Chapter IV

State Laws, Regulations, and Programs

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STATE LAWS

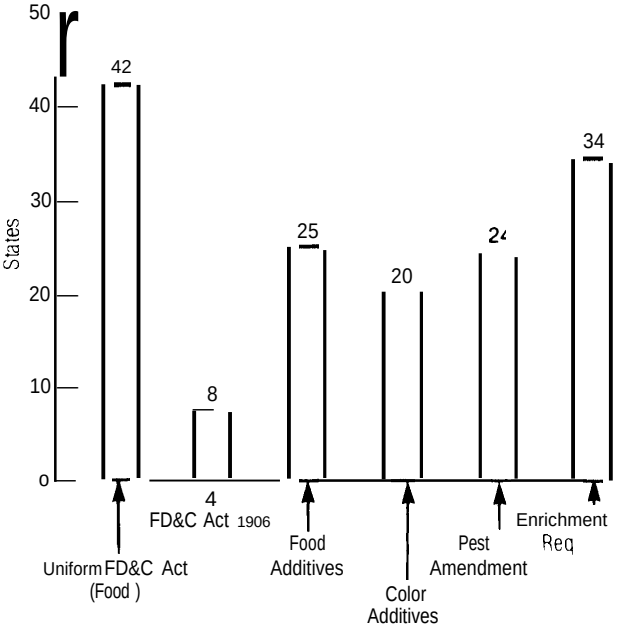
State food and drug laws, and the organizations that administer them, vary widely. Basic State food and drug statutes are based on the Federal food laws; however, not all States have adopted the model uniform State food, drug, and cosmetic bill of the Association of Food and Drug Officials. As shown in figure 3, 42 States have adopted the model statute, which is almost identical to the 1938 Federal Food Drug and Cosmetic Act. Consequently, these 42 States have the same legislative authority for regulating food contaminants within their borders as the Federal Government does for food in interstate commerce. The 1906 Act, still retained by eight States, does not contain the tolerance-setting provisions of the 1938 Act under which environmental contaminants are regulated (l).

Authority for regulating environmental contaminants in food rests with two or more agencies in most States. Usually the Department of Agriculture and the Department of Health share responsibilities for food regulation. In some States a variety of other agencies and bodies are also involved in regulatory or research activities: departments dealing with commerce, fish and game, consumer protection, environmental improvement, public administration, conservation, along with university divisions, independent laboratory agencies, and various independent boards and commissions (2).

The Food and Drug Administration (FDA) believes that this variability in laws and regulatory organizations makes it more difficult for the States to accomplish their goals:

> The variability of organizational structure complicates the problems of many of the individual State agencies in accomplishing their program goals because of overlapping responsibilities and the lack of a clear delineation of responsibilities. For example, it is not uncommon to find authority granted to two agencies for some divided program segments of a single program category (e.g.,

Figure 3.— State Food Laws



SOURCE Food and Drug Administration *State Programs and Services in Food and Drug Control, 1978*

milk, shellfish). Frequently, two or more independent agencies of relatively equal rank are charged with enforcement of portions of the same general food and drug law. In still other States, there is no central State control over the food and drug program. In these instances, the State agency has an unclear role as an advisor or consultant to the local government. However, the local agency may not be legally bound to follow the advice and/or direction that may be suggested by the State agency (1).

STATE Monitoring PROGRAMS

Non-Federal monitoring is limited almost exclusively to programs originated and carried out by individual States. In some cases there is close coordination between State and Federal activities. Federal agencies may decrease their monitoring in a given area if State monitoring is considered sufficient. For example, FDA does not monitor seafood for kepone (3) even though the concentrations in finfish, crabs, or shellfish remain essentially unchanged since its discovery in 1975 (4). FDA feels that the ongoing monitoring programs in Virginia are sufficient to protect the consumer.

Analysis of the OTA State survey reveals that State food-monitoring laboratories are equipped to analyze for those substances that are regulated in foods through action levels or tolerances. For instance, most had instrumentation (atomic absorption spectrophotometers and gas chromatography) to analyze for mercury and chlorinated hydrocarbon pesticides.

FDA published a study entitled "State Programs and Services in Food and Drug Control" in September 1978 (l). The publication provides a compilation of States' analytical capabilities during the years 1975 and 1976, listing numbers and educational levels of chemical analysts, types of analytical equipment, and expenditures for food inspection.

