Chapter VII

Monitoring Strategies

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Monitoring involves the systematic collection and chemical analysis of food samples or other samples from the environment. The aim is to protect consumers by determining short- and long-term trends in the levels of various chemicals in food and the environment.

STRATEGIES

Monitoring strategies can be shaped to achieve either of two objectives. The first is to identify food lots that violate established tolerances and action levels. The second is to identify new environmental contaminants as they enter the human food chain.

The first objective is met by regulatory monitoring: the second through investigatory monitoring. Each of these strategies could be complemented by specimen banking. Neither is incompatible or mutually exclusive.

Regulatory Monitoring

The Federal agencies responsible for limiting consumer exposure to contaminated food now conduct regulatory monitoring. Food samples are collected and analyzed for environmental contaminants for which action levels and tolerances have been established. Based on available information or agreements with States, not all samples are analyzed for all regulated substances. Regulatory monitoring employs standardized, accepted analytica1 techniques. Because the procedures are standard and can be verified by other laboratories, they generate data that can be presented in courts of law with little probability of being successfully contested.

Chapter III reviewed Federal monitoring programs and chapter IV reviewed State monitoring programs. It is unlikely that these monitoring programs will detect new environmental contaminants, since both are restricted to searching for regulated chemicals. Therefore, investigatory monitoring approaches are vital.

Investigatory Monitoring

Investigatory monitoring attempts to detect unregulated chemicals as they enter the food chain. This strategy involves the collection and analysis of samples which may or may not be foods, The analytical techniques employed for the detection of unregulated chemicals may or may not be accepted as standard methods comparable to those used for regulatory monitoring.

Analytical methods for investigatory monitoring include broad-spectrum determinations that may sacrifice some quantitative information (i. e., exactly how much of a given substance is present in a sample) for more qualitative information (i. e., better assessment of what or how many foreign substances are in the sample). These analytical methods are not necessarily designed for use in litigation, They are designed primarily to indicate the presence of a potentially hazardous substance. If one is found, an accepted analytical method to detect the substance would have to be developed—a method compatible with instrumentation existing in regulatory-monitoring laboratories.

Investigatory monitoring includes two discrete types of monitoring: monitoring for *suspected* environmental contaminants, and monitoring for uncharacterized environmental contaminants. Each of these (as well as

regulatory monitoring) can be complemented by specimen banking.

Monitoring for Suspected Environmental Contaminants

Some chemicals that are not regulated by action levels or tolerances are suspected to be dangerous to humans if consumed in foods. This group includes chemicals that may be present in food because of their use, toxicity, production volume, and persistence. Examples of these chemicals can be found on the Environmental Protection Agency (EPA)/ Natural Resources Defense Council (NRDC) priority pollutant list established in June 1977. These substances may be called "suspected" or "potential" environmental contaminants.

Monitoring for suspected environmental contaminants involves a different strategy than the one used in monitoring for regulated contaminants. Under the latter strategy, foods are analyzed for compounds with specified action levels and tolerances to provide information for regulatory enforcement. This is not required for investigatory monitoring. Thus, the monitoring program for suspected environmental contaminants is generally not as intensive (see chapter 111), Furthermore, the analytical methods for detecting suspected environmental contaminants may not be as prescribed as those for regulated contaminants.

Suspected environmental contaminants could be identified by surveying the universe of industrial chemicals and ranking them according to their potential for entering the food supply in toxic amounts (l). Such an approach has been recommended to FDA by an internal study group established by former Commissioner Donald Kennedy (7),

This method has been employed by the Food and Drug Administration (FDA) to develop a list of chemical contaminants in food, The criteria used in selecting the chemicals included: occurrence in food, volume of production, associated impurities or byproducts, predicted environmental stability, pattern of use, oil/water partition coefficients, bioaccumulation potential, known toxicity, and means of disposal. The FDA list of chemical contaminants in foods is shown in table 17.

This approach is limited by available analytical methods. Most of the chemicals recognized as food contaminants are those that are relatively easy to detect by gas chromatography or atomic absorption spectrometry. Chemicals that cannot be easily detected by these methods may, of course, remain unidentified and unrecognized as food contaminants (l).

