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"PCB-US Agency 100" "FDA"

In addition to instituting the new relationships between Washington and the field, Hile's group is working on possible ways to improve FDA's field operations. A pilot test in the field, slated to last from 6 to 9 months, will test different approaches to inspection, sample collection, and analysis -- with the hope that techniques can be formalized into a national approach. The tests may involve giving emphasis to certain critical areas in specific segments of industry, or to certain geographical areas.

FDA-ers hope that the pilot test will lead to conclusions about random sampling of plants and products, and about the kinds of attention needed by specific segments of industry.

Hile's staffers also will institute an 8 or 9 month field test of statistical analytical methods to determine whether FDA is successful in effecting changes in specific situations. Such an approach was recommended in a study of FDA's field operations by Booz, Allen & Hamilton, and a pilot test has been conducted.

FOOD STUDYING ECONOMIC IMPACT ON INDUSTRY

The Food and Drug Administration is creating an Industry Economics Unit to determine the economic impact of agency decisions on industry.

FDA decisions are not based upon economic considerations, FDA-ers say, but they add that industry economics should be understood by the agency. Knowledge of where the regulated industries are going economically would help FDA to do a more effective job, agency spokesmen say.

The survey is also expected to cover such subjects as the number and location of plants, and may have a bearing on FDA planning of inspections. Another benefit seen by FDA-ers from the economic study of industry would be in budget justifications.

The new Industry Economics Unit will be headed by David B. Dorsey, assistant to FDA Deputy Commissioner James Grant. Before joining FDA, Dorsey was in Allied Chemical's Office of International Finance. Working with him is William McVickers, who was formerly in the Chemical Division of the Commerce Department's Bureau of Defense Services Administration. A third economist is expected to be added to the Unit.

FDA TO SURVEY FOR PCB'S IN FOOD PRODUCTS

The Food and Drug Administration has asked its 17 District Offices to survey food commodities that have the potential for contamination by polychlorinated biphenyls, with particular emphasis on fluid milk.

FDA-ers have been expressing concern about possible environmental contamination from industrial chemicals, including PCBs (See FOOD CHEMICAL NEWS, Oct. 19, Page 3), and have been planning new programs to gather information on a number of chemicals.

The PCB directive, which is identified as an addendum to the agency's pesticide program, is a surveillance operation, which is aimed principally at obtaining information, but it does not preclude regulatory followup.

FDA issued special instructions on the number of fluid milk samples it wanted covered in the program. Other commodities, which FDA said are to be included in the Districts' regular survey coverage of pesticides on a planned basis, that will be analyzed for PCBs include manufactured dairy products, fish, animal feeds (non-medicated, particularly those with fishmeal components), shell eggs, and any others where the Districts feel there is information of potential contamination with PCBs.

FDA to Use Same Multiresidue Techniques Utilized for Organochlorines

FDA noted that the multiresidue methodology now used for organochlorine pesticides also detects PCBs, and ordered analyses conducted at the same time for the PCBs.

PCBs have been detected in foods (fish, milk, and eggs) as well as fish-eating birds and other wildlife, FDA told the field, noting, however, that the exact routes of contamination are still subject to speculation.

Earlier this year, FDA issued informal guidelines to the field on PCBs as an aid to States that had encountered problems with contamination of food products (See FOOD CHEMICAL NEWS, July 20, Page 2).

Noting that PCBs have been used as plasticizers, modifiers in paints, electrical insulators, lubricants, fire retardants, and in printing inks, textile dyes and transfer fluids, FDA speculated that some theories on the route of contamination point to industrial wastes from plants using PCBs, leaching of PCB from plastic objects in waste disposal, and accidental uses of PCBs as solvents, for which they are not intended, such as vehicles for spray preparations.

In one instance, FDA advised the field, the use of PCB in silo coatings has been correlated with the finding of residues in stored feeds and in the milk of dairy animals.

FDA noted that the PCBs are manufactured by Monsanto under the trade name Aroclor, with differing physical properties. The agency said that the firm has reported that they have discontinued sale of Aroclor for uses other than those in "closed systems" (See FOOD CHEMICAL NEWS, July 27, Page 2), a report the agency said "has not been validated by FDA."

