

Chapter IX

# **Congressional** Options

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The present system of controlling environmental contaminants in food consists of two parts: regulatory procedures to set and enforce limits for environmental contaminants, and monitoring procedures to detect lots of food in violation of established limits. Each State has authority for regulating food grown and consumed within its boundaries. The Federal Government is responsible for regulating food in interstate commerce.

Congress can choose to maintain this system. But if it wishes to put greater emphasis on protecting consumers from contaminated food, one or more of the options discussed below could be adopted. None of these options (except for the first) are mutually exclusive.

## **OPTION 1—MAINTAIN THE PRESENT SYSTEM**

The current regulatory approach to controlling environmental contaminants in food involves the setting of action levels (and occasionally tolerances), coupled with regulatory monitoring for known [and a few suspected] contaminants. Food containing an amount of a contaminant that exceeds the action level or tolerance can be identified through such monitoring. This food is then removed from the marketplace. Public exposure is thus theoretically limited to those foods containing quantities of contaminants that fall under prescribed action levels or tolerances.

Pros: There are two principal advantages to maintaining this system. No additional appropriations or legislation are required. No changes in existing regulations are necessary.

Cons: There are a number of disadvantages in retaining the current system. The time needed to identify an environmental contaminant in food and take corrective action would not be shortened. The people would continue to be exposed until a contaminant was detected and identified, and an action level put into effect.

Moreover, action levels and tolerances tend to institutionalize rather than protect

people against exposure. In other words, action levels and tolerances permit a certain level of contaminant to be present in food. Unless action levels or tolerances are reduced, little effort will be made to eliminate the contaminant. The threshold concept on which action levels and tolerances are based—that there are exposure levels to toxic substances below which there are no effects on health—is being increasingly challenged (especially when carcinogens are involved).

If high action levels or tolerances are established, exposure is not reduced. Lowered action levels and tolerances may reduce public exposure. But even low limits are set on the basis (among other things) of nationwide per capita consumption of a particular food. Contamination problems, however, may be localized and further influenced by regional food consumption patterns. Thus, a local population may be highly exposed to a toxic substance although the tolerance, based on national consumption, may be low.

Moreover, there is no requirement for review once an action level has been established. An agency is under no pressure to actively seek out new data that might alter a prescribed level.

Tolerances and action levels have other weaknesses. They are often not easily applied when the environmental contaminant involved is a suspected carcinogen (such as polychlorinated biphenyls (PCBs)). Furthermore, the time required to perform a complete chemical analysis for contaminants in nonprocessed foods such as fish makes its dif-

ficult to prevent some shipments from reaching the marketplace.

Finally, there are procedural problems in the present system. States have no clearly defined authority to which they can turn when they suspect environmental contamination of food.

## OPTION 2-AMEND THE FOOD, DRUG, AND COSMETIC ACT

The Food, Drug, and Cosmetic Act has been amended several times since its passage in 1938 to deal with new food regulatory problems. Environmental contamination of food is now a national problem which Congress has never directly addressed through legislation. Thus, Congress could choose to give regulatory agencies more guidance by clarifying its position on environmental contaminants in food.

An amendment to the Food, Drug, and Cosmetic Act could include one or all of the following points. None are mutually exclusive.

### Option 2A-Simplify Administrative Procedures

Under current law and regulations, the Food and Drug Administration (FDA) sets an action level for a contaminant soon after an interstate shipment of contaminated food is discovered. FDA will then presumably launch the elaborate rulemaking proceedings that culminate in the establishment of a tolerance (under section 701(e) of the Food, Drug, and Cosmetic Act). In reality, the costs and delays involved in the complex rulemaking procedures now required for the adoption of tolerances have discouraged FDA from moving from the first (action level) to the second (tolerance) state of the process.

Congress could amend the Food, Drug, and Cosmetic Act to simplify the administrative procedure through which tolerances are set. The changes could be modeled after section 553 of the Administrative Procedures Act. This process involves publication of a toler-

ance proposal in the Federal Register, along with (as required by recent court rulings) the rationale and factual data underlying the proposal. The public can then respond to the proposal with written comments. FDA may also hold legislative-style public hearings to allow presentation of oral arguments and evidence.

