

UCB - Article

The Agriculture Department was applying redoubled inspection and detaining procedures to turkeys, broilers and other animals last week in [REDACTED] after a new incident of feed contamination (See FOOD CHEMICAL NEWS, Sept. 13, Page 36). Specific cause of the contamination was still a mystery over the weekend after [REDACTED] some rendering plants was causing it. [REDACTED] both USDA and FDA investigations. PCBs exceeding guidelines were found in several thousand turkeys.

NUTRITIONAL labeling tests by food chains (See FOOD CHEMICAL NEWS, Sept. 13, Page 13) will be studied by Cornell University under a contract from FDA. The University will be asked to determine which of the three alternative methods of labeling is best and to attempt to measure consumer benefits. The store tests are expected to be completed by April 1972, and FDA hopes to have a preliminary decision by summer.

INFANT FOOD code dating has been replaced by open dating based on a 15 to 18 month time period for liquid and up to 21 months for liquid concentrates. The move by the Infant Formula Council was disclosed by the Consumer Federation of America, which has been pushing for open dating on infant formulas (See FOOD CHEMICAL NEWS, June 14, Page 2). CFA last week urged retailers to enforce stock inventories and ban placement of stickers, markings, or labels over expiration dates. The Federation said manufacturers "have adopted a policy of full credit replacement on outdated goods." CFA said it is pushing FTC to institute controls on retailers to prevent sales of outdated formula, and that a plea for freshness standards for formulas to FDA "remains unresolved . . ."

CARCINOGENICITY quick test was promised by deoxyribonucleic work of Dr. Paul Ts'o and colleagues at Johns Hopkins University in Baltimore. Results were reported during the American Chemical Society meeting in Washington, Sept. 12-17.

ANIMAL DRUG Certification Program, which is six months old (See FOOD CHEMICAL NEWS, March 1, Page 2; and March 29, Page 2), will be checked for effectiveness by a statistical analysis conducted by Doane Agricultural Service under contract from the Animal Health Institute. The survey will involve meat packers, farmer-feeders, and feed-lot operators. The poultry part of the program has been deferred. AHI, which hopes results will be in by Jan. 1, expects the survey to give leads for program improvement.

ANTI-TOOTH DECAY substance has been produced from sugar, according to the International Sugar Research Foundation, which said the Colonial Sugar Refining Co., Ltd. of Australia has won approval of the substance, Anticay, for use as a food additive in that nation and has filed a petition in the United Kingdom and given the U.S. Food and Drug Administration a master file on its research. The Foundation said the substance also is an excellent dietary source of calcium and phosphorus.

PINE BLUFF toxicological laboratory scientific conference, originally scheduled by FDA for this Fall, is now expected to be held shortly after the first of 1971. The contract with the University of Arkansas to arrange the meeting has been amended to make the deadline March 1.

FD&C RED 2 use data collection will be discussed by FDA-ers and association representatives at a meeting called by the agency for Wednesday (Sept. 22) at 1 p.m. at FDA's Washington headquarters building at 200 C St., S.W. (See story, Page 36).

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levels found in mice, a woman would have to eat 45,000 lbs. of food a day for 10 days. He concluded:

"To require absolute safety is not realistic and would be a disastrous course of action."

Another speaker on the same symposium program, Dr. Fred Knight of the University of Michigan, said that the perfect pesticide could not be developed and said he felt DDT should not be banned, but should be used under controlled conditions. He suggested a need for four areas of clarification in public debate over pesticides issues - -

- - Eradication of a particular insect is a "poor" attitude, except in rare instances.
- - Insecticides should not be used simply as a way to make the environment "more comfortable."
- - Pesticides should be used only when needed, not "by the calendar."
- - "Preservation" of wild areas should not be a goal for the use of pesticides or other control measures. Fires and insect outbreaks are natural phenomena in wilderness areas, and both should be allowed to run their course.

~~Dr. William L. Darby of Vanderbilt University, who is co-chairman of EPA's Hazardous Substances Advisory Committee (the committee) appeared on the symposium program to give a status report on implementation of the original Mrak Committee report (See FOOD CHEMICAL NEWS, January 12, 1970, Page 19).~~

He told of the successful implementation of recommendations for interagency coordination and coordination within the Department of Health, Education and Welfare. Darby also noted that the Mrak Committee's recommendation concerning DDT and DDE

- - that only uses essential to human health and welfare be retained - - "was possible achievement without excessive economic disruption."

~~He said that this judgment has been confirmed by the discovery that "much of the evidence so far as the result of DDT was, in fact, the effects of polychlorinated biphenyls."~~

Before the Mrak report as a whole was issued, he noted, the Secretary of Agriculture issued action to cancel all DDT registrations. Darby characterized this as "indiscriminate application of zero tolerance limits."

