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REPORT ON ALLEGED DIOXINS AND DIBENZOFURANS IN PCB'S

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The Food Chemical News, page 9 and page 30, October 18, 1971 issue states:

> "FDA's Mildred Porter described work with a method that separated three chlorodioxins, including the highly toxic 2,3,7-Trichlorodibenzo-p-dioxin, from polychlorinated biphenyls detected in fish and wildlife."
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> ... and further ... "The issue of a possible tolerance for PCB is made more complex, the lab said, by the heterogeneity of these materials, some containing polychlorinated dibenzofurans and other highly toxic components."

With statements like the above plus the University of Utrech's work on PCB's, we can foresee continued Government and University lab work and press emotionalism on this subject.

John Mason and I feel we should summarize our total work and knowledge on this subject, so we can report our information to the FDA or Dr. Burger's group. Would you and Bob Keller, therefore, prepare this report as quickly as possible? If we need more information please state that also and particularly if we need to do more test work or methodology test development work.

W. S. BERGEN

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DOW's 2,4,5-T dispute over the procedures of cancellation is being handled personally by EPA Administrator Ruckelshaus with top-level company officials, who have been guaranteed "their day in court" (See FOOD CHEMICAL NEWS, Oct. 4, Page 2). Dow seems less than satisfied.

[redacted] following assurances from a study carried out by the State (See FOOD CHEMICAL NEWS, Sept. 6, Page 21). USDA's three-part inspection is continuing in Alabama, Delaware, Georgia, Kentucky, Mississippi, North and South Carolina, Tennessee, and Virginia.

GRAS survey cooperation by industry was urged by FDA in a news release last week. The agency noted that NAS survey questionnaires on the use of substances have been circulated since July 15 (See FOOD CHEMICAL NEWS, Oct. 11, Page 19). FDA said it is anxious to reach small users and those who are not affiliated with trade associations. Commissioner Edwards noted that answering the questionnaire is "purely voluntary," but said users should have an opportunity to participate in the survey which will help FDA to reach decisions about toxicity data needed. FDA directed those wishing to obtain questionnaires to contact Durwood Dodgen, NAS/NRC, 2101 Constitution Ave., N.W., Washington, D.C. 20037.

PEANUT BUTTER SPREAD is the new name kicking around FDA for the temporary permit requested by CPC to market a nonstandard product with nonfat dried milk and 75% peanuts (See FOOD CHEMICAL NEWS, Sept. 6, Page 20). USDA on Oct. 14 proposed a revision of its grade standards for peanut butter to gibe with FDA's standard, requiring 90% peanuts.

TALC, contaminated by asbestos, used on rice in Japan as a dust to preserve flavor may be a carcinogen or co-carcinogen responsible for the high incidence of Japanese stomach cancer, according to a report in Science, which FDA is looking into.

SUCROSE study, sponsored in part by the International Sugar Research Foundation, showed no significant differences in serum cholesterol or triglyceride concentrations between swine consuming cholesterol-containing diets in which approximately 60% of the calories were derived from either sucrose or cornstarch, according to ISRF.

PHS will not be abolished, despite recommendations of an HEW study group, Secretary Richardson told the American Public Health Association convention in Minneapolis last week (See FOOD CHEMICAL NEWS, June 28, Page 2).

JOHN E COUNTRYMAN, retired chairman of the board of Del Monte, has been named interim executive vice president of the National Canners Association, succeeding Milan D. Smith (See FOOD CHEMICAL NEWS Oct. 11, Page 2).

PESTICIDES genetic effects are discussed in the "Mutagenicity of Pesticides: Concepts and Evaluations," written by FDA's Dr. Marvin Legator and Dr. Samuel S. Epstein, of Case Western Reserve School of Medicine.

POULTRY inspection in Puerto Rico is to be taken over by federal inspectors, USDA announced, but New Jersey's program has been certified as "equal to" the Department's. CMS' meat inspection regulation on sexual odor as a cause of adulteration of swine carcasses (See FOOD CHEMICAL NEWS, Aug. 23, Page 27) effective date on Oct. 13 was postponed to Dec. 13.

In his final decision on the case, Judge Mitchell said that, ". . . Expert microbiologists for both parties hereto have found the coffee beans in question to be within the allowable tolerance," concluding that "said coffee beans have been brought into compliance with the law under the decree of condemnation heretofore entered."