The factors used to identify a chemical's potential for entering the food supply are based on knowledge of the properties and environmental behavior of other chemicals already known to be in food. This knowledge, in turn, is based on our information about the extent of contamination information that depends on our analytical capabilities. Thus, there is an inherent tendency to identify as potential food contaminants those chemicals that are similar to chemicals already identified in food. Such a tendency can only be offset by the use of good scientific judgment or the development of new data. This bias illustrates a general weakness in all systems for setting priorities: chemicals on which there is no information will automatically be given low priority unless some room is left for largely intuitive judgments (1). The scientific criteria and methods used in determining what priority various toxic substances receive in monitoring programs are discussed in more detail in appendix F.

Although these exercises in setting priorities suffer from many limitations (including lack of data, poor choices of criteria on which to set ranks, deficiencies in the scoring and ranking systems, and deficiencies in scientific judgment), they still can serve a valuable function in guiding monitoring systems. Setting priorities is a prescreening exercise in which a compromise is struck between the effort expended in preparing a priority list and the effort that would be wasted in identifying and quantifying all the chemicals present in a sample,

Table 17.—Chemical Contaminants in Foods[a]

Chemical contaminant	Range in ppm	Locations
Aromatic amines		
1-naphthylamine	0.01-0.12	Delaware River, Del. Buffalo River, N.Y.
N-ethyl-N-phenyl benzylamine	0.001-0.17	Delaware River
N-ethyl-N-(m-tolyl) benzylamine	0.001-0.01	Delaware River
3,3'-dichlorobenzidene	0.1-0.3	Muskegon County, Mich. (water)[b]
Benzidene	2.5	Muskegon County, Mich. (water)[b]
Triaryl phosphates		
Pydraul 50E	up to 1	
triphenyl phosphate	up to 1	Waukegan Harbor, Ill.
cumylphenyl diphenyl phosphate	up to 1	
nonylphenyl diphenyl phosphate	up to 1	
isopropylphenyl diphenyl phosphate	01-10	Saginaw River, Mich.
	0.1-10	Kishacoquillas Creek, Pa.
trixylenyl phosphate	0.02-008	Columbia River, Wash.
tricresyl phosphate	002-0.04	Columbia River, Wash.
2-ethylhexyl diphenyl phosphate	1.4	BUF-DO (animal fat)
Chlorinated benzenes		
monochlorobenzene	tr-6.7	Tombigbee River, Ala.
1,4-dichlorobenzene		Ohio River, Ohio
1,2-dichlorobenzene		Niagara River, N.Y.
1,3,5-trichlorobenzene		White Lake, Mich.
1,2,4-trichlorobenzene		Spring Creek, Pa.
1,2,3-trichlorobenzene		Bald Eagle Creek, Pa.
1,2,3,5-tetrachlorobenzene		Mississippi River, La.
1,2,4,5-tetrachlorobenzene		Kimmswick, Mo.
1,2,3,4-tetrachlorobenzene		
pentachlorobenzene		0.11 in peanut oil
hexachlorobenzene		0.07 in peanut oil
Chlorinated benzotrifluoride		
4-chlorobenzotrifluoride	03-2.0	
3,4-dichlorobenzotrifluoride	tr-0.1	
2,4-dichlorobenzotrifluoride	0.2-0.8	Niagara River, N.Y.
trichlorobenzotrifluoride	unknown	
tetrachlorobenzotrifluoride	unknown	
Chlorinated toluenes		
monochlorobenzylchloride*	unknown	
dichlorobenzylchloride*	unknown	Niagara River, N.Y.
trichlorobenzylchloride*	unknown	
2,3,4-trichlorotoluene	unknown	
Other chlorinated aromatics		
p-chloronitrobenzene	0.01-0.33	Kimmswick, Mo.
	0.01-0.33	Cape Girardeau, Mo.
	0.01-0.33	St. Louis, Mo.
o-chloronitrobenzene	0.006-0.12	St. Louis, Mo.
3,4-dichloronitrobenzene	0.05	Kimmswick, Mo.
2,3-dichloronitrobenzene	0.01	Kimmswick, Mo.
tetrachloronitrobenzene	tr	peanut oil
pentachloronitrobenzene	0.03	peanut oil
pentachloroaniline	0.26	peanut oil
pentachlorophenyl methyl sulfide	0.08	peanut oil
pentachloroanisole	tr-0.15	many rivers and lakes
	0.1	peanut oil
pentachlorophenol	tr-0.02	Mississippi River, La.
octachlorostyrene	0.02-0.1	Lake Ontario, N.Y.
	0.02-0.1	White Lake, Mich.
Chlorinated cyclics (non-aromatic)		
1,2,3,4,7,7-hexachloronorbornadiene	0.03-162	Mississippi River, La.
1,2,3,4,5,7,7-heptachloronorbornene	0.03-162	Mississippi River, La.
5,6-epoxy-1,2,3,4,7,7-hexachloronorbornene	0.03 -16.2	Cape Girardeau, Mo.

