

Chapter I

Summary

Summary

The environmental contamination of food is a nationwide problem. A number of recent incidents dramatically illustrate the potential health hazards and economic harm that can be caused by such contamination—animal feeds in Michigan contaminated by polybrominated biphenyls (PBBs), the Hudson River contaminated by polychlorinated biphenyls (PCBs), and Virginia's James River contaminated by kepone.

These are some of the more serious of the 243 food contamination incidents identified in an OTA survey of the 50 States and 10 Federal agencies. These incidents have occurred in every region of the country. They have involved all categories of food. While the OTA survey clearly shows the national character of such contamination, the true extent of the problem is still unknown.

The latest major food contamination incident—one not included in the OTA survey—graphically points up the ominous dimensions of the problem. PCBs from a damaged transformer contaminated animal fats at a packing plant in Billings, Mont. The plant used the adulterated fats to produce meat and bone meal that were sold both to feed manufacturers and directly to farmers. The contaminated feed spread through at least 10 States—polluting poultry, eggs, pork products, and a variety of processed foods (including strawberry cake). The result: contaminated food found in 17 States, and hundreds of thousands of pounds of food products seized or destroyed.

This assessment, undertaken at the request of the House Committee on Interstate and Foreign Commerce, examines the adequacy of current Federal and State efforts to deal with the environmental contamination of food. In particular, the study evaluates the effectiveness of 1) Federal and State monitoring systems in detecting contamination episodes before they reach crisis proportions, and 2) Federal efforts to regulate contaminations. The study explores alternative approaches to the problem and presents policy options for Congress.

Environmental contaminants in food fall into three categories—synthetic or natural organic chemicals, metals or their organic and inorganic derivatives, and natural or synthetic radioactive substances. Such contaminants are regulated under the Federal Food, Drug, and Cosmetic Act. To regulate them under the law, the Food and Drug Administration (FDA) defines environmental contaminants as “added, poisonous, or deleterious” substances that cannot be avoided by good

manufacturing practices, and that may make food injurious to health.

Unlike food additives, environmental contaminants inadvertently find their way into the human food supply (including sports fish and game). They can enter food directly or indirectly as a result of such human activities as agriculture, mining, industrial operations, or energy production. In no instance is their presence in food ever intended.

HEALTH IMPACTS OF ENVIRONMENTAL CONTAMINATION

Four factors determine whether and how seriously the environmental contamination of food will affect human health: the toxicity of the contaminant, the amount of the substance in the food, the amount of the contaminated food eaten and the physiological vulnerability of the individual or individuals consuming the food.

Based on other countries' experiences, there is considerable evidence of human illness caused by the consumption of food containing various organic chemicals and metals. **In such cases**, the level of the contaminant in food exceeded the levels usually found in the U.S. food supply. The effects of mercury poisoning are well-documented. The best known case involved the consumption of mercury-contaminated fish from Japan's Minamata Bay. Some of the offspring of exposed mothers were born with birth defects, and many victims suffered central nervous system damage.

Another incident in Japan stemmed from the inadvertent contamination of rice oil by PCBs. The consumption of food cooked with this oil resulted in 1,291 cases of so-called "Yusho disease"—a condition marked by chloracne (a severe form of acne), eye discharges, skin discoloration, headaches, fa-

tigue, abdominal pains, and liver and menstrual disturbances,

No such mass-poisoning episodes have occurred in the United States. But there are studies indicating that present levels of some environmental contaminants may cause physiological changes. For example, the accidental contamination of animal feed in 1973 exposed most of the population of Michigan to PBB in dairy products and other foods. Evidence on what impact this exposure has had on human health is conflicting, although some disparities in white blood cell function have been noted in farm families. The long-term significance of these physiological changes is not yet known.

The clinically obvious harmful health effects of radiation are usually associated with massive, high-level exposures. Past cases of radioactive contaminated foods have involved relatively small amounts of radioactive substances with low dose rates. Generally, the young are most sensitive to radiation exposure. However, since any amount of radiation is potentially harmful, prudent public policy must assume that any unnecessary exposure to high-energy radiation should be avoided.

ECONOMIC IMPACTS OF CONTAMINATION

The economic impacts of a contamination incident have traditionally been stated in terms of the estimated dollar value of the resulting food loss. Only limited data on such costs are available. Dollar value estimates for condemned food were available for less than **30 percent** of the contamination episodes noted in the OTA survey. Thus, the real cost of environmental contamination of food during the **1968-78** decade is at least several times the **\$282 million** reported to OTA.

The loss of food only partially reflects the total economic impact of environmental contamination. Health and "distributional" costs are also involved. The health costs include

medical expenses and lost workdays from illness resulting from food contamination incidents. Since the health effects may not immediately be evident, the expected illnesses or deaths from an episode are usually estimated on the basis of available toxicity data for a particular contaminant. In other words, estimated health costs are more likely to be projections than actual figures based on known cases of illness or death.

