# Chapter III

# Federal Laws, Regulations, and Programs

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## FEDERAL LAWS

Congress has enacted several laws that not only regulate but also attempt to limit or restrict the introduction of toxic substances into the environment. Table 7 summarizes the Federal laws affecting toxic substances control.

Some of these laws give Federal agencies authority to prevent unsafe food from reaching consumers. Most important in terms of this assessment is the Federal Food, Drug, and Cosmetic (FD&C) Act (l). Broadly speaking, this statute prohibits the introduction of adulterated food into interstate commerce. The FD&C Act allows the Food and Drug Administration (FDA) to establish tolerances for toxic substances whose occurrence in food cannot be avoided. The Poultry and Poultry Products Inspection Act (2) and the Federal Meat Inspection Act (3) give the U.S. Department of Agriculture (USDA) authority to inspect meat, poultry, and their byproducts. The adulteration provisions of these Acts govern all environmental contaminants except for pesticides that may occur in meat and poultry. Under these laws, section 408 of the FD&C Act applies to such pesticide contamination. In practice, USDA uses the tolerances established under the FD&C Act and consults with FDA and the Environmental Protection Agency (EPA) to determine an action level when no tolerance exists.

Following is a brief summary of the pertinent provisions of the FD&C Act:

Section 402(a)(l) declares that any food that "bears or contains any poisonous or deleterious substance which may render it injurious to health" is adulterated. The single exception is if the substance is not, in the language of the Act, "added" to the food. In such cases, the presence of the substance does not imply that the food is adulterated unless it is present in sufficient quantity to "ordinarily render it injurious to health. "

The FD&C Act recognizes that certain "added" toxic substances in foods require special attention, Section 406 empowers FDA to establish tolerances for "added'" poisonous substances whose occurrence in food cannot be avoided or whose use is "necessary" to produce the food. Thus, Congress authorized FDA to "license" the presence of certain potentially toxic substances in food, seemingly because of their economic utility or the inability of existing, commonly used production methods to eliminate them. The legislative history of section 406 is skimpy. But Congress' principal objective apparently was to permit continued use of pesticides on raw agricultural commodities while giving FDA an effective means of control—the power to declare illegal any food that contained any amount of an added substance that exceeds FDA tolerance. Congress left the distinction between "added"' and other constituents undefined, and did not attempt to clarify the concepts of "necessary" or "unavoidable"' in section 406(4).

Amendments to the 1938 FD&C Act deal with specific categories within the broad class of substances "added"' to foods including pesticides, food additives, vitamins and minerals, and animal drugs. Each amendment in effect establishes a system under

**Table 7.— Federal Laws and Agencies Affecting Toxic Substances Control**

| Statute | Year enacted | Responsible agency | Sources covered |
|---|---|---|---|
| Toxic Substances Control Act | 1976 | EPA | All new chemicals (other than food additives, drugs, pesticides, alcohol, and tobacco) and existing chemicals not covered by other toxic substances control laws |
| Clean Air Act | 1970, amended 1977 | EPA | Hazardous air pollutants |
| Federal Water Pollution Control Act (now Clean Water Act) | 1972, amended 1977 | EPA | Toxic water pollutants |
| Safe Drinking Water Act | 1974, amended 1977 | EPA | Drinking water contaminants |
| Federal Insecticide, Fungicide, and Rodenticide Act | 1947, amended 1972, 1975, 1978 | EPA | Pesticides |
| Act of July 22, 1954, (codified as Section 346(a) of the Food, Drug, and Cosmetic Act) | 1954, amended 1972 | EPA | Tolerances for pesticide residues in food |
| Resource Conservation and Recovery Act | 1976 | EPA | Hazardous wastes |
| Marine Protection, Research, and Sanctuaries Act | 1972 | EPA | Ocean dumping |
| Food, Drug, and Cosmetic Act | 1938 | FDA | Basic coverage of food. drugs, and cosmetics |
| Food additives amendment | 1958 | FDA | Food additives |
| Color additives amendments | 1960 | FDA | Color additives |
| New drug amendments | 1962 | FDA | Drugs |
| New animal drug amendments | 1968 | FDA | Animal drugs and feed additives |
| Medical device amendments | 1976 | FDA | Medical devices |
| Federal Meat Inspection Act | 1967 | USDA | Food, feed, and color additives; |
| Poultry Products Inspection Act | 1957 | USDA | pest icicle residues in meat and |
| Egg Products Inspection Act | 1970 | USDA | poultry products |
| Fair Packaging and Labeling Act | 1976 | FDA | Packaging and labeling of food and drugs for man or animals, cosmetics, and medical devices |
| Public Health Service Act | 1944 | FDA | Sections relating to biological products |
| Occupational Safety and Health Act | 1970 | OSHA, NIOSH | Workplace toxic chemicals |
| Federal Hazardous Substances Act. | 1960 | CPSC | Hazardous (including toxic) household products (equivalent in many instances to consumer products) |
| Consumer Product Safety Act | 1972 | CPSC | Hazardous consumer products |
| Poison Prevention Packaging Act | 1970 | CPSC | Packaging of hazardous household products |
| Lead-Based Paint Poisoning Prevention Act | 1973, amended 1976 | CPSC, HEW, HUD | Use of lead paint: on toys or furniture, on cooking, drinking, and eating utensils, in federally assisted housing |
| Hazardous Materials Transportation Act | 1975, amended 1976 | DOT (Materials Transportation Bureau) | Transportation of toxic substances generally |
| Federal Railroad Safety Act | 1970 | DOT (Federal Railroad Admin.) | Railroad safety |
| Ports and Waterways Safety Act | 1972 | DOT (Coast Guard) | Shipment of toxic materials by water |
| Dangerous Cargo Act | 1952 | | |
| Federal Mine Safety and Health Act. | 1977 | Labor (Mine Safety and Health Admin.), NIOSH | Toxic substances and other harmful physical agents in coal or other mines |