Table 17.—Chemical Contaminants in Foods[a]—(cont.)

Chemical contaminant	Range in ppm	Locations
tetrachlorocyclopentene*	unknown	White Lake, Mich
pentachlorocyclopentene*	unknown	White Lake, Mich
hexachlorocyclopentene	unknown	White Lake, Mich
Chlorinated aliphatics		
hexachlorobutadiene	tr-4.6	White Lake, Mich.
	tr-4.6	Mississippi River, La
	tr-4.6	Ohio River, Ohio
	tr-4.6	Cape Girardeau, Mo.
hexachloroethane	0.13	Ohio River, Ohio
trichloroethylene	unknown	Ohio River, Ohio
tetrachloroethylene	unknown	Ohio River, Ohio
pentachloroethane	unknown	Ohio River, Ohio
pentachlorobutadiene	unknown	Ohio River, Ohio
Brominated aromatics		
polybrominated biphenyls	tr-1.1	Pine River, Mich.
	tr	Ohio River, W. Va.
	0.18	DET-DO (animal fat)
	43.8	DET-DO (chicken fat)
1,4-dibromobenzene	tr	Pine River. Mich
1,2,4-tribromobenzene	0.05	Pine River. Mich
1,2,4,5-tetrabromobenzene	0.04	Pine River. Mich
monobromobiphenyl*	unknown	Pine River. Mich
dibromobiphenyl*	unknown	Pine River. Mich
Haloforms		
CCl_4	unknown	Houston Channel
C_2Cl_4	unknown	Houston Channel

[a]All samples analyzed were freshwater fish except where indicated
[b]Water samples containing dichlorobenzidine and benzidine were obtained near plant effluent
*Specific isomer(s) unknown

SOURCE: Food and Drug Administration, Division of Chemical Technology, Mar. 20, 1978.

By applying appropriate criteria to the universe of industrial chemicals, it may be possible to detect potential environmental contaminants in food that have not been identified as significant by other methods. Although there is no truly independent way to verify the reliability y of priority lists, such lists could be generated for a pilot program designed to evaluate this approach vis-a-vis uncharacterized monitoring.

Monitoring for Uncharacterized Environmental Contaminants

Uncharacterized environmental contaminants are substances that may have entered the food supply but which have not been classified as regulated environmental contaminants or suspected environmental contaminants. Compounds may fall into this category because they are not known or suspected to occur in food. Because of a lack of toxicity data on compounds, they may not be recognized as threats to human health. This class of substances is similar to suspected environmental contaminants in that there are no stipulated analytical methods to detect them and no monitoring is mandated. Uncharacterized environmental contaminants are different from suspected contaminants in that none have been placed on lists of potentially harmful substances.

Although validated analytical methods for identifying uncharacterized environmental contaminants may be lacking, data on their presence or absence can be generated. Chemical analyses that are designed to show only the presence or absence of a compound in a sample are called qualitative analyses. In many cases an accepted analytical method for one class of compound will yield quantitative results for those compounds and qualitative results for others, Therefore, the pres-

ence or absence of some suspected or uncharacterized environmental contaminants may be determined even though the chemist is not specifically looking for them.