The Judge entered a judgment "releasing the bags of coffee to claimant, Leon Israel & Bros., Inc., for introduction into interstate commerce."

From FDA's standpoint, of course, Judge Mitchell's decision this year was more of a defeat than his 1969 decision, in which the coffee beans would have had to have been exported.

Basing his decision on the 10% guideline level, Judge Mitchell said, "In considering whether an article is adulterated. . . , the Court may accept the applicable allowable tolerances permitted by the Secretary of Health, Education, and Welfare." He said - - as the Circuit Court had - - that, "When the Government seeks to condemn, as adulterated, products seized. . . , the claimant of the product is entitled to be informed what standard of allowable tolerance is applied to determine whether the product is adulterated."

The Judge stated his interpretation of §402(a)(3) that it "does not mean then unless an article is completely free of any filthy, putrid, or decomposed substance, it is necessarily subject to seizure and condemnation," adding: "On the contrary, the article which is within the allowable tolerances for such article is not in violation of subsection 3."

AOAC SETS UP TASK FORCE TO MEET RITTS CRITICISMS

FCN 29

The Association of Official Analytical Chemists has appointed a task force to develop a new plan of support to meet criticisms of the Ritts Committee which had urged that the AOAC be moved outside of the Food and Drug Administration to avoid the appearance of a conflict of interest (See FOOD CHEMICAL NEWS, May 31, Page 28).

AOAC President Henry A. Davis, Chemist in Charge of New Hampshire's Analytical Services Laboratory, disclosed that the task force had been charged with the "responsibility of developing a plan of support for the AOAC that would be mutually beneficial and operate within the scientific, legal and administrative requirements of all concerned."

Davis acknowledged that AOAC has had FDA's strong support and active participation in its activities, notably because of the need of the agency for the AOAC's development and validation of methods of analysis.

Recounting the recommendations of the FDA Ad Hoc Science Advisory Committee, chaired by Dr. Roy Ritts of the Mayo Foundation, Davis noted that the report suggested that the AOAC would be in a better position if it were entirely self-funding and operating independently of any one group of governmental agencies.

He continued:

> "Further it states that this does not imply that support should not be given by these agencies, rather perhaps such support should be on a grant or some direct allocation basis."

Davis said that the AOAC task force was directed to report in six months on the steps the organization should take to make it more self-supporting.

A variety of new methods were reported at the annual meeting Oct. 11-14 in the more than 200 papers heard in Washington.

In a session on mycotoxins, a new screening method for aflatoxin in shelled corn, corn meal, canned sweet corn, and corn breakfast cereal, with a sensitivity to 5 p.p.b., was unveiled by FDA scientists. Another rapid screen for peanuts and peanut products was modified for use on corn and soybeans with a sensitivity of 10 p.p.b.

FDA

A report from the Department of Agriculture's Northern Region Research Laboratory at Peoria, Ill., indicated that suspect corn samples can be located rapidly by a greenish gold fluorescence, allowing for segregating dockage or damaged corn from uncontaminated supplies.

In the report, USDA's R.D. Stubblefield noted that no sample of whole, undamaged corn was contaminated, but damaged kernels with the characteristic fluorescence contained from 285 to 101,400 p.p.b. aflatoxin B_1, and particles from foreign material with the same kind of fluorescence contained from 245 to 54,800 p.p.b B_1.

Improvements in the screening methods for aflatoxin in cottonseed and cotton seed meal were reported from USDA's Southern Region Research Laboratory in New Orleans, with sensitivities of from 10 to 20 p.p.b. reported.

Confirmatory tests for aflatoxin M_2, M_1, B_1, and G_1 were also reported in various stages of development.

Method for Aflatoxin in Milk Is Studied

USDA's Stubblefield, in a referee's report, highlighted work being done under the auspices of the International Union of Pure and Applied Chemistry and AOAC, which is aimed at establishing a method for determining M_1 in milk. He reported that aflatoxin M_1 has been found in the urine of Philippines children who consume locally manufactured peanut butter, which had an average aflatoxin B_1 content of 500 p.p.b.

Analysis of specimens obtained from seven volunteer families, he said, revealed that in the 14 subjects studied, 15 p.p.b. B1 a day was the minimum dosage required to detect M_1 in the urine. Of 35 samples collected from subjects who consumed more than the minimum dosage, Stubblefield continued, 30 were positive for M_1.