CPSC = Consumer Product Safety Commission
DOT = Department of Transportation
EPA = Environmental Protection Agency
FDA = Food and Drug Administration
HEW = Health Education and Welfare
HUD = Housing and Urban Development
NIOSH = National Institute for Occupational Safety and Health
OSHA = Occupational Safety and Health Administration
USDA = United States Department of Agriculture

SOURCE Environmental Law Institute, *An Analysis 01 Past Federal Efforts To Control Toxic Substances* Washington D C 1978

which FDA is empowered to license, and thereby limit, the use (or in the case of pesticide residues, the occurrence) of potentially toxic substances in or on food.

The Pesticide Chemicals Amendment of 1954, now section 408 of the FD&C Act, provides that a raw agricultural commodity shall be deemed to be adulterated if it bears or contains any residue of a pesticide that does not conform to a tolerance established under section 408, Pesticides that are unintentionally present on commodities are usually considered environmental contaminants by FDA, and are regulated under section 406.

At no point, in 1938 or subsequently, has Congress specifically addressed the problem of environmental contaminants in food. FDA could have regulated them all under the "may render injurious" language of section 402(a)(1). But this provision would not have given FDA authority to determine administratively what levels of a contaminant could be tolerated. FDA would have been required to prove its claim of hazard each time it seized a contaminated product.

Accordingly, since the early 1970's FDA has classified environmental contaminants as "added poisonous or deleterious substances' whose occurrence cannot entirely be avoided, thus avoiding the less rigorous "ordinarily injurious" standard of section 402(a)(l). The tolerance-setting authority of section 406 can then be applied to environmental contaminants in food.

## ACTION LEVELS AND TOLERANCES

Relying on section 406, FDA prescribes the level of a contaminant that, under section 402(a)(2)(A), will render a food adulterated. Before FDA can ascertain this level, sufficient scientific data must be accumulated to answer several questions implicitly posed by sections 402 and 406. FDA must be able to determine that the environmental contaminant in question is:

1. added,
2. poisonous or deleterious,
3. a substance unavoidable by good manufacturing practice, and
4. one which may make the food injurious to health.

Furthermore, an analytical method that can reliably detect, measure, and confirm the identity of the contaminant in the food under scrutiny must be available (5).

To determine whether these requirements can be met, FDA scientists explore and review the scientific literature, consult FDA files, and draw on information available in other agencies, in academia, or in private industry. Then, based on the best scientific data available (which are often incomplete), FDA will prescribe what level of contamination will trigger enforcement action (5).

Regulatory procedures employed to control environmental contaminants in food include the establishment of action levels or tolerances. A *formal tolerance is a regulation having the force of law*. Tolerances are adopted through formal rulemaking procedures and specify the level of a contaminant that will render a food adulterated. If supported by substantial evidence in the rulemaking record, FDA's tolerance cannot be questioned by any court. An action level is an in.formed judgment about the level of a food contaminant to which consumers may safely be exposed. It is a statement of FDA's professional judgment and represents a commitment to initiate regulatory enforcement action against any lots of food discovered containing excess levels. Essentially the same criteria are considered in establishing tolerances and setting action levels. The principal differences between the two approaches lie in the procedures for their adoption, the strength of the scientific data supporting them, and the differing weight they carry in court (4).