In setting up a system of monitoring for uncharacterized environmental contaminants, some preliminary judgments would be made about the chemical nature of the target substances. Classes of compounds to be monitored would be selected on the basis of their structural characteristics, their use, and their suspected toxicity. Trace metals, halogenated hydrocarbons, or radioactive substances are examples of such classes. The class of compound determines the type of extraction required to separate the substance from other constituents of food, as well as the instrumentation needed to detect the presence of the substance.

The available analytical methods best suited for the class or classes of compounds under consideration would be selected. The question of whether analytical techniques are sufficiently advanced to support uncharacterized monitoring is explored in chapter VIII.

The establishment of an uncharacterized monitoring program would require the development of appropriate sampling and sample-handling guidelines. It would also be necessary to modify currently used analytical procedures. For example, a typical program for organic contaminants would involve preliminary screening to establish baseline levels of contamination in samples of food and water or selected indicator species over a given period of time. This information would then be used to develop an appropriate sampling plan to determine changes or trends over time. An increase in levels of an uncharacterized substance indicates its entry into food and water. This finding would trigger additional analytical efforts to characterize the new compound. Preliminary information on the substance's structure would be transmitted to toxicologists for evaluation and comparison with available information on known toxic compounds. If alarming trends or changes were observed, corrective regulatory actions could be taken.

Specimen Banking

It is difficult to detect environmental contaminants unless one is specifically looking for them, Monitoring methods for identifying suspected and uncharacterized environmental contaminants promise to partially alleviate the problems. Yet, even as new analytical instrumentation is developed and scientific knowledge expands, there will be new classes of compounds discovered in foods that have been present for years but were undetectable with then-existing instrumentation. Information on how long the compounds have been in food, what kinds of foods are affected, and from what areas the foods were derived would be of great help to epidemiologists and public health officials who must decide whether or not the chemicals have had (or will have) an adverse impact on the public.

One approach to this problem is the collection and storage of samples on a regular basis and in a manner that will protect their chemical integrity. In the future, when new instrumentation is developed or a toxic compound is discovered in foods, samples can be withdrawn from storage and analyzed. This in effect would be retrospective analysis. Investigators could go back in time, reconstruct events leading to a current situation, and estimate human exposures from the consumed foods.

There are examples of this kind of retrospective detective work. When high concentrations of mercury were discovered in tuna and swordfish, pollution was widely held responsible, But analysis of museum specimens that had been stored for decades indicated that the mercury levels were probably as high a century ago as now. Therefore, the mercury in fish may be from natural sources and may have always been so. This does not mean that the metal is not a potential health threat but rather that the potential exposure from eating the fish has not changed much over the years.

There is a problem in utilizing most existing collections for retrospective chemical analysis. Since samples were not collected for use in chemical testing; they were not stored in a manner to maintain their chemical integrity. A 1975 survey of environmental specimen collections in the United States by Oak Ridge National Laboratories concluded that few of the existing collections were suitable for retrospective chemical analyses (2). Therefore, a need exists for a national program to collect, store, and maintain environmental samples (including food) to allow retrospective investigations,

EPA and the National Bureau of Standards are now working towards developing such a program by testing various methods of preserving samples for long periods of time without either adding unwanted chemicals or losing ones that are already in the sample. A number of scientists are encouraging this program and similar efforts (3-5). If continued funding is made available for specimen banking of environmental samples (including foods), future investigators will have an easier job of assessing what impact environmental contaminants in foods may have.

SAMPLING

Sampling involves the systematic collection of information from a portion of the environment. Sampling is done in such a way that the collected samples represent the whole in terms of the information desired. In regulatory monitoring the samples must be food commodities because the intent of the program is to determine the levels of regulated substances in the food supply. This information is the basis for enforcement actions.

Food samples may not be the best indicators if the monitoring is meant to serve as an early warning system—in other words, to detect a substance soon after it enters the environment and before it gets into foods. It may be better to analyze nonfood samples such as river sediments, water, or uneaten organs from food animals (the organs may concentrate the substance to analytically detectable levels before it can be seen in the flesh). The finding of an environmental contaminant in nonfood samples would trigger the examination of foods.