In 1974 and 1975, the States spent annually about $64.9 million for food inspection and analytical activities. This amounted to 72 percent of their total inspection and analytical expenditures (l). Table 8 shows program areas and expenditures for States. These figures do not include the estimated $75 million expended by local governments.

Table 8.—Program Areas and Expenditures for States

Program	Expenditures: Millions of dollars	Expenditures: Percent of total (food and drug)
Food	$64.9	72.3
Drugs, devices, cosmetics	9.7	11.0
Feed	6.4	7.0
Weights and measures (food)	5.5	6.0
Pesticides	3.3	3.7
Total	$89.8	100.0

SOURCE Food and Drug Administration *State Programs and Services in Food and Drug Control.* 1978

The educational levels of the chief chemist, supervisory chemist, and chemist and laboratory technicians are presented in table 9 (l). The salary ranges for the chemical personnel are shown in table 10 (l). Only 1 percent of the chemists working in State food and drug programs earned more than $20,000 per year in 1975 and 1976. Approximately 64 percent of them had annual salary ranges of $8,000 to $15,000.

The available analytical equipment and physical facilities are listed in table 11 (l). These data confirm the OTA survey findings, since gas chromatography and atomic absorption spectrophotometers rank first and third, respectively, in numbers. A breakdown of food commodities analyzed, samples collected, and analyses performed is given in table 12 (l). The FDA document urges caution in interpreting these data because ". . . some States do not maintain comprehensive analytical records on food analyses especially if food is not the major laboratory workload."

Table 9.—Number of Employees by Category and Education Level in Various State Food and Drug Programs

Personnel	Number of employees	Advanced degree	College degree	Some college	No college
Chief chemist	109	68	40	1	0
Supervisory chemist	232	62	167	3	0
Chemist	633	66	561	6	0
Laboratory technicians	833	0	127	375	332

SOURCE: Food-and-Drug Administration, *State Programs and Services in food and Drug Control 1978*

Table 10.—Salary Ranges of Various Chemical Personnel in State Food and Drug Programs

Salary-ranges	Number of chief chemists	Number of supervisory chemists	Number of chemists
$ 6,000- 9,000	0	3	0
$ 7,000-10,000	0	0	26
$ 8,000-12,000	0	0	70
$ 8.000-14,000	2	17	153
$10,000-15,000	2	143	139
$12,000 -18000	17	53	5
$16,000-20,000	71	7	0
over $20,000	8	0	0

SOURCE: Food and Drug Administration, *State Programs and Services in Food and Drug Control* 1978

Table 11.—Physical Facilities and Key Equipment in 114[a] State Food and Drug Laboratories

Key equipment items	Number of key equipment items[b]
Spectrophotometers	269
Flame photometers	90
Atomic absorption spectrophotometers	125
Spectrofluorimeters	88
Gas chromatography	348
Polarographs	42
Polarimeters	54
Mass spectrometer	19
Electrophoresis	86
Auto analyzers	120
Liquid chromatography	18
Physical facilities	
Average floor space ($ft.^2$)	10,245
Average bench space (lin. ft.)	845
Average storage ($ft.^2$)	1,150

[a]Two States not reporting lab equipment or space
[b]Shows only total number of equipment items reported by the State agencies. Does not show those labs that do not have one or more of the equipment items listed

SOURCE: Food and Drug Administration, *State Programs and Services In Food and Drug Con Ire/* 1978

This probably accounts for the extensive analytical activity reported in the "other food" category, rather than in the categorical program areas"' (l). Even so, it is evident that milk and milk products are the most commonly sampled and analyzed food commodities.