FDA will set a tolerance when the following conditions exist:

1. The substance cannot be avoided by good manufacturing practice.
2. The tolerance established is sufficient for the protection of the public health, taking into account the extent to which the presence of the substance cannot be avoided and the other ways in which the consumer may be affected by the same or related poisonous or deleterious substances.
3. No technological or other changes are foreseeable in the near future that might affect the appropriateness of the tolerance established **(6).**

To establish a tolerance, FDA first publishes a proposal, accepts comments, and issues a "final'* regulation, Formal objections can be raised to this "final" tolerance. Such objections can, if they raise material issues of fact, require a lengthy trial-type hearing before an FDA administrative law judge, who then issues an initial decision based on the formal hearing record. That decision, in turn, can be appealed to the FDA Commissioner (who issued the original "final" tolerance). The Commissioner's ultimate decision is subject to review in a court of appeals (l).

Because the tolerance-setting procedure is cumbersome and time-consuming, FDA initially relies on an action level when it regulates an environmental contaminant. An action level is an administrative guideline and the functional, though not legal, equivalent of a section 406 tolerance. It is established when "technological or other changes that might affect the appropriateness of the tolerance are foreseeable in the near future" (6).

To set an action level, FDA simply announces in the Federal Register that it is establishing an action level for a contaminant, and states that the data supporting the designated level are available for public inspection. This announcement may briefly discuss the pertinent factors that went into the decision, but any discussion is not likely to be (nor is required to be) extensive. While the announcement also notes that public comments will be accepted, FDA makes no commitment to respond to any comments or, indeed, to reconsider the action level within any specified period (6). The process does not require a detailed public discussion of the selected levels, nor does it trigger a public debate about the correctness of FDA's premises or its balancing of relevant factors.

Finally, the Commissioner of FDA may exempt from regulatory action any contaminated food if he determines "based upon all available scientific evidence, that the food is safe for consumption and that destruction or diversion of the food involved would result in a substantial adverse impact on the national food supply" (6). This has only happened once, and the action did not involve human food,

If the environmental contaminant is a pesticide for which no tolerance has been established by EPA, FDA relies on EPA to recommend an action level (as it did in the case of kepone). In other respects, the procedures and criteria for regulating pesticides as environmental contaminants are the same as for other contaminants.

## Criteria for Setting Action Levels and Tolerances

For the setting of action levels or tolerances, neither the law nor regulations require FDA or EPA to follow a standardized set of toxicologic protocols to evaluate risk. No policy exists defining the relative weight to be given to evidence. The burden of proving there is a health hazard lies with FDA. When setting an action level or tolerance, FDA considers the following types of data:

1. available acute and chronic toxicological data, including information on the biological half-life of the substance and its metabolic fate;
2. available data on the levels and incidence of the contaminant in the overall food supply and specifically in the food commodity or commodities that are being considered for an action level or tolerance;

3. normal serving sizes of the concerned food(s) and frequency of ingestion;
4. susceptibility of certain population groups, such as infants and the aged, to adverse effects from anticipated dietary exposure to the contaminant:
5. the level at which available analytical techniques can detect, measure, and confirm the identity of the contaminant;
6. capability of manufacturers to monitor their food production to ensure that the products comply with the action level or tolerance; and
7. the anticipated impact of various possible levels of regulation on the national food supply.

In response to questions on how FDA evaluates these data, Commissioner Donald Kennedy wrote:

> Each factor is assessed individually (assuming information on each is available) and then collectively brought into balance by a composite analysis in terms of the estimated risk to the public health versus both the extent to which the substance is unavoidable and the quantity of food that would be unlawful under levels being considered (5),

FDA has not fixed the weight to be given to each of the above factors. Each will, to some degree, influence the final decision; generally, the more information about a particular factor, the greater its influence, This is one reason that FDA offers for not prescribing a predetermined quantifiable set of criteria for each factor. The amount and quality of information available when FDA encounters an environmental food contamination problem are inevitably unpredictable, FDA maintains that because of this uncertainty, it is impractical to state in advance the precise weight of each factor in the final determination. However, FDA maintains that the public health factor outweighs all others in its considerations (5).

## Determining Action Levels and Tolerances

In general, EPA and FDA follow similar procedures when evaluating the health risk associated with consumption of a toxic substance in food, Both agencies consider three areas when evaluating the scientific information: 1) existing animal toxicity data, 2) existing human toxicity data, and 3) exposure data based on the level of the contaminant in food and the average consumption of that food. Both agencies also consider what effect an action level or tolerance will have on the availability of food.