The "distributional" costs of environmental contamination disclose the expenses or losses incurred by affected businesses, individuals, and government bodies. These might include farmers, fishermen, food processors,

animal feed suppliers, chemical companies, consumers, and local, State, and Federal agencies. Although the individual organizations suffering such losses are usually identi-

fied, their actual dollar losses are not known. To understand who is bearing the major economic brunt of a contamination episode, actual cost data are required.

MAJOR PROBLEMS IN IDENTIFYING ENVIRONMENTAL CONTAMINANTS

To determine whether an environmental contamination incident has occurred, it is necessary to establish the presence of the contaminant in food. In some instances, people or animals have become ill before the responsible contaminant was identified. No one knew or even suspected that the particular substance was present in food. This has been the pattern in many major contamination incidents—those involving PBBs, PCBs, and mercury.

Our regulatory monitoring system has failed to detect such environmental contaminants as they entered the food supply. Thus, this assessment identifies and evaluates other approaches for monitoring either food or the environment for toxic substances that may harm human health. The ultimate objective of monitoring is to prevent or minimize human exposure to environmental contaminants in food.

The only sure way to prevent this kind of contamination is to make certain that toxic

substances are not released into the environment. There are various Federal environmental laws that are designed to limit such releases. But the laws and regulations are not likely to prevent the deliberate or accidental misuse or disposal of the thousands of toxic substances manufactured in the United States.

The problem is compounded by disposal and handling practices that was accepted in the past but are now recognized as posing serious environmental hazards—hazards that will persist for many years to come. The toxic chemical waste dump at the Love Canal near Niagara Falls, N. Y., clearly illustrates the threat. According to Environmental Protection Agency (EPA) estimates, there are **1,200 to 2,000** of these abandoned chemical and radioactive waste sites in the United States that pose an imminent danger to human health and will cost as much as \$50 billion to clean up. As long as these substances remain in the environment, the potential for food contamination exists.

PROBLEMS OF REGULATING ENVIRONMENTAL CONTAMINANTS

Once an environmental contaminant is found in food, limits are established to control and restrict its presence. Such regulations are set up and enforced by FDA for food traded in interstate commerce, and by State agencies for food produced and sold within a State. In either case, the aim is to limit the public's exposure to a particular contaminant.

Key factors involved in such regulation are time and information. After a contaminant is identified, authorities must have information

on its toxicity, the amount present in the food, and how much and what kinds of food are contaminated. By monitoring the food supply for the contaminant, regulators can determine the level and extent of the contamination. With this information and necessary toxicity data, they can establish regulatory limits for the contaminant in food.

However, this kind of information generally takes time to generate—usually longer than the public is willing to wait in the event of a food contamination incident. As a result,

authorities are often pressed to set regulatory limits before they have enough time to

develop information on the nature and extent of the contamination.

FINDINGS AND CONCLUSIONS

This assessment has focused on two central problems: regulating environmental contaminants and identifying environmental contaminants. Following are major findings and conclusions growing out of this assessment.

- **FDA relies on action levels rather than tolerances to regulate environmental contaminants in food.**

Under the Food, Drug, and Cosmetic Act, FDA is given authority to set tolerances for the amount of an unavoidable contaminant permissible in food. However, the procedures required to set a tolerance are complex, cumbersome, and time-consuming. Therefore, FDA relies on action levels, informal judgments about the level of a food contaminant to which consumers may safely be exposed.

Action levels are administrative guidelines that can be developed and promulgated more easily and quickly than tolerances. Action levels are used when scientific data are incomplete. Public input is not required. They are used when new information is likely to be forthcoming that might alter the level. FDA is under no constraints to review action levels or to replace action levels with formal tolerances. FDA has sometimes lowered or raised action levels as new data became available. FDA is now in the process of lowering the PCB tolerance.

- **No policy exists defining the relative weights to be given to the evidence when setting an action level or tolerance.**

In setting an action level or tolerance, FDA takes into account short- and long-term toxicological data, available information on the levels of the contaminant in food, the amount of contaminated food consumed by various population groups, the level that can be measured, and the potential impact of various action levels or tolerances on the national food supply. Generally, the more information about a particular factor, the greater its in-

fluence. Because the amount and quality of information available when FDA encounters an environmental food contamination problem are inevitably unpredictable, it does not predetermine the weighting of various factors. However, FDA maintains that the public health factor outweighs all others in its considerations.

The Food, Drug, and Cosmetic Act does not specify the role that the costs of a regulatory decision should play in setting a tolerance or action level. The Act does require that FDA take into account the extent to which a substance cannot be avoided in food production. FDA interprets this requirement as justification for weighing the costs of food condemned against the health benefits derived from a tolerance.