FDA said knowledge of the toxicity of PCBs is somewhat limited, but there is evidence which indicates that the chemical may increase the toxicity of pesticides, adding that investigations of the effects of PCB on growth, mortality, and reproduction are in progress.

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FDA emphasized that the preliminary results of these studies are such that it is important to know how widespread PCB contamination may be.

FDA LAWYER TAKES TOUGH STANCE ON FOOD VIOLATIONS

Alvin L. Gottlieb, Deputy Assistant General Counsel of the Department of Health, Education and Welfare, recently attacked laxness in the food industry - - raising the spectre of criminal prosecutions at all management levels.

Specifically, Gottlieb attacked conditions in the food industry in Puerto Rico, at a Seminar for Puerto Rican Food Industries held at San Juan (See FOOD CHEMICAL NEWS, Nov. 16, Page 3). However, his remarks apparently were intended to apply to the food industry generally.

The attorney, who handles Food and Drug Administration matters, said that when a food plant violation is found, the agency is often told "we will clean it up" and "But you know how hard it is to get good people these days." Gottlieb said:

"How much thought, how much interest, how much concern is given by people in the food industry to the health and well being of the astronomical numbers of people who rely on them every day, three times a day, for sustenance, for life itself? In today's civilization, if the food industry doesn't do its job, the Nation will starve. And if it does its job poorly, the Nation may sicken because of malnutrition, or it will sicken because of disease, as a result of poor sanitation practices which cause, generate, and encourage the dissemination of harmful organisms in the food.

"There is no other single group that I can think of that has so frequent and so terribly important contact with the whole population every single day of our lives, and in a context in which we are so vulnerable . . .

". . . how much solace will we, as a Nation, derive out of the phrases, 'I told them to keep the place clean' and 'You know how hard it is to get good help today' if half the country is down with sickness due to Salmonella or other food borne contamination?"

Gottlieb urged food companies to properly motivate their personnel "to become the kind of good people whose lack we lament . . ." He added: "It must be obvious that if the workers see and feel that management doesn't really care whether or not the product is produced under sanitary conditions, certainly they won't care."

The attorney said that if a food firm is involved in a violation, "some of the management people, from the president down, may be criminally prosecuted for that violation, whether or not they knew they were violating the law, whether or not they knew about the particular violation, whether or not they were in the plant when the violation occurred, whether or not they had instructed the work force properly, and whether or not, it is difficult to get good people these days."

A firm cannot "escape responsibility for the shipment of a violative food if it contracts out any or all of the work, including the actual shipment of the product," Gottlieb added. He continued:

"For those who come under the jurisdiction of the Federal Food, Drug and Cosmetic Act, it is not enough to simply give proper instructions. It is not enough to contract out the work to another. It is not enough to want to do a good job. And it is not enough to bemoan the fact that one can't get good people anymore -- whatever that may mean. It is enough in this field only when the job is done right. Unless and until an appropriate system is set up with close supervision at every level, designed to produce and result in the production of a non-violative food, all members of management stand in danger of acquiring a criminal record and perhaps going to jail."

Management must bear the "brunt of the penalties which result from the activities of others," Gottlieb said, because "it is management who profits most, . . . it is management who is responsible for setting into motion and permitting the continued existence of many of the circumstances which lead to, and result in, violative conditions, . . . (and) who has the power to change and improve most of these conditions."

Specifically discussing the food industry in Puerto Rico, Gottlieb said, ". . . there are disagreeable things to talk about concerning the food industry of Puerto Rico," giving several examples of violations. The lawyer said that FDA's purpose "is to see to it, among others, that the food industry of Puerto Rico does its job of producing the food and feeding our people without violating the law." He commented: "I have serious questions whether it is doing that now." Gottlieb concluded that, "It is time that the food industry of Puerto Rico accepted its serious responsibilities as a full grown, vitally important industry."

FOOD SEIZURES WERE UP SLIGHTLY IN 1970

The Food and Drug Administration made 267 seizures of food products during fiscal year 1970, as compared with 232 during fiscal year 1969, according to agency figures. Total number of seizures of all types of products rose from 449 to 600.