In another part of the same paper, he reported that from a survey of commercially available milk samples in the United States, none was found to contain M_1. He said the reporting official concluded that this underscored the feeling that there should be no cause for concern about milk being aflatoxin-contaminated, and, at worst, there may be an isolated case from animals being fed contaminated feed.

FDA's Leonard Stoloff, who chaired the session on mycotoxins, disagreed, saying there is still cause for concern because the method is inadequately sensitive, and because of the fact that young infants rely entirely on milk as the sole source of their food supply.

A new method, recommended for collaborative study, detects aflatoxin B_1 down to 1 p.p.b. in products containing up to 10% alcohol.

Othe mycotoxin papers dealt with methodology for ochratoxins in cereal products and barley.

FDA Scientists Report on Mercury Levels in 10 Foods

In a session on metals, FDA's Dr. James Tanner reported on determination for mercury made by neutron activation in a survey of flour, sugar, nonfat dry milk, potatoes, ground meat, chicken breasts, shrimp, beef liver, eggs, and whole milk.

He reported that all recoveries fell below the WHO-recommended limit of 50 p.p.b., with shrimp containing the highest average at 17 p.p.b., and the highest reading of 43 p.p.b.

Other mercury highs detected by Tanner's group were in potatoes at an average of 4 p.p.b., with a high reading of 15 p.p.b.; in sugar at an average of 3 p.p.b., and a high level of 10 p.p.b.; and in milk at an average of 2 p.p.b., and a high recording of 9 p.p.b.

A variety of papers on mercury determinations were presented, including methods for detecting the metal in fish and flour, and from theblood and central nervous system of beagle dogs.

A study of 36 samples of five species of fish - - swordfish, tuna, northern pike white bass, and perch - - indicated that essentially all mercury present was found in the methyl mercury form.

A new method for lead in fish, at a sensitivity of 1 to 11 p.p.m., was recommended for adoption.

FDA's Mildred Porter described work with a method that separated three chlorodioxins, including the highly toxic 2,3,7-trichlorodibenzo-p-dioxin, from polychlorinated biphenyls detected in fish and wildlife.

Low levels of chlortetracycline from broiler tissues and organs were detected in a method reported by the Rutgers University Department of Animal Sciences. The

FDA has been quietly investigating a similar problem with anchovies imported from Spain by Uddo & Taoramino, Jersey City, N.J., which distributed the product under the Progresso Foods Corp. label.

Army Quartermaster Corps officials reported the problem to FDA after swollen cans were detected by some commissaries. The Army's Natick, Mass., laboratories confirmed finding botulinum spores, but there apparently was no evidence of toxin formation because of the use of salt as a preservative.

Progresso reportedly withdrew the product from the market, but under FDA s new recall policy no official announcement was made. Product withdrawals are undertaken by the firms voluntarily when there is no demonstrable evidence of a legal violation. These are no longer called recalls, and they do not appear on FDA's weekly recall list (See FOOD CHEMICAL NEWS, June 21, Page 20; and Aug. 2, Page 2).

The Progresso brand anchovies were imported by March & Co., New York City, from Hoya Anchovies in Spain. FDA is checking to determine whether the same Spanish firm is the packer of the S&W product.

More Swordfish, Oats Seized Because of Mercury

Meanwhile, FDA made another seizure of swordfish because of mercury, (See FOOD CHEMICAL NEWS, Oct. 11, Page 15). The agency seized swordfish fillets, shipped by Slade Gorton Co., Boston, Mass., to Millbrook Terminals, Inc., Somerville, Mass.

Two seizures were made of bulk oats because of the presence of mercurial compounds. Oats were seized in possession of West Freight Yards, Davenport, Iowa. The other seizure involved oats shipped by Farmers Elevator Co., Alice, N.D., to Benson Quinn Co., Stapler, Minn.

On grounds the product did not have an effective New Animal Drug Application, FDA seized Rachelle Super Chlorachel 250-Swine Medicated Feed Premix, shipped by Rachelle Laboratories, Inc., Long Beach, Calif., to Heinhold Elevator Co., Kouts, Ind.

The agency recently made another seizure of shell eggs because of the presence of polychlorinated biphenyls (See FOOD CHEMICAL NEWS, Sept. 20, Page 34). The eggs had been shipped by Chestnut Farms, Inc., Chestnut Mountain, Ga., to Blessing Brothers, Inc., Bastian, Va.