- **To assess human risk from exposure to chemicals, FDA and EPA rely on already-existing animal studies and epidemiological evidence derived from previous human exposures,**

When a new environmental contaminant is discovered in food, regulatory agencies are under intense pressure to act to protect the public. FDA and EPA (if the contaminant is a pesticide) review the available literature on the contaminant and calculate an action level based on that evidence. Rarely are new studies commissioned—even when the data are inadequate.

New human epidemiological studies and conventional 2-year animal studies are of little immediate help because so much time is required to generate results. However, toxicologists have developed a variety of tests that can evaluate a substance's possible toxic effects in 90 days or less. Some of these short-term tests measure the potential of a substance to produce mutations and possible cancer,

Short-term tests could be used more widely in screening environmental contaminants to determine whether they are mutagens or potential carcinogens. Although the results of such tests do not provide the data needed to set an action level or tolerance, they still can alert regulators to latent dangers that require further investigation.

Conventional 2-year animal studies (which usually entail an additional year for data analysis) would continue to serve an important role in the setting of tolerances. If data from a carcinogen bioassay are available at the time an environmental contaminant is discovered in food, the information can prove crucial in reaching a regulatory decision. If data were nonexistent or inadequate, a newly commissioned carcinogen bioassay could be used to revise an initial action level.

Epidemiological studies would remain useful for confirming suspected chronic effects of a toxic substance to which a population has unknowingly been exposed over a period of time. They can also confirm retrospectively or refute the adequacy of regulatory actions.

No currently available toxicological testing methods or statistical interpretation techniques are adequate for evaluating the combined effects of low-level exposure to toxic substances. Indeed, there are no satisfactory techniques for testing the interactions of more than two substances.

- **Current monitoring at both Federal and State levels is regulatory, designed to ensure that substances in food do not exceed prescribed limits. Little effort is made to detect and identify substances in the food supply for which no action levels or tolerances exist.**

Technology now exists that would make possible a national investigatory monitoring system to detect unregulated chemicals as they enter the food chain. Such advanced technology is available in some Federal regulatory monitoring laboratories and in a limited number of State labs. It is not routinely

employed in Federal or State regulatory monitoring.

The goal of food monitoring is to protect consumers by determining short- and long-term trends in the levels of various chemicals in food and the environment. Investigatory monitoring could be designed to complement already-existing regulatory monitoring. Each of these approaches could be complemented by specimen banking—the regular collection and storage of samples that could be later analyzed if a new contaminant is found in food. EPA and the National Bureau of Standards are now working towards developing such a specimen-banking program.

However, food sampling may not be the best approach to investigatory monitoring. To discover a substance as it enters the environment and before it gets into the human food supply, it is necessary to monitor water, soil, air, river sediments, and nonfood organisms.

- **Management of food contamination incidents is hindered by the complexity of the food system, the rapidity with which food is moved through the system, and failures by State and Federal agencies to coordinate their information-gathering activities.**

Many food contamination incidents initially fall under State jurisdiction. Technically, the Federal Government does not become involved unless requested by a State or until contaminated food enters interstate commerce. This country's food marketing system is complex. Most food produced or processed within a particular State is distributed for consumption in other States. Thus, most environmental contamination incidents are likely to become interstate problems. Figure 1 illustrates the extent of food contamination that can occur from a single source of contamination, in this case PCB-contaminated animal feed from a meatpacking plant in Billings, Mont.

The number of State and Federal agencies involved complicates the generation and dissemination of scientific information on the

toxicological and chemical properties of the contaminant, the amount and type of food contaminated, and the concentration of the substance in food. At least three Federal agencies (EPA, FDA, and the U.S. Department of Agriculture (USDA)), each with different responsibilities, may provide technical assistance. At the State level, departments of health, agriculture, and the environment may share accountability for regulating environmental contaminants in food.

In the absence of a clear authority to coordinate activities of various agencies, the po-

tential exists for breakdowns in communication. This was the case in the recent PCB contamination of animal feeds in 10 Western States. The Idaho Department of Agriculture did not inform the Idaho Department of Health and Welfare of the PCB contamination. USDA would report the results of its investigations only to the Idaho Department of Agriculture. EPA attempted to determine the source of the PCBs by analyzing air and water samples, but failed to report its negative results to the State.

CONGRESSIONAL OPTIONS

There are four basic options for Congress to consider regarding the Federal response to the environmental contamination of food. Each is discussed in greater detail in chapter IX. Congress can:

1. Allow the present system to continue by taking no action. The present system consists of regulatory monitoring and the establishment of action levels (and occasionally tolerances) for environmental contaminants in food.
2. Amend the Food, Drug, and Cosmetic Act to specifically address the unique problems posed by environmental contamination of food.
3. Establish a national investigatory monitoring system.
4. Improve the Federal response to new contamination problems by designating a lead agency or establishing a center to orchestrate the delivery of Federal assistance to affected States.