### Evaluation of the Scientific Data

When a food contaminant is identified, the first step in establishing an action level or tolerance is to assemble and evaluate all available information on its toxicity. This information comes from articles published in the scientific literature, information provided by private industry, and data from other Government agencies. From animal toxicity data and whatever human toxicity data may be available, a no observed effect level (NOEL) is calculated and expressed in milligrams per kilogram of body weight per day. NOEL is the level at which the substance had no observed effects.

An acceptable daily intake (ADI) is then calculated by dividing the NOEL by a safety factor. The term “acceptable” does not imply absolute safety for all people in all cases, and the term “safety factor” implies more than it seems. The safety factor reflects the uncertainty of translating animal data to humans, the variability of the human population, the insufficiency of the data available, and the severity and reversibility of toxic effects.

When 2-year chronic toxicity studies in animals are available, the safety factor used is 100. When threshold levels have been observed in humans, the safety factor employed is 10. If long-term studies are available and show no irreversible effects, a much smaller safety factor might be selected. If evaluation of available toxicological data indicates that no threshold exists, a very large safety factor (on the order of 1,000 or more) maybe used. F. ‘I’. Arnold, chairman of the Kepone Action Level Hearings, stated that “the determination of an appropriate safety factor is an art

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rather than a science and is dictated by the chemical in question, its toxicological properties and surrounding circumstances" (7).

The next step is to calculate the maximum permissible intake. The maximum permissible intake is the product of ADI and the average weight of an adult (this figure varies from 60 to 70 kg). This figure is then compared to the maximum potential exposure through consumption of contaminated food. Tolerances are set so that the amount of the contaminant consumed in food is less than or equal to the ADI. Mathematically, this can be expressed as:

$$\text{Tolerance} = \frac{\text{ADI} \times \text{Average body weight of consumer}}{\text{Food factor} \times 1.5\ \text{kg}}$$

**Where** ADI = the NOEL divided by an appropriate safety factor

Average body weight of consumer = 60 kg for EPA calculations, and 70 kg for FDA calculations

Food factor = percentage of the average daily diet made up by the food in question

1.5 kg = the average weight of food consumed in a day

Appendix B provides a detailed example of how these concepts were applied by FDA in the development of tolerances for polychlorinated biphenyls (PCBs) in food,

These procedures have several limitations. The data on toxicity of an environmental contaminant for humans and animals may often be inadequate for setting a tolerance. Because of time constraints and the necessity to make a regulatory decision, action levels for environmental contaminants in food may be based on incomplete, scanty toxicological information. Once a level is set, however, no law requires FDA to collect new evidence on the toxicity of the substance in question even though that issue may well continue to be of critical importance to the population receiving the highest exposure and to food producers.

Because of the nature of the problem presented by environmental contaminants in food and because so little data are usually available, EPA and FDA cannot have formal requirements for toxicity data. Moreover, in most instances there are no petitioners or sponsors of commercial uses of the material to which FDA can look for the necessary additional tests. Available industry data are frequently used because of the lack of published or publicly available information on the substance. While known toxic effects of metabolic products of the substance in question are considered, unknown metabolizes cannot be. Finally, additive and synergistic effects between the contaminant and other toxic substances in food are not considered in the tolerance-setting procedures.

Questions are frequently raised about safety factors and the extrapolation from animal data to humans. Comparisons between animals and humans are based on milligrams of the toxic substance per kilogram of body weight, although many maintain that milligram of toxic substance per square centimeter of body surface area is a more appropriate comparison,

Little scientific evidence exists to support safety factors. Historically, a factor of 10 in extrapolating from animals to man and a factor of 10 in extrapolating from the least-sensitive human to the most-sensitive have been used although they have little theoretical or factual basis. Many believe that the use of different safety factors for different toxicological effects (a greater safety factor for irreversible effects, a smaller factor for reversible effects) or the use of mathematical models to extrapolate from animal to human risk would be more appropriate. Finally, the safety factor approach may not make allowances for vulnerable groups such as infants, except in those instances in which infants are considered the primary population at risk. Individuals with predisposing conditions or previous exposure may not be adequately covered by safety factors. In truth, it may be impossible to protect every individual with allergies or predisposing physiological conditions.

The methods used for estimating dietary exposure to toxic substances are limited by lack of sound data. FDA bases some tolerance decisions on their Total Diet Studies, Because

these are based on the diet of a teenage male, they do not reflect the dietary patterns of vulnerable groups, nor do they reflect ethnic and regional preferences or vegetarian diets. EPA and FDA rely on USDA's Food Consumption Survey, which was completed in 1965-66. It is believed that some shifts have occurred in consumption patterns since then, and USDA is now conducting a new Food Consumption Survey.

