FOOD CHEMICAL NEWS

Editors: Louis Rothschild, Jr.; Raymond Galant
Subscription Manager: Natalie Pargas

October 19, 1970

HALOGENATED CYCLIC COMPOUNDS GETTING NEW LOOK FROM FDA

Expressing concern about possible environmental contamination from industrial chemicals, Dr. Henry Fischbach, Director of the Food and Drug Administration's Office of Pesticides and Product Safety in the Bureau of Foods, has indicated his agency may give special attention to halogenated compounds.

[redacted] uses of such compounds [redacted] food additives [redacted] Fischbach indicated in an article in the September issue of FDA Papers, the agency's official magazine.

After discussing the problem of [redacted] the FDA-er said these "are only one of the many industrial organic chemicals undoubtedly present in our environment in such quantity or under such conditions as to cause residues in food and in man itself." Calling for the gathering of "sound scientific information" on these materials, Fischbach said:

> "Among the industrial organic chemicals requiring scrutiny, perhaps the halogenated compounds, such as those containing chlorine, should be studied first. For example, the chlorinated naphthalenes and chlorinated paraffins are widely used in much the same way as PCBs.
>
> "An FDA food additive regulation (§121.2572) permits the use of chlorinated paraffins as cross-linking agents in resins used in coating packaging materials for dry foods. Many other chlorinated industrial chemicals are widely used. Chlorothiophenes, chlorinated pyridines, and chlorinated phthalate and phosphate esters are only a few. The Federal Register of April 15, 1970, carried an FDA notice that a Food Additive Petition . . . has been filed by Dow Chemical Company for 2,3,5,6-tetrachloro-4-(methylsulfonyl)pyridine as a preservative for food-packaging adhesives. There is an existing food additive regulation (§121.2520) permitting use of tri-8-chloroethyl phosphate in adhesives used in food packaging."

In addition to the food additive uses of the compounds, Fischbach noted that hexachloropentadiene is used in compounds that impart fire-retardant features, and that chlorendic anhydride in resin-based laminates is used to suppress combustion. The FDA-er said these compounds "are related to such pesticides as dieldrin and endrin and should be evaluated from the standpoint of a future hazard in the environment . . ."

MONS 082885

Fischbach noted that, "A host of chemicals are used as plasticizers, a use which seems a very likely source for residues eventually becoming part of the food supply." He added that they can be released into the environment through incineration. The FDA-er also expressed concern about chemicals used in rubber processing.

Calling for information on the volume of use, chemical stability, and toxicity of industrial chemicals related to pesticides, Fischbach said:

> "The initial efforts might be directed at the halogenated cyclic chemicals since we have methodology based on years of work detecting pesticide residues containing such compounds. From this information a knowledgeable selection might be made of the chemicals most likely to cause hazardous residues in food, feed, or in man himself."

Chemical and physical properties should be evaluated, techniques developed for measuring residues, and surveys should be made to determine the extent of their presence in the environment, Fischbach said. If one of these industrial chemicals is found in food or feed," he wrote, "pharmacological studies at low levels would be essential to determine the potential hazard."

Fischbach urged "the industrial and scientific community" to "consider the development and adoption of a mechanism for pretesting new industrial chemicals prior to their introduction into the environment." He said that, "Stable chemicals that may be used in significant tonnage should be scrutinized by an appropriate panel for their net 'benefit' to society when the proposed new chemicals are presented to the U.S. Patent Office." Fischbach said "such an evaluation at this point in time should fit into the framework of our economic system with a minimum of disruption."

He wrote that "limited information is available" about the PCBs, but that "essentially nothing is known about possible residues of . . . many nonpesticidal industrial chemicals in man's food supply and in man himself." Fischbach particularly noted the dearth of toxicological data, especially regarding low levels ingested over long periods.

Meanwhile, there was controversy in Washington over a move by the Internal Revenue Service to suspend tax exemptions to public interest law firms which go to court on environmental issues and other public interest matters. The exemptions are suspended for 60 days while IRS considers a final decision. The Council on Environmental Quality has strongly recommended that the tax exemptions be continued, and Council Chairman Russell E. Train recently wrote IRS that: "Litigation brought by private groups which must rely on contributions for their support . . . (has) strengthened and accelerated the process of enforcement of anti-pollution laws." Late last week, IRS modified its stand slightly, but the Senate Labor subcommittee announced hearings on the directive for next month. In an editorial opposing the IRS action, the Washington Post speculated: "With public interest lawyers all too eager to use the law to protect both the environment

MONS 082886

and the consumer, the thought occurs - - though these things are hard to prove - - that business interests may have sent an SOS to the Nixon Administration saying, in effect, get the kids off our backs." The newspaper said some Senators "are talking about hearings on the whole subject," and concluded that: "They are needed - - fast."

Meanwhile, the Interior Department's Bureau of Sport Fisheries and Wildlife said its study of the effects of mercury on the Great Lakes aquatic environment includes the topics of "distribution and cycling in the water, toxicity to fish, and uptake and loss in fish."

EDWARDS SAYS FDA WILL REVIEW APPROVED PRODUCTS FOR SAFETY

"One of the Food and Drug Administration's commitments for the 1970's is to create a single standard of safety and effectiveness for both new and established products," Food and Drugs Commissioner Edwards last week told the 84th annual meeting of the Association of Official Analytical Chemists in Washington.