Seizures made recently of Bon Vivant soups (See FOOD CHEMICALS NEWS, Sept. 27, Page 24) shipped by Bon Vivant Soups, Inc., Newark, N.J., were made in possession of:

Sole Sales Co., Orlando, Fla.; (2) Specialty Food Distributors, Tampa, Fla.; Fancy Foods of the Carolinas, Charlotte, N.C.; (4) G. Giovino Co., Everett, Mass.; (5) [illegible] Distributing Co., E. Longmeadow, Mass.; (6) Big Tea Party Store, Ann Arbor, (7) Kramer Food Co., Hazel Park, Mich.; (8) Specialty Foods Co., Inc., Detroit,

A recent comment filed with FDA on the CTFA proposal came from Rep. Mink (D-Hawaii), who called for "mandatory" registration of manufacturers and listing of ingredients. Urging label declarations, Mrs. Mink noted she has introduced a bill (HR 6551) "to require the labeling of mercury in any instances where it is a cosmetic ingredient."

In his testimony, Nader - - in addition to hitting the Business Council - - urged some sort of regulation of National Academy of Sciences advisory committees. He said that NAS does not seem to consider itself as falling within Executive Orders on advisory committees or under the Freedom of Information Act.

Nader said that when he asked for the minutes of an NAS advisory committee, he was referred to a private law firm in Washington. A Nader associate who accompanied him at the hearing commented that he tried unsuccessfully to obtain minutes of a meeting of the Food Protection Committee.

Urging Congress to "act decisively" by enacting legislation to regulate advisory committees, rather than depending upon administrative reform, Nader said that advisory committees constitute "an unconstitutionally authorized fourth branch of government," representing an "erosion" of the status of Congress. He said that advisory committees are dominated by special interests and are "formalizing the lobbying process."

P.C.B - NEXT PAGE

NO SACCHARIN ILL EFFECTS AFTER 95 WEEKS, LAB NOTES

Saccharin feeding studies in monkeys have shown no adverse effects in 95 weeks, it was disclosed in Washington as Albany Medical College sought additional funding for a National Center for Environmental Quality.

The Center would be located at previous Air Force research facilities at Holloman Air Force Base, New Mexico, where non-military research was halted in mid-1970 by the Mansfield amendment to military appropriations.

Largely, through the efforts of Sen. Anderson (D-N.M.), the facility, which was about to close down, found a new sponsor, Albany Medical College, and received a $500,000 primate research grant from the National Institutes of Health. It has the largest breeding colony for primates in the U.S., the Senator's office said.

A range of other studies on 2,4,5-T, mercury, lindane, polychlorinated biphenyls and other compounds was disclosed in a document setting forth current and planned research at the Holloman AFB facility. The lab is seeking funds from the National Science Foundation and the Environmental Protection Agency.

The saccharin feeding studies are being conducted under grants of $16,000 from the Canadian Food and Drug Directorate and $134,166 from the Food and Drug Administration (See FOOD CHEMICAL NEWS, March 29, Page 5).

Doses used in the study are 500 mg./kg., which compares to the 15 mg./kg. of body weight per day set as a safe level in FDA's interim Food Additive Order proposed last summer (See FOOD CHEMICAL NEWS, June 28, Page 9).

Albany elaborated further on the studies:

> "In the course of our metabolic studies on saccharin we have evolved greatly improved methods of separating the small, often minute, amounts of metabolites from the large bulk of unchanged saccharin excreted in urine. The species of animals already studied comprise the rat, rabbit, dog and monkey. Present plans envisage also the use of the hamster and guinea pig for the same purpose."

For the future, officials of the lab said they wish to explore the potential of the chimpanzee "as a model for the metabolism and effects, if any, of saccharin in other species and man."

Also, the lab seeks to conduct a combined teratogenicity, mutagenicity and carcinogenicity study of saccharin in the rhesus monkey. "If proved feasible and practicable," the background document said, "the procedure could be usefully applied to other compounds."

Another artificial sweetener study would be an investigation of "the phenomenon of bladder carcinogenesis by calcium cyclamate.".

[redacted]

The lab seeks to clarify the question as to whether observed carcinogenesis "is a true instance of chemical carcinogenesis or a secondary consequence of the operation of physical effects elicited by primary changes induced by cyclamate." Abbott Labs defended the safety of cyclamate during recent hearings and had noted the presence of worms in the bladders of some mice developing cancer (See FOOD CHEMICAL NEWS, Oct. 11, Page 19).