The large number of samples and analyses indicate that the States perform extensive monitoring for regulated contaminants in food, But the low salary ranges, the lack of sophisticated analytical equipment such as mass spectrometers, the time spent per analysis, and the sample-type distribution indicate that State monitoring programs are as inadequate as Federal programs in detecting environmental contaminants in food for which no action or tolerance levels have been established,

Table 12.—Total Number of Samples, Sample Determinations, and Man-Hours by Food Commodity Categories With Number and Percentage of States Reporting Analytical Activity

Food commodity categories	Number of States reporting analytical activities	Percent of States	Number of samples (thousands)	Number of determinations (thousands)	Number of man-hours (thousands)
Bakery products. ., ...	35	70	11.5	23.3	31.5
Soft drinks	35	70	18.7	64.6	17,5
Candy	29	58	7.0	18.1	13.6
Grade A milk (raw)	50	100	342.0	1,157,1	319.0
Other milk products.	47	94	200,7	546.8	185.6
Canned foods. . .	35	70	21.3	870	48.5
Frozen foods	27	54	7.3	27.6	19.3
Seafood.	34	68	6.6	34.4	33.2
Shellfish	24	48	37.6	106.3	67.6
Raw agricultural products	29	58	40,1	89.6	112,7
Other foods.	40	80	103,0	326.3	220.1
T o t a l s			7958	2,481,1	1,068.6

SOURCE Food and Drug Administration *S/ate Programs and Services in Food and Drug Control 1978*

FEDERAL/STATE LIAISON

Many environmental contamination incidents are initially State problems. Theoretically, the Federal Government does not become involved until a contamination incident is determined to be an interstate problem. Given the complexity of this country's food-marketing system, 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 concerns. Figure 4 reveals the extent of food contamination that can occur from a single source of contamination, in this instance polychlorinated biphenyls (PCBs) contaminated animal feed from a meatpacking plant in Billings, Mont. (5). This widespread contamination of food occurred during an estimated time period of 2 to 5 months.

The States and the Federal Government establish liaison when contamination crosses State lines. Liaison is also established at the request of States. States often require Federal assistance in investigating a contamination incident. The objective is to generate scientific information on the nature and extent of the contamination. This information would include the toxicological and chemical properties of the contaminating substance, the amount and type of food contaminated, and the concentration of the substances in food.

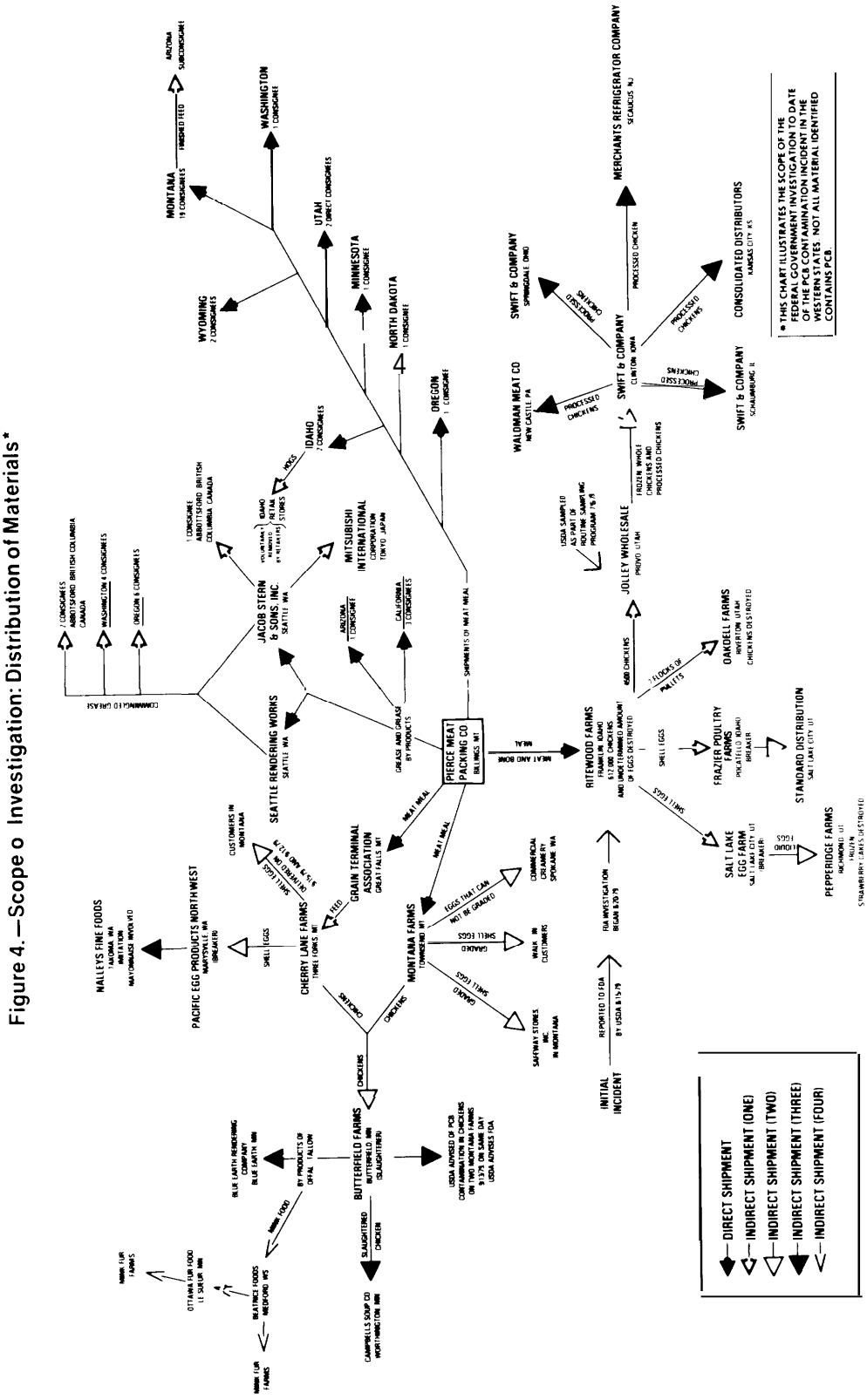
Such information is used by State and Federal authorities to: 1) determine the appropriate Government response for protecting the public health and 2) inform the general public about the incident and explain the Government response. To contain an incident, scientific information needs to be accurate and immediately available. This is as true for an episode involving a substance that has previously contaminated food (1979 PCB contamination of animal feed in Billings, Mont.) as for a substance which has not (1973 polybrominated biphenyl (PBB) contamination of animal feed in Michigan).