The following discussion outlines the primary considerations in selecting samples for investigatory monitoring systems. Constructing a sampling plan for such systems involves a number of decisions based on preliminary information about the nature and extent of environmental contamination. Such decisions include the number, sites, frequency, and types of samples.

The number of samples to be taken depends on how much risk of being wrong we are willing to accept. In other words, to what degree of certainty do we want to know that our food is free from environmental contaminants? One-hundred percent certainty would require analysis of every food item. Acceptance of a lesser degree of certainty allows the use of less costly sampling approaches.

Before preliminary data are collected, there is no way to calculate the exact number of samples needed to yield an answer of specified certainty. The most difficult factor to estimate is the variation specific to each contaminant and how it changes over time and space. This kind of information would have to be collected in pilot programs for suspected and uncharacterized monitoring before a national sampling plan could be developed. The number of samples taken will probably be constrained by the money, manpower, and available laboratory resources.

The density and location of sampling sites depend on the socially acceptable level of uncertainty, whether the contaminant stems from a point or nonpoint source, and how it is transported in the ecosystem.

If one is dealing with widely distributed nonpoint source environmental contaminants that are transported through water, the ideal sampling locations would be rivermouths that

are discharge points of major watersheds. one could very effectively monitor the industrial portion of Michigan by sampling shellfish or fish from some two dozen major rivers just as they enter the Great Lakes. Baseline levels in these foods could be determined, but the origins of the contaminants would be difficult to determine (6).

The other extreme is to monitor food products on a production, site-specific basis. If the aim were to inventory all industries (including agriculture) that utilize and/or discharge a toxic substance, one could then routinely monitor food products, fish, and game at each identified site. Theoretically, the kepone and polybrominated biphenyls (PBB) situations would have been detected much earlier with such a system. The number of operations (large and small) that would need to be monitored is unknown, but the total appears to be so large that the costs would preclude consideration of this alternative (6).

A reasonable compromise approach is to use information generated under the Toxic Substances Control Act on the types of chemicals manufactured at various locations to guide in the development of a sampling plan for use in investigatory monitoring systems. The sampling plan would focus on some food organisms and some nonfood items. The data derived from analyses of such samples would yield the greatest information about environmental contamination trends in the region from which the samples were drawn.

The frequency of sampling depends on the rates a t which the contaminant moves through, accumulates in, and decomposes out of the food production system being monitored, Different food production systems have different genetic and environmental characteristics that determine the rates of material dynamics or transfer. For a beef feedlot, a range of 50 to 180 days would include the period involving a single-batch process. For an apple crop, a single sample per year would suffice. The frequency of sampling may be different for each type of production process. Once the species and the characteristics of the production systems have been identified, the appropriate sampling frequency can be determined (6),

The selection of the types of samples to be collected is also critical in identifying environmental contaminants as they enter the food chain. Although biological samples offer many advantages in monitoring systems, nonliving samples may be preferable in some instances. An example might be bottom sediments from rivers, lakes, or estuaries. Bottom sediments are derived, for the most part, from erosion of land and often bring with them to the aquatic environment substances that are used on land such as herbicides or pesticides. Moreover, once they are in the aqueous environment, they can “sorb” or concentrate many substances found in industrial discharges. The contaminated sediments then serve as a mechanism to expose the plants and animals that live in the waters to a particular chemical. Contaminated sediments may also be used to pinpoint the source of a chemical once it has entered the river, lake, or estuary (6).

Other types of nonliving samples might include air, river water, drinking water, or rain. All have certain advantages and disadvantages. For instance, the concentrations of many environmental contaminants in air and water are very low, causing problems for the analytical chemist. When a substance is found in air or water, it is sometimes difficult to determine where it entered the system. However, because we breathe the air and drink the water as well as eat the food from these environments, air and water cannot be eliminated as potential samples (6).