After considering all of the comments, FDA publishes a final rule (in this case, a tolerance). This final rule includes explanation of any changes from the original proposal and responses to factual points raised by the public. Most agencies now use this model for rulemaking. It is a process that can be carried out expeditiously with modest investment of an agency's resources.

**Pros: Adoption of this streamlined rulemaking procedure would reduce the time and expense now involved in setting a formal tolerance. It may encourage FDA to move from action levels to tolerances, thus bringing more public participation into the process.**

**Cons: Because action levels are administrative guidelines, they can easily be changed when new scientific information becomes available. Even if FDA comes to use a simplified procedure to set tolerances, it may still be slow to revise them in the light of new data.**

### Option 2B--Require the Establishment of Tolerances

Congress could amend the Food, Drug, and Cosmetic Act to require the establishment of

a tolerance within a specific time after the setting of an action level.

**Pros:** This change would encourage FDA to gather additional information on a contaminant's toxicity and the public's exposure. It would speed up a process that now operates under no deadlines. And it would result in definitive tolerances that FDA could enforce with less concern about judicial questioning.

**Cons:** This option, however, would substantially increase FDA's workload unless tolerance-setting procedures were simplified. Indeed, it has been the costs and delays of the current rulemaking process that have deterred FDA from moving from action levels to tolerances. Thus, tolerances should not be required without also simplifying present rulemaking procedures,

#### Option 2C--Clarify the Role of Economic Criteria

Congress could amend the Food, Drug, and Cosmetic Act to clarify to what extent economic criteria can be used in setting tolerances. The Act does not specify that costs (the adverse economic effects) of a proposed tolerance be considered when setting a tolerance. FDA, in practice, does weigh the cost of food lost when establishing a tolerance.

The Food, Drug, and Cosmetic Act could be amended to prohibit FDA from considering costs when setting a tolerance. Prohibiting any economic assessment would ensure that public health would be the first priority in setting a tolerance.

Conversely, the Act could be amended to require FDA to weigh the costs against the benefits of a proposed tolerance. Requiring FDA to evaluate the economic consequences of a tolerance would give FDA clear authority to weigh such estimated effects together with the potential health risks when establishing a tolerance. Congress could require FDA to gauge only the primary costs (as is now done with food lost) or all associated costs (food lost, employment impacts, distributional and indirect effects) for a proposed tolerance. The techniques available for estimating costs

require up to a year for generating the necessary data. Thus, weighing the costs is best suited for setting tolerances, not action levels.

The advantage in including costs in tolerance-setting decisions is that adverse economic impacts are likely to be reduced. The disadvantage is that tolerance levels are likely to be higher than would be the case if costs were not considered.

**Pros:** By clearly defining to what extent costs can enter into tolerance-setting decisions for environmental contaminants in food, Congress would eliminate ambiguities of interpretation and provide clear guidance to FDA.

**Cons:** FDA has interpreted the Food, Drug, and Cosmetic Act as allowing cost considerations, Legislation requiring economic assessment could limit FDA's discretion to weigh the costs of food lost if it judges the situation warrants such a treatment.

#### Option 2D--Establish Regional Tolerances

This option would give FDA the flexibility to set different action levels or tolerances for different regions, based on expected levels of exposure, regional levels of contamination, and eating patterns.

**Pros:** Action levels and tolerances may not be set low enough to protect those populations that are most highly exposed, previously exposed, or most vulnerable. States may not exercise their authority to set tolerances which are more restrictive than the Federal tolerance because of budget limitations, inadequate information, or political pressures. FDA can provide guidance to States and suggest more restrictive tolerances or warnings to the public, but FDA has no authority to intervene if the contaminated food does not enter into interstate commerce.

**Cons:** Regional tolerances would complicate monitoring and enforcement programs. Regional tolerances might also be viewed as Federal infringement on State authority.

## OPTION 3-ESTABLISH AN INVESTIGATORY MONITORING SYSTEM

Environmental contaminants could be detected earlier in the food chain by improving present environmental monitoring capabilities—establishing an investigatory monitoring system while maintaining current regulatory monitoring programs.

Congress could set up a national investigatory monitoring system that monitors for either suspected or uncharacterized environmental contaminants. A system combining elements of both approaches could also be established. Since any of these monitoring approaches would require some research and development before a fully operational system could be devised, Congress could choose to create a pilot program. Such a program would spur research and development and assess the feasibility and cost-effectiveness of the various approaches.