## Evaluation of Decisionmaking Approach

As discussed earlier, FDA regulates environmental contaminants in food under section 406 of the FD&C Act. This section does not specifically address environmental contaminants, but authorizes FDA to regulate food for potentially toxic substances that are "added" and "unavoidable'" in the production of food. When setting an action level or tolerance, FDA considers the impacts on the national food supply or, stated in another manner, the impacts on the availability of food to the American consumer. In quantifying this criterion, FDA estimates the amount of food that would be banned from commerce because of the action level or tolerance.

The final rule reducing PCB tolerances (8) illustrates FDA's interpretation of section 406 of the FD&C Act for environmental contaminants in food. FDA clearly states that for PCBs "(i)t has had to decide, in effect, where the proper balance lies between providing an adequate degree of public health protection and avoiding excessive losses of food to American consumers. "

FDA later goes on to state that:

> (I)n establishing a tolerance for PCBs in fish, FDA must take into account the amount of fish a given tolerance would remove from commerce. Sect ion 406 of the Act, however, neither requires nor authorizes FDA to weigh secondary economic impacts when it considers the level at which a tolerance should he set. Consideration of such impacts would be inconsistent with the paramount concern of section 406, which is protection of the public health, and would complicate the decisionmaking process under section **406 in** a way Congress did not intend. Obviously, consideration of the amount of food loss caused by a tolerance helps to ensure that the direct economic consequences of the tolerance (in this case, decreased sales and employment in the commercial fishing industry) will not be disproportionate to the increased degree of public health protection accomplished by the tolerance: but FDA considers secondary economic consequences, such as potential impact on the recreational fishing industry, totally beyond the scope of section 406 (8).

The decisionmaking process used by FDA is a form of cost-effectiveness analysis—a procedure to compare the change of health effects in biological terms with the change of the cost in dollars (a further analysis of this procedure appears in chapter VI). In the PCB decision, FDA compared change in human risk data for 5 parts per million (ppm), 2 ppm, and 1 ppm levels in fish with the estimated amount of food that would be condemned in order to arrive at a 2-ppm tolerance level. In FDA's judgment, a 2-ppm tolerance was a proper balance between "providing an adequate degree of public health and avoiding excessive losses of food to American consumers. " While other factors were considered by FDA in its decision, the estimated human risk data and loss of food are the two principal factors weighed in the decision.

The language of section 406 provides FDA with the flexibility to interpret the unavoidability requirement as it sees fit. FDA recognizes that its regulatory decision will have an economic impact, but FDA considers only a component of the total economic impact in its decision-i. e.. food condemned. FDA also realizes that the amount of food condemned will have an effect on employment and commercial sales associated with the contaminated food product. It must be recognized that even for such a widespread contaminant as PCBs, an action level for an environmental contaminant is likely to have a more severe impact on local employment and commercial sales than on the amount of food available to the American consumer.

In addition, FDA's attempt to measure the impacts on availability of food by estimating cost of food condemned has several flaws. First, FDA estimates the amount of food expected to be condemned for one year from a proposed action level or tolerance. For substances such as PCBs in freshwater fish, estimates for the amount of food expected to be condemned should be for more than one year. This is because PCBs are ubiquitous in the environment and degrade very slowly. It is highly likely that freshwater fish will be contaminated with PCBs at levels above 2 ppm and consequently restricted from commerce for several years.

Second, estimating the cost of food banned by the tolerance does not necessarily reflect the impact on the availability of food. While this might occur for small amounts of food condemned—a herd of cattle or a few hundred gallons of milk—this would not be the case for incidents that condemn significant amounts of food. A more accurate estimate of the impact on the availability of food would be to consider the percentage or amount of a food product condemned out of the total amount of that particular product that is produced in this country, Then an estimate of the relative importance of the affected food product to the American diet would need to be made, FDA does not do this second step. This type of analysis would also attempt to estimate the impact such a tolerance would have on the supply and price of other foods available to and consumed by the American consumer.

While the latter analysis may be theoretically sound, given the time constraints for setting an action level for a newly discovered contaminant, it may not be practical for an initial regulatory decision. The more thorough analysis is more applicable to tolerance-setting.

## FEDERAL MONITORING PROGRAMS

On the Federal level, the responsibility of monitoring foods for environmental contaminants falls mainly on two agencies, FDA and USDA. USDA limits its monitoring activities to meat and poultry products, while FDA analyzes samples of animal feeds, fruits, vegetables, grain, eggs, milk, processed dairy products, and seafood. Most monitoring activities of these two agencies could be classified as regulatory monitoring-analysis of food samples for known environmental contaminants and for some suspected environmental contaminants for enforcement purposes.