The generation and dissemination of scientific information on an incident is hindered by the number of State and Federal agencies involved. As already noted, three Federal agencies (the Environmental Protection Agency (EPA), FDA, and the U.S. Department of Agriculture (USDA)), each with different responsibilities, can be involved along with various State agencies. The PBB incident in Michigan and the PCB incident in Montana reflect this particular problem.

Generating Information

Before the needed scientific information for developing regulations is generated, the

Figure 4.—Scope o Investigation: Distribution of Materials*



contaminating substance in food must be identified. This identification process may require lengthy investigative work which could be hindered by a multiplicity of involved Federal and State agencies. The PBB incident provides an example of the extensive investigations sometimes necessary.

The Michigan Department of Agriculture (MDA) initially analyzed blood and feed samples from a herd owned by Mr. Frederic Halbert (at his urging). These samples proved to be negative because MDA was not analyzing for PBB. Additional samples were analyzed by the USDA's National Animal Disease Center in Ames, Iowa. While the Disease Center detected an unusually high peak of an unidentified substance, it did not determine its identity. The substance was eventually identified by Dr. George Fries of USDA's Agriculture Research Center at Beltsville, Md., who had previous experience in chemical analysis of PBB (6). The discovery came nearly 8 months after adverse symptoms occurred in the herd at the Halbert farm.

The laboratories and agencies involved in identifying PBB are part of the agriculture system in the United States. They were the obvious institutions to which Mr. Halbert would go for assistance. If he had initially contacted the Michigan Department of Public Health (MDPH), it is likely that different Federal laboratories and agencies would have analyzed the samples. There was and still is no systematic procedure at the Federal level for assisting States in identifying a potential food contamination problem like PBB. Were it not for the perseverance of Mr. Halbert and the experience of Dr. Fries, the identity of PBB might have taken longer and the people of Michigan would have been exposed to PBB-contaminated food even longer.

Once a contaminant has been identified in food, the necessary scientific information can be generated for either regulating or controlling the contamination. In the PBB incident, FDA helped to develop and evaluate this information and worked with MDA in controlling the incident. FDA's involvement was based on the fact that it has the Federal authority for regulating contaminants present in food. Examples of actions taken by State and Federal authorities in such instances include removing food from the market, setting action levels or tolerances for the contaminant in food, and disposing of the contaminated food. Because little scientific information on PBBs was available, it took time to generate the information and establish final permissible levels (although contaminated herds and food were identified as quickly as possible and removed from the market). The PBB incident involved FDA, USDA, MDA, and MDPH. Even more State and Federal agencies were involved in the PCB contamination episode in the Western United States.