Option 1

Maintain the present System

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

Cons: The time needed to identify an environmental contaminant in food and take corrective action would not be shortened if the current system were retained. Moreover, action levels and tolerances permit a certain level of contaminant to be present in food. If tolerances or action levels are not reduced, little effort will be made to eliminate the contaminant. There is no requirement for review of an action level once it is established. Thus, FDA is under no pressure to actively seek out new data to verify the appropriateness of an existing action level. Finally, States have no clearly defined authority to turn to when they suspect environmental contamination of food.

Option 2

Amend the Food, Drug, and Cosmetic Act

An amendment to the Food, Drug, and Cosmetic Act could contain one or more of the following changes. Each change is discussed in greater detail in chapter IX.

- Congress could amend the Food, Drug, and Cosmetic Act to simplify the administrative procedure for setting tolerances. The change could be modeled after section 553 of the Administrative Procedures Act. This would encourage FDA to move from action levels to toler-

ances, thus bringing more public participation into the process,

- Congress could amend the Food, Drug, and Cosmetic Act to **require the establishment of a tolerance within a specified time after the setting of an action level.** This would encourage the FDA to gather additional information on a contaminant's toxicity and the public's exposure. It would result in a definitive tolerance that FDA could enforce with less concern over legal challenge.
- Congress could clarify to what extent economic criteria can be used in setting tolerances for environmental contaminants in food,
- FDA could be granted authority to set regional tolerances. This would provide FDA with flexibility to set different levels for different regions based on expected levels of exposure, regional levels of contamination, and local eating patterns.

Pros: Since its passage in 1938, the Food, Drug, and Cosmetic Act has been amended several times to deal with new problems of food regulation. Congress has never directly addressed the environmental contamination of food. There are several unique characteristics of this problem that could be clarified through an amendment dealing specifically with the environmental contamination of food.

Cons: Even though the Food, Drug, and Cosmetic Act does not contain provisions on environmental contaminants, FDA has been able to regulate them through interpretation of sections 402 and 406.

Option 3

Establish an Investigatory Monitoring System

Congress could establish a national investigatory monitoring system based on monitoring for either suspected or uncharacterized environmental contaminants. Some chemicals are not regulated by action levels or tolerances but are suspected to be dangerous to

humans if consumed in food. Uncharacterized environmental contaminants are substances that may have entered the food supply, but are not regulated or suspected food contaminants. A system that combines elements of both approaches could also be set up. Because any of these monitoring approaches would require some research and development before going into full operation, Congress could choose to establish a pilot program. Such a program would spur research and development and assess the feasibility and cost effectiveness of the various approaches.

Pros: Investigatory monitoring would increase the probability of detecting unregulated substances in food. Present food-monitoring efforts are not designed to detect unregulated environmental contaminants in food. The limited amount of investigatory monitoring that does exist is primarily concerned with trace metals. To identify new contaminants as they enter the food supply, more of this type of monitoring is needed.

Cons: The costs of setting up an investigatory monitoring program could be large, and there is no certainty that the sampling plan would identify all environmental contaminants before they enter the food chain. Furthermore, investigatory monitoring relies on sophisticated instrumentation that is generally not found in Federal or State monitoring laboratories,

Option 4

improve Federal Response to New Contamination Incidents

The Federal response to new contamination problems has been hampered by the multiplicity of agencies with regulatory or monitoring responsibilities for the environment and for food. Congress could designate a lead agency or establish a center to orchestrate delivery of Federal assistance to affected States.

Pros: With a clearly delineated agency or center, States suspecting contamination of

food would have one reliable Federal source for generating, evaluating, and disseminating technical information. Response time might be shortened, duplication of effort reduced, and effective management of the incident enhanced.

Cons: Better coordination among FDA, USDA, and EPA could accomplish the same goals without the expense of establishing a new research center. Historically, the major impediment to timely Federal response to chemical contamination of food was lack of awareness that food contamination had taken place. When contamination became apparent and one or more Federal agencies were alerted, response was rapid. Furthermore, establishment of a lead agency or a new cen-

ter would not ensure that information would be generated more quickly than is now the case.

* * *

Options 2 through 4 are not mutually exclusive. If Congress wishes to put greater emphasis on protecting consumers from contaminated food, one or more could be chosen. For example, Congress could decide to simplify the administrative procedures for setting tolerances (Option 2), require the setting of a tolerance at some specified time after an action level is set (Option 2), establish a pilot program of investigatory monitoring for organic chemicals (Option 3), and designate FDA the lead agency to deal with new contamination problems (Option 4).