### Food and Drug Administration

FDA collects approximately 8,000 food and feed samples a year and analyzes them for a variety of chemical residues, mainly pesticides. Domestic food commodities comprise about 70 percent of this total, imported commodities make up around 30 percent. In addition, approximately 1,300 seafood samples are collected for analysis annually. Most food and feed samples are collected at their point of origin or processing, and attempts are made to collect the seafoods as close to the point of origin as possible (9).

Some agricultural products are analyzed for the presence of trace metals—lead, zinc, and cadmium—as well as for synthetic organic chemicals. All fish samples collected for determination of chlorinated pesticides and PCBs are also analyzed for mercury. Some canned-tuna samples are analyzed for lead, cadmium, arsenic, selenium, and mercury. Because some containers have lead-soldered joints that may contaminate the food, an unspecified number of canned-food samples are analyzed to determine lead content (9).

FDA also determines the total dietary intake and exposure trends of some known and suspected environmental contaminants in its Total Diet Studies. The contaminants included in this program include some pesticides, PCBs, mercury, lead, cadmium, arsenic, selenium, and zinc, Other organics and metals are excluded (9). Because it involves

not the analysis of individual raw food products but rather combinations of prepared cooked foods which approximate a total dietary intake, this program differs from the regulatory monitoring activities of FDA.

Monitoring for known environmental contaminants is carried out through the use of specified "accepted" methods for extraction, cleanup, and identification. The procedures, when applied to samples in which regulated synthetic organic chemicals such as pesticides are to be determined, will often indicate the presence of other compounds that are chemically similar to those under analysis. The FDA Compliance Program Guidance Manual (10) specifies that if, during the regulatory monitoring analyses, unidentified analytical responses appear (thus indicating an uncharacterized chemical) with "significant" intensity, data from the sample collection and analysis should be transmitted to the Bureau of Foods Laboratory in Washington, D. C., which presumably will identify the uncharacterized chemicals.

FDA may select a chemical for further study based on production volume, toxic byproducts, environmental stability, volubility, behavior, toxicity, uses, and methods of disposal. After an analytical method is developed, samples that have the highest probability of being contaminated with the particular (selected) compound are collected. These samples are often fish, since rivers, lakes, and estuaries receive chemicals not only from direct discharges from municipalities and industry but also from erosion and runoff. Further research and monitoring activities on a given chemical depend on the results of these initial analyses (9).

The present radionuclide-monitoring program is a joint undertaking by FDA, EPA, and the States, This program monitors: 1) foods grown near eight selected nuclear power facilities for tritium, gamma emitters, and strontium-90; 2) food samples from the total diet studies; 3) specified imported foods; and 4) milk, fruit, vegetables, and water collected near phosphate mines in Florida (11).

EPA monitors milk, air, water, and soil for radioactivity. The milk-monitoring program is a joint effort with State and local agencies, FDA advises and monitors the milk-sampling program, which is carried out by 63 State and local health agencies. Milk from each area is sampled once a month by the State and/or local inspectors and submitted for analysis to the EPA laboratory in Montgomery, Ala.

## U.S. Department of Agriculture

USDA is responsible for evaluating the quality of meat and poultry products and providing the consumer with products that meet the criteria spelled out in the Meat and Poultry Inspection Acts. These criteria include monitoring for environmental contaminants. The majority of compounds evaluated are those that are approved for use in agriculture, either administered directly to food animals (such as growth promoters), or applied to agricultural crops to which food animals may eventually be exposed (such as pesticides).

Testing of meat and poultry products for residues by USDA falls into broad monitoring and surveillance categories. The monitoring activity, called the National Residue Monitoring Program, is designed to determine the frequency at which tolerance-exceeding amounts of monitored compounds are occurring in the national meat supply. In effect, the monitoring program is designed to evaluate how effectively users and/or manufacturers of the compounds are complying with the laws or use restrictions (12).

Under the monitoring program, animal tissues are collected from slaughterhouses under Federal inspection throughout the United States at a rate that will detect violations if they are occurring in at least 1 percent of the animal population [13). Based on statistical calculations, 300 samples per compound per species have to be collected annually to determine a l-percent incidence with 95-percent assurance. In effect this means that the same sample of tissues may be analyzed for more than one compound. This level of testing re-

quires sampling approximately 1 in 8,000 head of livestock and 1 in 700,000 poultry. These collections are stratified according to geographic areas, with more samples being collected from areas where meat or poultry are slaughtered.