The investigatory monitoring systems discussed in this assessment would call for different sampling and quality control procedures. The development of these procedures is as important as the development of monitoring technology (some of it still in the experimental stage). Indeed, there is no comprehensive investigatory monitoring system for toxic substances in food and the environment at any level of government.

Consequently, Congress might opt for a pilot project to assess the capabilities and resource requirements of various national monitoring systems instead of mandating a particular monitoring approach. Such a pilot project would focus on the monitoring of organic chemicals, inorganic, and radioactive substances. It would determine the technology, sampling, and quality control needs for monitoring these three toxic substance categories in food, air, water, and soil. The broader purpose of the project would be to develop a comprehensive monitoring program that would meet the Government's regulatory needs, provide data to make cost-effectiveness assessments of the alternative strate-

gies, and reduce public exposures to environmental contaminants as much as possible.

### Option 3A-Establish a National Monitoring System for Suspected Environmental Contaminants

Suspected environmental contaminants are substances that are most likely to enter the food supply and pose potential health hazards. Lists of such substances could be drawn up for organic chemicals, trace metals, and radioactive substances in order that they be monitored in the food. Various criteria such as toxicity, volume of production, occurrence in the environment, persistence, and biodegradability could be used in putting together the lists.

Pros: Present food monitoring efforts are not designed to detect new environmental contaminants in food. The limited amount of monitoring for suspected contaminants that does exist is primarily concerned with trace metals. But far more of this type of monitoring is needed to anticipate new contaminants in food.

Cons: To draw up such lists successfully, considerable information is needed. Substances for which there is little or no data would automatically be given low priority. In large part, the makeup of the lists would depend on scientific judgments. However, scientific judgments often vary (or even conflict). Thus, the reliability of the lists may be in question,

Priority lists of trace metals and radioactive substances, which are limited in number and already well-investigated, would be more reliable than a list of organic compounds. There are thousands of such organic agents manufactured, and there is little toxicological or environmental information available on a great many of them.

If such lists were developed, the number of substances monitored would necessarily be

limited. Standards would be set up for determining which substances would get priority. Of course, there would be no certainty that unlisted substances might not get into the food supply and threaten human health. The cost of such a monitoring system would depend on how many substances were being traced as well as the expenses of equipping and staffing laboratories.

### Option 3B--Establish a National Monitoring System for Uncharacterized Environmental Contaminants

Uncharacterized monitoring would be designed to detect substances that are: lacking toxicity data for potential human risk, not known to be present in food, and not even known to exist in the environment. This kind of monitoring is most needed for synthetic organic chemicals. The purpose is to detect changes in the levels of various synthetic organics in environmental or food samples over time.

Scientists would not necessarily know the identity of individual substances they were monitoring. But if the concentration of a particular compound substantially increased, they could analyze it further to establish its identity. The literature would be reviewed on the substances toxicological properties. Or perhaps the substance would undergo toxicological testing. Depending on what informa-

tion is developed, regulatory agencies could then take appropriate action.

This approach tries to create a mechanism for quantitatively measuring uncharacterized substances in food. Proper guidelines are necessary since the cost of quantitatively identifying one substance can range from \$10,000 to \$100,000. Moreover, this monitoring approach requires sophisticated equipment for analyzing food samples. Also, the information generated by the analyses has to be computerized. Computer technology makes it possible to correlate and interpret chemical data to provide a continuous surveillance of the levels in food.

**Pros:** The uncharacterized monitoring approach is in the research stage at several laboratories in the country. If it is successfully developed, this type of monitoring would reduce the time during which the public is exposed to high concentrations of uncharacterized environmental contaminants in food. Kepone, for example, was polluting the James River, and people were eating kepone-contaminated fish for several years before the chemicals presence was discovered. With an uncharacterized monitoring system, kepone may have been detected years earlier.

**Cons:** This combination of sophisticated instruments, dependence on computers, and highly trained personnel is expensive. And the "hardware" needed is generally not found in Federal or State monitoring laboratories.

