FOOD CHEMICAL NEWS

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There seems to be some confusion about which products would remain under EPA control. Animal pesticides that do not clearly fit the definition of drug are still EPA's regulatory responsibility. There is also a difference of interpretation over which of the agencies has regulatory responsibility for so-called "old drugs."

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KREY PACKING FOUND IN COMPLIANCE BY MPI COMPLIANCE STAFF

A special review of Krey Packing, also known as Kelly Foods, by the Compliance Staff of the Agriculture Department's Meat and Poultry Inspection Program, released last week, found that the firm has corrected most of the deficiencies noted in an earlier report (See FOOD CHEMICAL NEWS, Nov. 17, Page 35).

In fact, the report concluded: "This plant, with minor exceptions has excellent formulation and thermal processing procedures," which "for the most par'...exceeded the requirements of the Federal MPI Regulations and Procedures."

"From the overall appearance, the formulation, cooking, transporting, retorting, chilling, incubation and storage procedures were in accordance with the written procedures described and recommended by the NCA (National Canners Association)," the special review report stated.

The review of the plant by MPI's Compliance Staff was undertaken as a result of an earlier report by Dr. J. C. Prucha criticizing several of the firm's procedures. The report said that "the deficiencies noted...had been corrected with recommended charts, procedures and controls being implemented."

A few of the deficiencies noted were not corrected, it stated. These included the fact that no changes were made in the single bar spreader, and globe valves on vent lines were not changed to gate valves. It was noted that MPI does not have requirements or specifications for either of these.

The review report listed the deficiencies which were corrected, including documentation of product preparation procedures; recording of initial temperatures and safeguards against temperature variations; written out and uniform venting procedures; strict adherence to thermal processing procedures recommended by NCA; orderly maintenance of can storage facilities; and installation of an air-vacuum type can cleaning device (which, however, was not equipped with a malfunction alarm system, as recommended).

It found that Kelly Foods had adequate product formulation cooking, transporting, filling and closing procedures; and had established incubation procedures and provisions for recalls.

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PCB'S ATTACKED ON THREE FRONTS

The efforts to reduce polychlorinated biphenyl levels reached a near-fever pitch last week with: (1) the filing of a petition with the Food and Drug Administration to reduce

all tolerances for PCBs in foods; (2) establishment of a Canadian guideline for PCBs in fish; and (3) introduction in Congress of a bill to ban all use of PCBs in the United States.

The petition filed with FDA by the Environmental Defense Fund and the Natural Resources Defense Council (See FOOD CHEMICAL NEWS, Nov. 24, Page 2) would provide for a step-wise lowering of tolerances - - starting with fish - - until there are only zero tolerances for PCBs in foods.

The two groups charged that FDA's current temporary tolerances "are completely inadequate to protect human health and welfare." They said favorable action on the joint petition "would significantly reduce human dietary exposure to PCBs."

Noting the reported carcinogenicity of PCBs, the groups said they are seeking "the establishment of a zero tolerance for. . .residues in food, to be achieved by means of a phased reduction to zero of appropriately set temporary tolerances." Conceding that a zero tolerance could not be established now "without condemning the nation's food supplies," EDF and NRDC said "that existing temporary tolerances can and should be substantially lowered immediately, to commence with a significant downward revision in the tolerances for fish."

The hazard from PCBs "is, of course, increased if one considers the possibility of additive or synergistic toxicity with other fat soluble chemicals found in the same foods," the petitioners said.

Avoiding specific tolerance level proposals, the two groups urged that FDA use "the Mantel-Bryan or a comparable formula establishing risk probabilities for a carcinogen," with periodic downward revisions of the tolerances.

The new, lower temporary tolerances, EDF and NRDC said, should be preceded in the regulations with the statement:

> "In keeping with the explicit legislative intent of §409 (the Food Additive Amendment) of the Food, Drug and Cosmetic Act. . .to prohibit carcinogenic food additives, and acting under the authority of §406. . .authorizing the establishment of tolerances for poisonous and deleterious substances in food, it is the express intention of the FDA progressively to reduce to zero tolerances permitted for PCB residues in food, downward revisions to occur as soon as is possible given the persistence of existing levels of PCBs in the environment."