The PCB contamination began in Montana with animal feed and quickly spread to 16 other States. Idaho was particularly affected by the contamination of poultry and eggs. This incident involved all three relevant Federal agencies—FDA, EPA, and USDA—as well as the Idaho Departments of Agriculture and Health and Welfare, and district health departments. USDA made the initial analysis of poultry samples which proved positive for PCB; FDA was involved with the removal of PCB-contaminated food from the market; and EPA with the proper disposal of the contaminated food. At least 5 days elapsed from the time USDA was confident it had a PCB contamination incident to the time it notified FDA of its findings. It took FDA an additional 5 days to begin its investigation of the contamination incident (7). Such delays would be unlikely if only one Federal agency were involved or communications between the two agencies were better.

PCB is a substance whose chemical and toxicological properties are fairly well understood. It has contaminated food in the past. Nevertheless, there was confusion among the State agencies in Idaho as to the proper response to the contamination. The confusion resulted from two conditions. First, some of the State officials involved were not familiar with the chemical and toxicological properties of PCB. PCB was a new food con-

taminant in Idaho, and the appropriate officials had little experience with this type of problem. Second, the involvement of three different Federal agencies obstructed efficient communication between the State agencies and the Federal Government.

While the Federal agencies had the most expertise on PCBs, the sharing of that experience was hindered by the fact that it was available in and distributed by three sources instead of one. Consequently, State agencies had to go to different Federal sources, depending on what information they needed. In addition, the Federal agencies did not always communicate with the various State agencies. EPA, for example, took air and water samples in the area surrounding Ritewood Farms to determine whether PCBs that contaminated Ritewood's eggs and poultry came from either of these two sources. This was before the PCB-contaminated animal feed was identified. EPA, however. did not report their negative findings to the State. In another instance, USDA initially would report its results only to the Idaho Department of Agriculture, the State agency with which USDA has had a long-standing association. The Idaho Department of Health and Welfare, which is concerned with protecting the public health, at first was not informed by either USDA or the State Department of Agriculture of the PCB contamination. Communication broke down at two levels, between the State and Federal Governments and within the State government (8). The fact that there are several different Federal and State agencies involved with different aspects of controlling and regulating a contamination incident further complicates an already complicated problem.

The major environmental contamination incidents that occurred in Idaho and Michigan continue to be major issues of concern among the residents of these States--a result of their fears over a potential health threat that cannot be seen, smelled. or tasted. In Michigan, for instance, the PBB episode remains a live and controversial political issue. Consequently, it becomes imperative that the information generated by the State and/or Federal Government on an incident is accurate and appropriately applied. This objective is hindered by the variety of State and Federal agencies that become involved.

CHAPTER IV REFERENCES

1. U.S. Department of Health. Education, and Welfare, Food and Drug Administration. State Programs *and* Services in Food *and Drug Control,* 1978.
2. OTA Survey of 31 States, 1978.
3. Food and Drug Administration. Compliance Program Evaluation (FY '77), Kepone and Mirex Contamination (7320. 79A).
4. Huggett, R. J., M.M. Nichols, and M. E. Binder. "Kepone Contamination of the James River Estuary, " Proceedings *of* Symposium on Con*taminants* and Sediments: Fete *and* Transport. R. A. Baker (cd.), Honolulu, Hawaii. April 1979 (in press).
5. Gardner, Sherwin, Acting Commissioner of Food and Drug Administration. Testimony before Subcommittee on Oversight and Investigation, House Committee on Interstate and Foreign Commerce, Sept. 28, 1979.
6. Michigan Department of Agriculture, Information and Education Division. "A Brief Chronology oft he PBB Incident ," (no date).
7. Foreman, Carol Tucker, Assistant Secretary for Food and Consumer Services, U.S. Department of Agriculture. Testimony before the Subcommittee on Oversight and Investigation, House Committee on Interstate and Foreign Commerce, Sept. 28, 1979.
8. Gallagher, Ed, State Health Officer, Idaho Department of Health and Welfare, personal communication, Oct. 10, 1979.

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