USDA does not monitor all compounds for which tolerances have been established. There are no suitable methods to analyze some of them within existing regulatory monitoring laboratory capabilities. Available resources may also limit the number and variety of compounds tested, The selection of which compounds to monitor is based on factors such as frequency and patterns of use, toxicity, previous testing results, and public concern. Major groups of compounds in the monitoring program include synthetic organic chemicals (mainly chlorinated hydrocarbon insecticides), trace metals, antibiotics, sulfonamides, and certain hormones and drugs used for growth promotion and disease control. Organophosphate pesticides were monitored for several years but this monitoring was discontinued because residues of the parent compound were not found in animal tissue and suitable routine methods for detecting the metabolizes were not practical (12),

In 1978, about 150,000 tests were completed on approximately 20,000 domestic samples collected under the national residue monitoring program. An additional 2,000 samples were collected from imported products (12). Many of these samples are analyzed for potential contaminants other than trace metals and synthetic organics. In 1977, for instance, around 2,300 out of 22,000 samples were analyzed for chlorinated hydrocarbon pesticides and 1,300 for trace metals. The remainder were analyzed for antibiotics, hormones, and drugs (13). Data generated by this program are used not only for regulatory functions but also to help pinpoint problems, assist in trend analysis, and indicate areas that need more intensive sampling.

Surveillance samples are those collected to evaluate a problem. The area of sampling may be as small as a single farm or as large as a State or region, depending on the circumstances. Indications of problems come from many sources: the National Residue Monitoring Program, activities of USDA inspectors, information from State or other Federal officials, or from public news sources. Because these samples are biased (i.e., collected in response to a given need), they do not reflect the overall condition of the national meat supply. In most cases the samples are used to determine either the extent of a problem or to evaluate the acceptability of a herd or product. Any product found to be in violation may not be released into commerce until subsequent samples show that it is in compliance. These followup samples are considered surveillance samples,

Analyses of samples collected in USDA programs are performed in a manner similar to those in the FDA program—prescribed analytical methods are used. USDA, like FDA, may try to identify an "uncharacterized" substance when "unknown" peaks appear in the analysis of a sample. Depending on the identity of the compound, further investigation and sampling may be carried out,

### Environmental Protection Agency

EPA has no mandate to regularly analyze food commodities for chemical contamination. Some of its programs designed to determine the ecological impact of pollutants may include certain types of foods for analysis. This is particularly true in the case of seafood. Samples from aquatic food chains are often selected for analysis to ascertain whether a pollutant is concentrated as it moves up the food chain.

In addition, the mobilization, degradation, and transfer of pollutants is often studied by EPA. For example, under the auspices of EPA's Chesapeake Bay program, trace metals and synthetic organic chemicals are being studied in water, living organisms, and sediments of the Chesapeake Bay by various State agencies and academic institutions. The results of this and similar studies are not designed to protect the public from consuming contaminated food and are seldom used as

such. Rather, the results are used in protecting the environment from chemical insults and helping EPA better regulate the introduction of toxic substances into the environment.

Some data transfer between EPA and other Federal agencies exists. For example, in the EPA-funded kepone studies in the Chesapeake Bay region, kepone concentrations in edible fish, shellfish, and crabs are obtained which assist the Commonwealth of Virginia and FDA in their efforts to keep contaminated sea food off the market. This is true even though the study is not designed specifically for this purpose.

Another program administered by the EPA is the Mussel Watch (14). It is designed to analyze shellfish collected from strategic locations in the marine coastal zone of the United States for selected organic chemicals, trace metals, and radionuclides. This program was started in 1976 and now involves the collection of oysters and/or mussels from 29 stations on the west coast, 34 stations on the east coast, and 26 stations on the gulf coast, Collections from these stations make up a total of 107 samples,

The trace metals for which samples are analyzed in this program include lead, cadmium, silver, zinc, copper, and nickel. The radionuclides measured in the samples include plutonium-238 and -239, americum-241, cesium-137, curium-242 and -244, and lead-210. The synthetic organic chemicals included in the analysis are the halogenated hydrocarbons p,p'-DDE and p,p'-DDD—two of the principal breakdown products of the pesticide DDT—and PCBs. Samples are analyzed for these synthetic organic chemicals as well as petroleum hydrocarbons, whose presence may indicate oil pollution. Recently, a number of uncharacterized substances have been found by Mussel Watch scientists. They are now designing the program to encompass systems to track and identify them (15).