The Canadian government announced that it had adopted a temporary enforcement guideline for PCBs in fish of 2 p.p.m., as expected (See FOOD CHEMICAL NEWS, Nov. 10, Page 39). In announcing the guideline, which is the first PCB limit established for fish in Canada, the Health Protection Branch of the Department of National Health and Welfare said that the decision was based on newly available toxicological data. It said the decision was made after consultation with Canada's Fisheries Inspection Branch. The U. S. tolerance is 5 p.p.m.

At the recent National Conference on PCBs held in Chicago (See FOOD CHEMICAL NEWS, Nov. 24, Page 31), Canadian toxicologist Dr. D. L. Grant said that surveys of PCB residues in human adipose tissue conducted in Canada suggested that females have lower residues than males. He also noted that residents of Central Canada (Manitoba and Saskatchewan) have lower levels than the rest of Canada and said that the majority of Canadians have an adipose tissue residue of 1-2 mg/kg. Grant noted that PCB residue in human milk of Ontario residents was found to be approximately 1 mg/kg fat.

The bill introduced in the House (HR 10815) by Rep. Aspin (D-Wis.) called specifically for the prohibition of introduction or delivery for introduction into commerce of the chemical compounds known as PCBs and was referred to the Committee on Interstate and Foreign Commerce. Aspin has been adding new sponsors to his proposal, and has introduced a number of identical bills to ban PCBs.

National Fisheries Institute Calls for Six Step Control for PCBs

At a special night session of the PCB conference in Chicago, Lee J. Weddig of the National Fisheries Institute, called for the following six steps to control the potential damage to the environment from continued use of PCBs:

(1) A nationwide system for safe disposal of PCBs already in use; (2) passage of the Toxic Substances Control Act to avoid future problems with other chemicals; (3) retention of the FDA tolerance level for PCBs in fish at the present 5 p.p.m., pending further investigation; (4) compensation to commercial fishermen whose livelihood is destroyed by prohibition of the sale of species of fish in which the level of PCBs exceeds the FDA tolerance; (5) Congressional investigation of the Environmental Protection Agency to determine why EPA has not yet established effluent standards for PCB discharge despite a clear legal mandate to do so and (6) an immediate ban on further sale, production, importation, or recycling of PCBs.

Thomas J. Billy, Chief of the Fishery Products Inspection and Safety Division of the National Marine Fisheries Service, asked for a more conservative approach, saying:

> "We believe responsible regulatory action has been taken already to deal with the public health issue and we fully support the current 5 p.p.m. temporary tolerances for PCBs in fishery products. However, our concern is that certain information presented at this conference and other pressures could result in precipitous further regulatory actions that are not based upon the full and complete information necessary to justify actions."

Billy said that no change in the present tolerance in fish should be contemplated until full consideration has been given to:

(a) New, conclusive toxicological information; (b) the role of the specific species in the diet; (c) probable further decreases in PCB levels over an extended period of time; (d) direct economic impact on the fishing industry as well as the overall economic impact, and (e) alternative government and industry approaches for assuring consumer protection.

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The Commerce Department official concluded:

> "There is a lack of recognition by some that an industry depends upon the natural resources we are discussing and we have imposed a serious problem on them that is not of their making. The seafood industry is concerned about the safety of their products and have been and continue to be willing to take responsible actions to protect public health.
>
> "However, NMFS is concerned that the lessons from the past in over-regulating or implementing unnecessary regulatory actions will not be heeded."

HEW Scientist Cites PCB Health Dangers; Independent Scientists Disagree

The most serious charges leveled against PCBs as a danger to human health during the meeting came from Center for Disease Control scientist Dr. Renate Kimbrough, who documented studies indicating that long term exposure to PCBs in rodents produces "a tumorigenic response which consists of the development of atypical areas, neoplastic nodules and hepatocellular carcinoma." She said that based on these and other findings in experimental animals, ingestion of PCBs in humans must be curtailed.