## OPTION 4--IMPROVE FEDERAL RESPONSE TO NEW CONTAMINATION INCIDENTS

All of the major food contamination incidents have been marked by confusion. This stems from the involvement of three Federal agencies—FDA, the U.S. Department of Agriculture (USDA), and the Environmental Protection Agency (EPA)—in the monitoring and regulation of environmental contaminants in food. To cut down on confusion and to improve delivery of Federal technical assist-

ance, Congress could choose to designate a lead agency or establish a center for the collection and analysis of data.

### Option 4A--Designate a Lead Agency

The problem of conflicting Federal assistance efforts was dramatized by several recent incidents including the most recent PCB

contamination. This sort of situation is not unique, Official reactions following the polybrominated biphenyl (PBB) episode in Michigan and the kepone incident in Virginia were similar.

The lead agency would serve as a clearinghouse for all information coming from and going to States. FDA would be the most likely candidate for lead agency when food contamination is suspected.

**Pros: With a clearly delineated lead agency, States suspecting contamination of food would have one reliable source of technical assistance. Conflicts of opinion would be settled internally, and public statements and technical assistance provided with less ambiguity.**

**Cons: Designation of a lead agency might decrease the amount of technical expertise made available to the States. It would require the lead agency to develop new agreements with the other two agencies, During a food contamination crisis the lead agency would need to coordinate responses from the other agencies.**

#### Option 4B--Establish a Center to Collect and Analyze Toxic Substances Data

Major delays in protecting the public from environmental contaminants in food now result from the time-consuming process of generating sufficient data on a substance's toxicity and dispersal in the food supply. Congress could overcome this problem by setting up a new technical center.

Such a center would be able to rapidly assemble technical teams skilled in the identification and analysis of organic, inorganic, and radioactive substances. A team would consist of a multidisciplinary group of experts, including chemists, toxicologists, food and animal scientists, epidemiologists, biochemists, biostatisticians, medical doctors, and others. Its mission would be to identify the cause of an actual or potential contamination incident, and assess the possible environmental and

human health impacts. It would have no regulatory function.

The group would be able to mobilize within 24 hours. It would be the lead Federal organization that affected States could initially contact. In the wake of an episode, the team could be responsible for followup scientific research that would lay the groundwork for epidemiological studies of the exposed population. It would also be able to conduct a range of short-term toxicological tests to determine the mutagenicity and potential carcinogenicity of uncharacterized substances. It would be able to examine an exposed population for any adverse health effects from ingesting a particular contaminant in food.

The new technical center, in essence, would be similar to the Center for Disease Control (CDC). It would have the same capabilities in chemical epidemiology as CDC has in infectious disease. The new center could be given responsibility for investigating all toxic substance problems in the United States, not just those limited to food. If it were placed under CDC, it could build on work now underway in that organization's Environmental Hazards Unit. Furthermore, the center would be able to capitalize on the longstanding relationships between CDC and the States. Since the center's sole mission would be the development of information on environmental contaminants, it would not be linked to regulatory decisions.

As an alternative, the center might be located within FDA's National Center for Toxicological Research or another Federal laboratory with existing analytical capabilities. It could then use the laboratory's equipment and trained personnel for investigative analytical chemistry and toxicology.

It would be better not to locate the center and the investigation teams in a regulatory agency with direct responsibilities for food. This would ensure that there is no possible conflict of interest between its job of factfinding and the agency's responsibility for regulating. By distancing itself from the regulatory process, the new center team would

strengthen its credibility with the media and the public.

Pros: Accurate scientific information on the nature and extent of food contamination has to be generated quickly when an incident occurs. Individual States often lack the scientific expertise to develop such data. The Federal Government does have the necessary capabilities, but the resources are scattered in several agencies with differing areas of authority. Such a dispersal of expertise hinders the gathering of urgently needed information following a contamination episode. Jurisdictional problems crop up, and States find they have to deal with more than one agency. The resulting delays slow the making of necessary health, environmental, and regulatory decisions.

Reaction time would be shortened and duplication of effort reduced by a technical or toxic substances investigation team which could react quickly in emergencies.

Cons: There is no assurance that a special team could generate information more quickly than is now the case. If the center were not part of a regulatory agency, it might not only grow out of touch with the needs but also could duplicate the investigatory work of the agency. Furthermore, the potential for an adversary relationship exists.

It could be argued that better coordination among FDA, USDA, and EPA would accomplish the same goals without the expense of establishing a new research center.