He said there has not been in the past "a systematic program to review the safety and efficacy of products once they have been considered and passed upon," and the Commissioner outlined some of the steps that will be taken in review of food products along with drugs, beginning with the agency's review of the "generally recognized as safe" list of food additives (See FOOD CHEMICAL NEWS, Oct. 12, Page 3). He remarked:

> "Given adequate funding and personnel and related sources, and this cannot be overemphasized, we can establish a continuing review cycle of all such products, utilizing advances in our nation's scientific capacity as they become available. We will thus provide the consumer with the kind of protection that is consistent with our scientific capability in the 1970's. It is only through such scientific services that we will be in a position to withstand the pressures from our critics - - consumer and Congressional."

FDA has reportedly been given the go-ahead to establish a new National Center for Safety Testing of Environmental Chemicals based on recommendations of the so-called "megamouse" report, which envisions, among other programs, a massive feeding experiment to help establish a threshold level for carcinogens (See FOOD CHEMICAL NEWS, Aug. 17, Page 3).

The Department of Health, Education and Welfare is reportedly seeking a supplemental appropriation to finance the new Center, whose costs would run from a recommended $4.8 million for the first year up to $52 million by the sixth year. Site of the new Center apparently will be the Pine Bluff (Ark.) Arsenal.

In his AOAC speech, Edwards acknowledged that funds for FDA's traditional, activities, such as plant inspection, sample testing and analysis in the food area, have increased less than 1%, but at the same time, he said, manufacturers' shipments of foods have increased some 15 times and consumer expenditures for food are 43 times greater in 1970 than they were in 1961.

He concluded that FDA's resources have not kept pace with the agency's responsibilities, and he made a renewed pitch for wider Congressional support of applied research, which Edwards said has lagged far behind the billions spent on basic research.

Edwards forecast additional organizational changes in FDA, noting that these must come frequently enough "to reflect the changing responsibilities and emphasis of a particular organization."

Bureau of Foods Reorganization Due Out Shortly

Slated for reorganization shortly is Dr. Virgil O. Wodicka's Bureau of Foods, whose new organizational structure has received Edwards' blessings and has been passed forward to HEW Secretary Richardson (See FOOD CHEMICAL NEWS, Sept. 14, Page 2). The new changes were made necessary by the loss of the Bureau's pesticides programs to the Environmental Protection Agency (See FOOD CHEMICAL NEWS, Oct. 5, Page 3), the establishment of a new Bureau of Product Safety, soon-to-be announced by Edwards, and mistakes of the hurried-up reorganization ordered by Edwards on the advice of aides of the former Secretary Finch when the new Commissioner took over.

Edwards complimented the work of the AOAC, reassuring the meeting that "we are well aware that the FDA would at least have to double its staff if we could not depend on the work done by members of this organization from industry, the States, universities, and other Government agencies, in creating and supervising the analytical methods which are the basis for so much of our work."

Chick Edema Factor Is Attributed to Chlorophenol Use

Several hundred papers were presented at the meeting, including new findings on the chick edema factor which is attributed to chlorophenol use. He reported that a number of toxic fats or so-called fleshing greases from the treated hides had been determined to be highly toxic and related to the chick edema factor.

He predicted that the chick edema factor could be eliminated by more severe rendering, and the discontinuance of chlorophenol compounds and glue emulsifiers. In response to a question, Metcalfe suggested that the contamination could also be found in vegetable fats, and he attributed this to the widespread use of chlorophenols.

MONS 082888

Related papers presented by [redacted] reported on the agency's testing of a variety of commercial chlorophenols, and his findings of chloro-dioxins, -furans, and -ethers in animal tissues, and FDA's examinations for toxicity by chicken embryo assay (See story, Page 3).

The concern over the chlorodioxin contaminants in pesticides was recently manifested in a notice to manufacturers by the Department of Agriculture's Pesticides Regulation Division warning that their presence "constitutes a possible hazard to man because these chlorodioxins (such as 2,3,7,8-tetrachlorodibenzo-para-dioxin) have been found to be extremely toxic to laboratory animals." PRD warned that appropriate regulatory action will be taken if the chlorodioxins are found in any economic poisons (See FOOD CHEMICAL NEWS, Oct. 5, Page 10).

Refinements on a variety of [redacted] were also presented at AOAC, reflecting the current concern over residues of this metal entering the food supply (See FOOD CHEMICAL NEWS, Oct. 5, Page 12).

A series of new methods for filth determination were presented, including analyses for reconditioned (coarsely ground) nutmeg, ground chicory, wheat- and oat-based ready-to-eat breakfast cereals, water-insoluble candies, and crude and refined papain.

Other methods for fruit juices, breaded fish products, nutmeats, and maple sirups were presented to help identify contaminants and/or cheapening ingredients.

Further refinements in pesticides and mycotoxin analyses were presented for AOAC approval, along with a new method for determining cyclamates in solid foods and a test for measuring the availability of iron.

Dr. D. G. Chapman, Director of the Food Advisory Bureau of Canada's Food and Drug Directorate, gave the AOAC an update on the liaison arrangements being worked out by AOAC with other international groups. Chapman, who chaired a special symposium on development of methods by international organizations, also disclosed that the AOAC together with the International Union of Pure and Applied Chemistry, the Chemical Institute of Canada, the Agriculture Institute of Canada, and the National Research Council of Canada, is sponsoring an International Symposium on Identification and Measurement of Environmental Pollutants in Canada in June of 1971.

o

CYCLAMATE BATTLE CONTINUED IN ABBOTT, FDA LETTERS

Although the battle of cyclamates seems to be over, the pros and cons were rehashed in letters included in the recent publication of last June's hearings by Rep. Fountain's (D-N.C.) House Intergovernmental Operations subcommittee (See FOOD CHEMICAL NEWS, Oct. 12, Page 15).

MONS 082889