FDA's Associate Director for Sciences in the Bureau of Foods, Dr. Albert C. Kolbye, Jr., had cited Kimbrough's data on carcinogenicity in animals in testimony presented in New York during hearings on the General Electric Company's alleged violation of the Environmental Conservation Law of the State of New York.

Another speaker at the PCB conference, Dr. J. C. Calandra, Industrial Bio-Test Laboratories, noted that in a rat study conducted at his lab no evidence of hepatocellular carcinogenicity of the PCB-containing products tested was found. Calandra said that one of the scientists who evaluated the slides had re-evaluated the Kimbrough slides and did not agree with the reported findings.

Dr. James R. Allen, of the University of Wisconsin, reported that female rhesus monkeys exposed to dietary levels of 2.5 to 5.0 p.p.m. of PCB developed irregularities of the menstrual cycles within 4 months. Allen said that after 6 months exposure, the animals were mated with control males. The University of Wisconsin pathologist summarized the results as follows:

Six of the eight females on the 5.0 p.p.m. PCB diet conceived; the remaining two animals continued to cycle and were mated five times without conceiving. Five of the six animals that conceived aborted or experienced early fetal resorption. Eight out of eight females on the 2.5 p.p.m. diet conceived. However, 3 of the 8 females did not carry their fetuses to term.

The six infants born to the PCB-fed females were small (350 vs 475 g) and displayed areas of cutaneous hyperpigmentation. Skin biopsies obtained shortly after birth contained PCBs. As a result of exposure to PCBs through lactating mothers, the PCB levels of the infants' tissues increased rapidly. Within 2 months the infants developed conjunctivitis, periorbital

edema, loss of eyelashes and acne. Three infants expired within 4 months following birth. The surviving 3 animals were weaned and showed decreased severity of symptoms after 4 months on a milk supplement diet free of PCBs.

Allen noted that in contrast to the severe effects of low PCB exposure experienced by female rhesus monkeys, male monkeys tolerated 5.0 p.p.m. PCBs as a dietary additive for one year without showing signs of severe intoxication. He pointed out that these males showed no reproductive abnormalities.

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RECALLS: MORE IMPORTED PIMIENTOS

The Food and Drug Administration last week disclosed two more Class II "priority" recalls of pimientos imported from Spain because of failure to control acidity in the canning process (See story, Page 22).

Osage Brand Whole Pimientos were recalled by Cherokee Products Company, Haddock, Ga., from Alabama, Arkansas, Texas, Florida, Georgia, Pennsylvania, Missouri, Tennessee, Louisiana, New Hampshire, Massachusetts, Michigan, Minnesota, Wisconsin, Kansas, North Carolina, South Carolina, West Virginia, Virginia, California and Nevada. The institutional size cans were packed by Jose Maris Garcia Gomariz, Murcia, Spain.

Cherokee also recalled La Molinera Brand Choice Whole Sweet Red Pimientos from Michigan and North Carolina. The manufacturer was Hernandez Perez Hnos. S.R.C. Molina de Segura, Murcia, Spain.

A criminal case was instituted by FDA against Hallam & Son, Inc., Springfield, Mo., on grounds stored foods were held under insanitary conditions and were rodent and/or insect contaminated.

Meanwhile, Barton's Candy Corp. reassured its stockholders at a meeting after the firm and its president, George Klein, pleaded guilty to a one-count charge involving insect-contaminated flour. The firm announced that the bag of flour, delivered early last year, was found to be unfit for use, and "it wasn't used in the production of any of Barton's products."

FDA recently seized: (1) frozen salmon, in possession of Traco, Inc., Seattle, Wash., on grounds of decomposition; and (2) frozen pancakes, shipped by Juno Chefs, Inc., Brooklyn, N. Y., on grounds they were held under insanitary conditions and were insect and rodent contaminated.

Regulatory Letters Hit Product Labeling

An FDA regulatory letter sent Nov. 11 to Edible Soy Products, Inc., Hudson, Iowa, said the product name Pro-Nuts was false and misleading "for a soybean product since it represents and suggests that the product is a nut product."