Incorporating primate facilities into environmental quality research involves, the backgrounder said, an intensive study of the characteristics of the primate species under study, and "use of the primate for its special qualities." It was noted:

> ". . . The chimpanzee is an animal of great importance for studies on environmental toxicants. Its potential in this direction is largely unexplored, yet it is the most readily available of the higher primates for this purpose."

The laboratory would be developed, it was noted, "as a research center available to all qualified investigators who have a justifiable need to use the facilities."

Other current studies at the Holloman facility include - -

Methylmercury - - Under a $36,174 contract from the State of New York, the lab is investigating effects on reproductive performance, on the fetus in utero, teratogenicity and postnatal development of offspring. It is also seeking to define threshold levels of intake of methylmercury for the effects observed.

For the future, the lab said, studies are needed involving prolonged administration of low levels of methylmercury to the mother before mating.

2,4,5-T and its esters - - Under a grant of $49,330 from C.H. Boehringer Sohn, Ingelheim (with additional funds sought from a U.S. source), the lab is studying reproductive effects of 2,4,5-T. Anticipated national benefits of the research were described as giving possible answers to the questions:

"1. Does 2,4,5-T pose a real threat to man under present conditions of use? 2. If the inadequacy of available data on which action was taken to ban 2,4,5-T led to the imposition of mistaken restrictions, how can similar errors be avoided in the future? If on the other hand, the action was justified, on what proportion of the complete toxicological picture was it based, and can this basis be considered adequate in similar circumstances in the future?"

Fluorocarbons - - Under a $236,446 grant from the National Aeronautics and Space Administration, the lab is evaluating the safety of fire extinguishers and retardants, with implications, the lab said, for fluorocarbon propellants "that are in widespread use in a wide variety of household products, toiletries, cosmetics and even foods." The study will utilize a "Closed Environmental System Chamber" for inhalation studies over long periods of time.

Lindane and dichlorvos - - The lab seeks funding for studies of combinations of oral and inhaled pesticides, stating:

"Far too little attention has been paid in the past to the effects of prolonged exposure to pesticides by inhalation as well as by ingestion. It would be valuable to carry out studies in the primate combining the two routes of exposure on a long-term basis. Two candidate compounds that come immediately to mind are dichlorvos ('Vapona') and lindane."

[redacted] - "Detailed study of the storage, mobilization and translocation of [redacted] in the animal," the lab said, "should be correlated with analysis of adverse effects exercised by these materials."

The issue of a possible tolerance for PCB is made more complex, the lab said, "by the heterogeneity of these materials, some containing polychlorinated dibenzofurans and other highly toxic components."

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FDA'S EDRO COORDINATES THE AGENCY FIELD ACTIVITIES

(Because of the importance of the Food and Drug Administration's Executive Director of Regional Operations and his organization, this article describes in summary fashion the makeup and functions of EDRO.)

The immediate Office of the Director, which is headed by J. Paul Hile, directs and coordinates the EDRO Office, and gives direction and counsel to the Regional and Deputy Regional Food and Drug Directors, evaluating the management of field operations.

Hile's Office determines monetary allowances for the Regions, based on overall budget allotments and FDA policy decisions, evaluating field office financial and management resources data. It also coordinates and evaluates the field's manpower utilization and training programs. In addition, the Office of the Director provides guidance and direction for the field offices' general administrative management support activities.

Deputy Executive Director is Ronald T. Ottes.

EDRO's Executive Office - - as distinguished from the Office of the Director - - advises the Regional Directors on management, and provides administrative and clerical services to the Director's Office. The Executive Office helps plan and administer budgets for the field, and administers and coordinates personnel activities in the field. Roy E. Keeney is EDRO's Executive Officer.

A general services program for field personnel and related staff in Washington is carried out by the Executive Office, which also determines the distribution of manpower resources among the field offices. This group reviews all manuals and forms developed for use in the field, handles training programs and conferences for the field, and coordinates employee suggestion and equal employment opportunity programs.

EDRO Divisions: Field Operations; Planning & Analysis; Federal-State

Recently brought in from a Regional Director post to head EDRO's Division of Field Operations was Charles A. Armstrong. His Division provides for day-to-day coordination of the total field investigative, consultant, inspectional, scientific, and compliance efforts, as well as directing foreign inspection programs.