confidence in current tolerance levels and therefore believe that any amount of residue is intolerable. Would they be more willing to accept residues if tolerance standards were based on up-to-date health effects, realistic exposure data were used, monitoring was adequate and enforcement truly effective (violators were penalized)?

Regulators state that review of old pesticides will likely continue for the next decade (Norman, 1988). Perhaps an interim policy goal of minimal or no residues backed up with increased monitoring, particularly of suspect materials, until all the risk assessments have been conducted, may be a viable alternative with benefits for all. For concerned consumers, anxiety about exposure to unknown risks would be reduced. Producers would be assured continued access to economically important materials pending completion of the review process. Chemical manufacturers could continue to market older chemicals with an incentive to complete the review process. Regulators would have the time they need to conduct proper scientific inquiry. Such a policy may require some changes in manufacturer’s use recommendations, post-harvest intervals, or sanitary standards, e.g., percentage of contamination by aphids, etc. It would provide an incentive for producers and chemical companies to reduce use, and watch timing of applications more carefully.

There are more than likely only a few “bad actors” among chemicals now in use (National Research Council, 1987). A ban on agricultural food uses of the these materials could
significantly change the atmosphere of trust as much as reduce expected health risks.

Producers, processors and retailers all told us they are interested in more self-regulation. They are convinced that better compliance would result if more self regulation were built into the system. There are alternative risk management mechanisms. One option to the current regulatory framework is to involve the public in the decision making process by giving them the information on health and environmental risks and trust consumer sovereignty. Another is to rely more on the private sector to provide regulatory checks and balances. This would, of course, be accompanied by consistent enforcement and rapid resolution when violations occur.

The present increase in the supply and utilization of private certification for pesticide residues provides some indication that the public is willing to accept new approaches. While the state could increase monitoring activities as a response, it could also consider providing services to assure that private laboratories maintain scientific standards. Such certification could be provided for a fee, generating revenues for other regulatory activities at the same time responding to consumer and retail demands for increased monitoring. It could be combined with random sampling of farmers by the state with high penalties for violators. Periodic reporting of actual residues could provide those concerned consumers with information that could enhance their confidence in the regulatory system.

Conclusion
We have raised many questions in this study and offered a few opportunities where compromise and cooperation may be to the benefit of all. In terms of "next steps", there is a clear need for further action. First, we should decide whether standards for chemicals used in food should be guided by a common safety standard. Should all chemicals in the human food chain be regulated on a "no risk to health" standard with no allowance for economic benefits? Is there a value to considering some minimal risk when economic benefits are very large as we do in other areas of society? Is a full "risk-benefit" framework where both risks and benefits are weighed likely to result in greater welfare for all? More basically, how do we go about achieving consensus?

If we agree that scientific risk assessment is the appropriate approach to determining risks to be regulated, how do we balance consumers' expectations for food safety guarantees based on "valid, complete and adequate" data and quantitative risk assessments with existing resources and scientific risk analysis capabilities? Particularly, how do we balance constantly improving scientific capabilities (e.g., improved detection) with industry's need for feasible, consistent and stable risk standards? Who should pay the cost of changing standards?

What education and/or information should consumers have to make well-informed choices? How do we communicate risks in an understandable way to facilitate informed consumer choice minimizing consumer anxiety rather than enhancing it? A more fundamental question, is whether formal risk assessment is appropriate for food safety regulation when the risks are low level and scientific uncertainty so high?

Criteria to guide the level of resources allocated to regulation of chemicals in the human
food chain are essential. Should those with the greatest possible exposure such as farm workers be given highest priority? What about protecting “sensitive groups.” What are the benefits and costs of regulating materials which affect only a small sub-group of the population? Is this a case where information, as opposed to control, is more appropriate, leaving consumers responsible? More generally, how do we assess the performance of the regulatory system? When do we know when our controls result in costs that exceed any possible benefits to society?

Our regulatory system is 20 to 30 years old; today we employ much more sophisticated production and processing technology. But we haven’t significantly changed our basic approach of licensing each new pesticide or food additive and setting standards of performance on each product for all uses, even though the number of products and materials has increased enormously. Are there more efficient, effective ways to control unwanted side-effects from technology that minimize environmental and health risks while maximizing gains in efficiency and productivity for society. What about self-regulation? What role can information and education play? We must be open to new approaches that do not constrain technological innovation or industry’s comparative advantage.

The questions are not easy ones. The bottom line is that consumers, producers and policy makers must have confidence in those assessing and managing risk. Trust in the safety of our nation’s food supply is axiomatic, and can only in part be achieved through regulatory controls. The differing, and even opposing, viewpoints that emerged from those interviewed in this study indicate that this trust is likely in need of some refurbishing. Only through cooperation and compromise among those of us involved can we work through the present policy quandary. The benefits from doing so are high, as are the costs of continuing to “muddle through.”

References