Referring to the Bionetics study which indicated carcinogenicity for 2,4,5-T and pointing up the contamination of early formulations of the herbicide with dioxins, Darby said: "It is not in the interest of the public to take action based upon anxiety."

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He called for a modification of the Delaney clause, saying that if the clause were rigorously enforced, it would require removal of most foods from the market. DDT would be a factor in this action, he said, as would naturally occurring substances.

Rep. Kyros (D-Me.), who was questioning Nader at the time of this statement, indicated disagreement with Nader, asking whether he felt that FDA laid off Campbell because of its size.

In response, Nader said he didn't think FDA would have moved as boldly against a company with 80 to 90% of the soup market if the situation had been reversed.

Nader asked the subcommittee for help in persuading USDA to summarize and produce a readable analysis of the enormous bulk of material it had made public on detention notices (See FOOD CHEMICAL NEWS, Sept. 13, Page 27). Tracing the battle of the Center for the Study of Responsive Law to make these records public, Nader reported that USDA agreed finally, and dumped the records in huge piles without any explanatory materials.

He offered the help of his Center to the subcommittee in going through the records to make some sense out of the enormous body of raw material.

Peter H. Schuck, who accompanied Nader, suggested the problem encountered by Campbell may be associated with a change in incubation procedures the company instituted in January of this year, which reduced the number of samples collected. He said USDA altered its requirements in July along lines of the changes introduced by Campbell.

He said the reduced incubation sampling may have been insufficient to protect the food supply.

EDWARDS DISCLOSES SEVERITY OF PCB PROBLEM TO NADER

The problem of polychlorinated biphenyl contamination is far greater than that associated with the industrial accidents which led to PCB levels in some poultry and eggs, Ralph Nader told Chairman Rogers' (D-Fla.) Public Health and Environment subcommittee hearings last week.

Nader said the severity of the problem was disclosed in a letter from Food and Drugs Commissioner Edwards, who told the consumer crusader "we must have a coordinated program to deal not only with industrial accidents, but also the broader problem arising from environmental contaminations."

Edwards did not specifically allude to the contamination of foods from packaging containing PCBs, but he was apparently referring to this area of concern, which prompted a meeting with industry last week (See FOOD CHEMICAL NEWS, Sept. 13, Page 22).

Food Industry Monitoring Products for PCBs

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Major firms in the food industry are testing their packaging materials and food products for PCBs, and the test results will be funneled through a Grocery Manufacturers

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of America committee to FDA's Bureau of Foods. It was indicated at a meeting of FDA and GMA representatives last week that PCB testing by firms has been going on for some time.

At the meeting, it was noted that food manufacturers cannot blindly accept the word from suppliers that paper packaging materials do not contain PCBs, since the suppliers might not be aware of the source of all the paper or the possible PCB content.

It was conceded that methodology needs improvement. GMA members said they do not always get the same results as FDA does, and FDA is making its methods available to industry. However, the agency will serve as a clearinghouse for obtaining better methodology.

A revision of the PCB method was sent to the field last week for use in the survey of 15 food categories. The survey is scheduled for completion by Nov. 1.

No decisions have been made by FDA on an approach to food packaging materials with PCBs, and there are differences of opinion within the agency.

Some FDA-ers believe it will be possible to set specifications for "food grade paper," and the American Paper Institute is believed investigating this approach. Presumably this could be done under the Food Additive Regulations. It has been suggested that "food grade paper" contains less than 15 p.p.b. of PCBs.

There has been much discussion about whether a p.p.b. level can or should be set for PCBs. There is no "administrative guideline" now for PCBs in packaging material. If a regulation set specifications for "food grade paper," the quantitative limit would then become a "tolerance," rather than a "guideline." Many FDA-ers think there should be no tolerance for PCBs in packaging materials.

At the present time there is in effect a "zero tolerance" for PCBs in recycled paper. The Food Additive Order for pulp from reclaimed fiber (§121.2546) clears salvage from used paper and paperboard but excludes "that which bears or contains, or has been used for shipping or handling, any poisonous or deleterious substance which may reasonably be expected to be retained in the recovered pulp."

This means that any food packaging from reclaimed pulp found to contain PCBs is illegal and subject to seizure. However, no plans for widespread seizure are in the works and none are expected at this time.

FDA Discusses Possibility of "Liner" for Food Packages

Another alternative approach discussed would be a requirement that a "liner" or "barrier" be used between food products and paper and paperboard packaging materials. This suggestion, of course, raised immediate problems of the time needed for such a change and of increased costs.