## Critique of Federal Monitoring Programs

A chemical substance found in food becomes the subject of Federal regulatory monitoring if it has caused a problem at some time in the past. In other words, a compound may enter the food supply and be undetected for years but categorized as a known contaminant when discovered. An example would be kepone in seafood of the James River in Virginia (16). This compound is an insecticide that had been entering the aquatic food chain for at least 7 years before discovery. Its presence in seafood was determined after workers in the facility that manufactured it became ill from industrial exposure to this toxicant (17)0

As soon as the sick workers were discovered, samples of fish and oysters from the adjacent river were analyzed and shown to contain kepone. Within a few months, action levels were established for kepone in seafood. Because existing monitoring programs analyze for known regulated environmental contaminants, the compound was not discovered because it was not sought. It is unlikely that the presence of kepone would be known and regulated today had the workers not become ill. In this case, kepone was placed in the known-environmental-contaminants category as a result of the illness of production workers, not chemical monitoring.

Another example of a toxic compound entering the food supply and going undetected is the fire-retardant polybrominated biphenyls (PBBs), PBBs entered the food supply in Michigan in the late spring or early summer of 1973 (18,19), Bags of a fire retardant containing these compounds were shipped to farmers' cooperative units in Michigan in place of the intended livestock feed supplement, The fire retardant was unknowingly mixed with cattle feed and fed to herds throughout the southern part of the State. Even though farmers soon noted the symptoms of poisoning in the cattle and reported the problem to State and Federal officials, it was almost a year before the causative agents, PBBs, were identified. During this year dairy products and beef contaminated with these compounds were consumed by the citizens of Michigan. Soon after the compound was identified in food products, action levels were established to protect the consumer. In this case the trig-

ger for designation of PBBs as known environmental contaminants was sick cattle, not chemical monitoring.

From these two case studies it appears that monitoring programs designed mainly to check for known environmental contaminants are insufficient to detect toxicants in food for which there have been no action or tolerance levels established.

## CHAPTER III REFERENCES


1. Federal Food, Drug and Cosmetic Act, 21 U.S.C. 321 et seq.
2. Poultry and Poultry Products Inspection Act, 21 U.S.C. 451 et seq.
3. Federal Meat Inspection Act, 21 U.S.C. 601 et seq.
4. Merrill, R.A. FDA *Regulation of* Food *Safety*, unpublished manuscript, 1978.
5. Kennedy, D., Commissioner, Food and Drug Administration, to J. B. Cordaro, Jan. 22, **1979,**
6. 21 CFR 109.
7. Arnold, F. T. *Kepone* Action Levels—Review, Analysis and Recommendations, Office of Special Pesticide Reviews, Environmental Protection Agency, Mar. 9, 1977.
8. ''Polychlorinated Biphenyls (PCBs), Reduction of Tolerances, " Federal Register 44(127): 38330, 1979.
9. Food and Drug Administration. Report in Response to the Office of Technology Assessment letter of June 5, 1978—''Request for Information on Federal Capabilities for Environmental Monitoring and Toxicity Testing, " 1978.
10. Food and Drug Administration. Compliance Program Guidance Manual, Compliance Program 7305.007 -''Pesticide and Metals in Fish Programs" (FY '78), Oct. 1, 1977.
11. Food and Drug Administration, Compliance Program Guidance Manual, Compliance Program **7305.006-'"** Radionuclides in Foods" (FY "78), Oct. 1, 1977.
12. Clark, G. U.S. Department of Agriculture, 1979.
13. U.S. Department of Agriculture. The National Residue Program, USDA-Food Safety and Quality Service, May 1978.
14. Goldberg, E, D., V. T. Barrington, J. W. Harvey, G. H. Martin, J. H. Parker, P. L. Risebrough, R. W. Robertson, W. Schneider, E. S. and E. Gamble. "The Mussel Watch, " Environmental Conservation, vol. 2, Summer 1978,
15. Risebrough, R. W. Bodega Marine Laboratory, University of California, Bodega Bay, Calif., personal communication, 1978.
16. Huggett, R. J., M. M. Nichols, and M. E. Binder. "Kepone Contamination of the James River Estuary, " Proceedings *of* Symposium on Contaminants and Sediments: Fate and Transport, R. A. Baker (cd.), Honolulu, Hawaii, April 1979 (in press),
17. Food and Drug Administration. Compliance Program Evaluation (FY '77), Kepone and Mirex Contamination (7320.79A).
18. McNally, J. M, ''Polybrominated Biphenyls: Environ-mental Conta-mination of Food, " special paper for OTA, Library of Congress, Congressional Research Service, 1978.
19 Michigan Department of Agriculture, Information and Education Division. "A Brief Chronology of the PBB Incident" (no date).