[illegible]tion to institu[illegible]ng the new relationships between Washington and [illegible]. [illegible]le's group is working on possible ways to improve FDA's field operation[illegible]. A pilot test in the field, slated to last from 6 to 9 months, will test differen[illegible] 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.

FDA STUDYING ECONOMIC IMPACT ON INDUSTRY

[illegible]T[illegible] Food [illegible]d Drug Administration is creating an Industry Economics Unit [illegible] determi[illegible] [illegible]th[illegible] ec[illegible]ono[illegible]ic 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 for [illegible] commodities that have the potential for contamination by polychlorinated biphenyls, with particular emphasis on fluid milk.

DSW 552329

STLCOPCB4090746

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.

DSW 552330

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

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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."

DSW 552331

STLCOPCB4090748

They are merely private scientific experts whose opinions form the factual basis for the agency's decision."

Meanwhile, BVM's newly created Division of Nutritional Sciences (See FOOD CHEMICAL NEWS, Nov. 9, Page 20) has begun as its first major project an efficacy review of low-level antibiotic combinations used for growth promotion that were not studied by the NAS-NRC panels.

FDA has been following a policy of requiring that effectiveness of each ingredient in combinations be established before granting new approvals, and has applied the same criteria to fixed combinations evaluated by the NAS-NRC (See FOOD CHEMICAL NEWS, April 6, Page 8). The new review will probably result in requests to manufacturers to supply data for previously approved combinations showing that each of the antibiotics used has an additive effect. FDA has already asked for this type of information from producers of fixed combinations that have been reviewed by the NAS-NRC panels.

Antibiotics will also be the subject of letters to manufacturers advising them that FDA does not have sufficient information on their use in liquid supplements. FDA has made a wide appeal to diethylstilbestrol producers and distributors to submit data showing that DES will be stable in liquid supplements under adverse conditions along with a request for submission of analytical methods for assaying DES liquid feed supplements and other data on safety and efficacy (See FOOD CHEMICAL NEWS, Nov. 9, Page 20).

A second letter has gone to DES producers who haven't responded advising them that if the information isn't received within 60 days, FDA will have "to consider discontinuance of Form 1800's for medicated liquid feed supplements manufactured with your DES premix."

This same approach will be taken with the liquid antibiotics - - first a request for information followed by a warning that the Forms 1800 will be discontinued unless the requested safety and efficacy data are submitted.

PRD ORDERS PCB'S OUT OF PESTICIDES IN 6 MONTHS

The Department of Agriculture's Pesticides Regulation Division has ordered polychlorinated biphenyls and polychlorinated terphenyls out of pesticide formulations either as active or inactive ingredients within six months.

The Food and Drug Administration recently ordered a study by its field offices to determine the extent of PCB contamination of food products (See story, Page 5).

The PRD notice Oct. 29 pointed to the accumulating data on the chronic toxicity of the chemicals to fish and birds and the potential contamination of the environment as the reason for the phasing out of their use in economic poisons, chief of which has been as extenders to prolong the persistence of pesticides.

DSW 552332

STLCOPCB4090749

"Although the use of these chemicals in economic poisons is not considered an acute hazard to man or his environment," PRD said, "they do contribute to environmental pollution," adding:

> "Any benefits derived from their use are outweighed by the resulting environmental contamination and the possible long range adverse effects on fish and wildlife. Therefore, the presence of these chemicals in economic poisons must be phased out."

PRD said it believed that six months is a reasonable period of time within which formula changes could be made, and requested copies of the revised statement of composition of new formulas plus new labeling for the affected products.

PRD also corrected an earlier notice in which it said it "erroneously listed" piperonyl butoxide in a group of compounds requiring teratogenic studies (See FOOD CHEMICAL NEWS, April 27, Page 6). This compound is one that requires further carcinogenic data, PRD said, "in order to properly evaluate its safety in view of current information."

In the earlier announcement, PRD listed a number of pesticides requiring teratogenic or carcinogenic testing to continue current registrations.

Meanwhile, Chairman Randolph (D-W. Va.) of the Senate Public Works Committee announced last week that his Committee would begin hearings Dec. 1 on the nomination of William D. Ruckelshaus, former Assistant Attorney General, as Administrator of the Environmental Protection Agency (See FOOD CHEMICAL NEWS, Nov. 9, Page 37).

Randolph disclosed that his Committee had jurisdiction after conferences with Chairman Magnuson (D-Wash.) of the Commerce Committee and Chairman Jackson (D-Wash.) of the Interior Committee. Randolph invited the chairmen and the ranking minority members of those two committees plus the leaders from the Agriculture and Labor and Public Welfare Committees to sit in on the Ruckelshaus nomination hearings.

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SENATE UNIT MOVES CPA TOWARD ENACTMENT

The Democratic leadership in Congress is hoping to move legislation to establish a new independent Consumer Protection Agency through both chambers by the first week of December.

The Senate Commerce Committee Nov. 19 ordered Sen. Ribicoff's (D-Conn.) bill (S 4459) to the floor with minor modifications, which appear acceptable to the Government Operations Committee where the proposal originated (See FOOD CHEMICAL NEWS, Oct. 5, Page 16).

DSW 552333

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DSW 552334

STLCOPCB4090751

"Although the use of these chemicals in economic poisons is not considered an acute hazard to man or his environment," PRD said, "they do contribute to environmental pollution," adding:

> "Any benefits derived from their use are outweighed by the resulting environmental contamination and the possible long range adverse effects on fish and wildlife. Therefore, the presence of these chemicals in economic poisons must be phased out."

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DSW 552335

STLCOPCB4090752