The most appropriate biological samples in an investigatory monitoring system should reflect key elements in the human food chain. Samples may include not only traditional agriculture products but also fish, game, shellfish, crustaceans, and wild fruits and nuts, Many of these wild foods also accumulate both point and nonpoint source environmental contaminants. Criteria for selection of

the exact organisms should include the following characteristics:

- position in the food chain,
- lifespan,
- feeding behavior,
- understanding of the organism's physiology and biochemistry,
- body fat content,
- mobility,
- availability for sampling, and
- utility to humans (6).

Once a sampling plan is developed and samples collected and analyzed, the data must be presented in a form useful to the regulator. The data analysis should be rapid and provide information on trends as well as specific concentrations without significant distortion or deletion. Even with the best-designed computer retrieval system, the necessary data bank would become extremely large, complex, and expensive.

The supply of data must also be timely. If one wishes to regulate the level of an environmental contaminant in food when concentrations vary weekly, a monitoring system that reports data with a 6-month delay is not workable.

Finally, to develop information on exposure trends and determine the effectiveness of regulatory monitoring and enforcement, human tissues, blood, and urine can be analyzed for the presence of environmental contaminants. Human monitoring can be performed for either regulated, suspected, or uncharacterized substances. A sampling plan to detect trends in exposure among different population groups could be developed, but data generated from human monitoring would be unable in most cases to identify the source of exposure. At the present time, EPA houses the principal human monitoring program. This program is primarily concerned with pesticide residues.

QUALITY ASSURANCE

To ensure that data generated by any monitoring strategy are as accurate as possible, schemes have been developed to pinpoint errors. These schemes are called quality assurance programs. Such programs are mandatory in analytical laboratories because the possibility y of errors always exist.

Errors arise from a number of sources. For instance, impure chemical reagents, dirty glassware, or sample containers can impart contaminants to the sample that may interfere with the analysis and result in false readings. Instruments are not always stable and may give false readings. Some samples may contain substances that interfere with analyses, or a substance may be bound in a sample in such a way that normal extraction met hods will not extract it. Another factor is the potential for human error in the laboratory. These factors, singly or in combination, can lead to reported concentrations that are in error. Since commodities that violate standards could be marketed and consumed if the results were erroneously low, human health might be affected. If the results are erroneously high, undue economic hardship may be imposed on the food producer.

The Federal agencies that monitor foods for environmental contaminants are aware of these problems. Thus they use standardized analytical methods that have been tested and therefore offer some assurance that the results will be acceptable in court. When a violative sample is found, the product or batch is reanalyzed whenever possible to assure that results are valid.

These two practices are part of a quality assurance program. There are others as well. When a new chemical extraction or analysis technique is tested, it is important to analyze a sample w i t h known composition t o check the validity of the technique. Also, during routine determinations samples of known composition should be analyzed to check on the other types of potential errors. The samples of known composition are called "reference material" and may come from

various sources including the National Bureau of Standards and EPA,

Available reference materials do not always satisfy the needs of current chemical monitoring programs, since such materials do not contain many known environmental contaminants. Moreover, the contaminants may not be stable under the storage method used. This is particularly true for synthetic organic chemicals. Another problem is that the type of reference material-i.e., beef liver—may not be similar enough to the food samples to be analyzed-–i.e., fish—to be very helpful.

This points up an important gap in our ability to analyze accurately for environmental contaminants in foods. The variety of reference materials and the variety of compounds of known concentration in these materials are insufficient to satisfy the needs of the analysts. More effort must be expended to correct this problem.

Collaborative studies that involve more than one laboratory or group analyzing the same sample by the same or different methods are part of a quality assurance program. If all results are similar within acceptable limits there is some assurance that the method(s) are precise and perhaps accurate,

Often, more than one method can be used to measure a given contaminant. Confidence in accuracy can be increased if the methods agree. This is one of the reasons that a monitoring laboratory should have several methods available.

All of these aspects are important to assure that the proper answers are generated by a monitoring laboratory. All are time-consuming and expensive. Therefore, any chemical monitoring program must allocate as much as 10 to 20 percent of its time for this increased workload.

CHAPTER VII REFERENCES

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