An FDA decision on an approach to take may await the final report of the inter-agency task force, of which the White House Office of Science and Technology and the Council on Environmental Quality are key members. The task force

has held an initial meeting to prepare an agenda and to split the data gathering tasks among the agencies involved.

The transcript of a recent seminar held by FDA on the PCB problem is being prepared, and this will also be considered. Another document under study is a report on PCB toxicity received by FDA recently from the Swedish Environmental Protection Board.

The PCB problem has raised questions about the thin-shelled bird eggs, traditionally linked by ecologists to DDT residues. There is now speculation that the thin-shell effect may have been caused instead by PCBs, or possibly by mercury contamination.

Ultimately the PCB problem could throw into question the politically popular program for recycling paper, one of the few concrete accomplishments of the current drive for environmental cleanup. It appears that recycling could be concentrating PCB content, and questions may be asked about how many times pulp is being recycled.

FDA-ers have also attempted to evaluate the toxicological effects of PCBs. The no-effect level in test mammals estimated by FDA is 10 p.p.m. Based on this animal data, with an allowance for a 1,500 gm. human dietary intake, the acceptable daily intake (ADI) would permit a 100-fold margin of safety if set at 150 micrograms PCBs per day.

Human data, based on Japanese experience, using a 10-fold safety margin, would permit an ADI at 300 micrograms per day, calculated on an estimated minimal positive effect level of 3 mg. per day.

FDA-ers believe that 1.1 mg/day of PCB in the dietary intake can be tolerated for the next six month period as a temporary measure, if new regulatory approaches can bring the contamination under better control.

In his appearance before Rogers, Nader voiced concern over the cumulative effects from PCBs, suggesting that because there is no acute toxicity problem, this is no reason for FDA to downplay the significance of such hazards.

Nader's earlier criticism on the handling of eggs contaminated with PCBs prompted the new reply from Edwards (See FOOD CHEMICAL NEWS, Sept. 6, Page 21).

He told Nader that FDA does not routinely notify consignees that consigned lots are suspect and have been sampled unless there is a possible hazard to health and/or a very evident likelihood of a significant violation of the law.

"Neither was true in the case of the lots of eggs destined for Metropolitan Poultry and Egg Company," Edwards continued. "In our experience, if we reveal why we are sampling products, some consignees will routinely distribute those products as rapidly as possible in order to avoid legal action." He added:

"Other consignees will hold lots until we do give them a report of our findings. Your belief that advising consignees will always solve the problem is not true. On a perishable product, the

government is open to a tort claim if the product becomes unfit for food while being held, and the government later finds the product is non-violative. The FDA employee may also be subject to a civil action."

Noting that FDA does not have the same continuous inspection authority or resources similar to the Department of Agriculture's, Edwards said it was not true, as Nader suggested, "What USDA has done, FDA can certainly do."

Edwards Says There Was No Reason to Track Down Eggs

"In our best judgment there was not sufficient reason to allocate the resources to track down the 60,000 contaminated eggs that had already been distributed to retail markets, since in the opinion of our key scientists there was no immediate hazard to consumers from ingestion of these containing the amounts of PCBs found in our samples," Edwards said, adding: "Our resources do not permit the extensive sampling of the sort that you suggest."

The Commissioner also defended the roles played by John T. Walden, Director of Public Information, and his Deputy Donald Berreth, who, Edwards said, did not distort the "danger or in any way abuse their authority." Edwards said neither were compelled to be quoted, since as spokesmen for the agency they do not make policy, but simply convey information to the public.

"This agency cannot and will not act on the basis of emotionalism," he told Nader, asserting that "we will not declare national health alerts when in the best opinion of science no such alert is justified." The Commissioner concluded:

"We reject scare headlines in favor of good science . . .
FDA welcomes public criticism. We cannot be fully responsive to the American consumer without it. At the same time, we expect our critics to exercise the same degree of reason and objectivity that they demand of us. In the case of PCBs, I do not think that this test has been met by you and your associates."

SCHUCK OUTLINES PROGRAM TO IMPROVE FOOD INSPECTION SERVICES

Peter H. Schuck, of Ralph Nader's Center for the Study of Responsive Law, last week outlined an eight point program to correct the institutional and legal defects which he said have led to the failures of the Food and Drug Administration and Department of Agriculture to adequately protect the food supply.

Schuck's list was presented in testimony before Chairman Rogers (D-Fla.) of the House Public Health and Environment subcommittee at hearings on food inspection (See FOOD CHEMICAL NEWS, Sept. 13, Page 36).