

Recalling his earlier testimony, Hutt said he would not disqualify himself on general procedural issues with wide applicability that arise in the context of "a specific substantive question on which I am disqualified."

ac
ex

Referring to the lists he promised Moss, which will cover the period Sept. 1, 1971, through March 1, 1972, Hutt explained that some of the cases may not yet have been filed and some of the proposals not yet published in the Federal Register.

"Premature public disclosure could prejudice the cases (by allowing the company to move the goods or to persuade the U.S. Attorney not to file a criminal action) but should have no appreciable impact on the Federal Register notices," the General Counsel wrote, saying he would attempt to indicate those cases for which there had not yet been confirmation of filing, and will request that they not be publicly disclosed at this time.

"I am in full agreement," Hutt concluded his letter, "that the FDA should be open to close scrutiny by the Congress, the public, and the related industries, and will be happy to cooperate in every way possible to achieve this objective."

PCB MILK GUIDELINE CUT IN HALF; STATEMENT DUE THIS WEEK

The Food and Drug Administration's policy statement on polychlorinated biphenyls, expected to issue this week, cuts in half the current residue guidelines on milk (from 5 to 2.5 p.p.m. on a fat basis) and sets an 0.1 p.p.m. limit in infant and junior foods.

Other guidelines set for one year in the upcoming statement are:

Dairy products -- 2.5 p.p.m. (fat basis); Poultry -- 5.00 p.p.m. (fat basis); Eggs -- 0.5 p.p.m.; Finished animal feed -- 0.5 p.p.m.; Animal feed components -- 5.0 p.p.m.; Fish -- 5.0 p.p.m. (edible portion), and Food packaging materials -- 5.0 p.p.m.

The statement in effect bans equipment using PCBs from all areas of food or feed plants, by calling for the following "special provisions" in these and in plants where food packaging material is manufactured:

(1) PCB-containing coatings or paints are not to be used in storage areas;

(2) New equipment is not to contain PCB fluids;

MCNS 067395

(3) Within 30 days of issuance of the statement, processors must -- (i) Sample the fluid in existing heat exchange equipment to determine whether or not it contains PCBs and, if so, replace it with heat exchange fluid that does not contain "PCB or other harmful or deleterious substance;" (ii) eliminate PCB from food or feed contact surfaces; (iii) eliminate any other source where PCB might contaminate food, feed or packaging by

March 13, 1972

accident, breakage or other mishap, and (iv) eliminate use of any packaging materials exceeding the 5 p.p.m. guideline.

FDA also disclosed the results of both a special nationwide study and a Total Diet study on PCBs (See FOOD CHEMICAL NEWS, Feb. 21, Page 7).

On the latter, FDA said of 900 food composites, 54 were found to contain PCB residues. The average PCB level found in market baskets was less than 0.0001 mg./kg. of body weight per day. FDA noted that this is a high consumption diet.

The results of the national survey, FDA noted, showed that even though 67% of the complete food packaging tested contained PCBs at levels as high as 338 p.p.m., only 19% of the foods in these packages contained PCBs.

The average concentration in food was 0.1 p.p.m. and the maximum PCB level found was 5 p.p.m.

Some 75% of the food in packaged infant cereals contained PCBs. The average concentration was 0.3 p.p.m., with a maximum of 1 p.p.m.

Stating that progress had been made recently in getting PCBs out of packaging, FDA noted that in the most recent study, 95% of recycled paper samples contained less than 5 p.p.m., but that during 1970-71, only 18% contained less than 5 p.p.m.

Meanwhile, both FDA and the Agriculture Department were continuing - - without success - - in an effort to find the cause of the latest large PCB incident in Maine (See FOOD CHEMICAL NEWS, March 6, Page 2). A lead pointing to fish meal contamination apparently has fizzled.

Latest count on the number of chickens destroyed, or about to be, because of the contamination was 1,086,908.

In another development, USDA has issued to its inspectors a set of instructions to examine heat exchange units in meat and poultry inspection establishments.

Without mentioning PCBs by name, USDA said inspectors should be alert to:

1. Use of (heat) exchange media that may have toxic components.
2. Evidence of contamination of product by color, odor, taste.
3. Evidence of leaks, such as need to replenish supply of heat exchange medium; and
4. Pinholes, hairline cracks, or other defects that could permit leakage into the product.

USDA noted that heat exchanges are used to heat and chill products, giving as examples: "Votators, Dowtherm units for deodorizers, certain types of deep fat fryers, and some giblet chillers."

FDA recently began intensified testing of fish meal for PCBs. Instructions issued to the field from the Bureau of Veterinary Medicine that five successive boatloads of fish meal entering each port are to be tested for PCBs, as well as five lots from each domestic producer of fish meal.

OCTYLtin STABILIZERS OK-ED FOR VINYL CHLORIDE-ETHYLENE COPOLYMERS

The Food Additive Order for octyltin stabilizers was amended March 9 to clear use of the stabilizers in polyvinyl chloride and vinyl chloride copolymers complying with §121.2609 for vinyl chloride-ethylene copolymers.

§121.2602 previously cleared the stabilizers - - di-(n-octyl)tin S,S'-bis(iso-octylmercaptoacetate) and di(n-octyl)tin maleate - - for use in polyvinyl chloride and vinyl chloride copolymers complying with §121.2521 for vinyl chloride-propylene copolymers. The broadened clearance was requested in a Petition filed by American Can's M&T Chemicals (See FOOD CHEMICAL NEWS, April 5, Page 30), which was amended Oct. 27.

The stabilizers are cleared for use in articles intended for contact with nonacid aqueous foods, aqueous acid products, aqueous acid or nonacid products containing free fat or oil, low-moisture fats and oils, beverages except for malt beverages and carbonated nonalcoholic beverages, moist bakery products, dry solids, and dairy products and modifications except liquid milk.

FDA PROPOSES WITHDRAWAL OF NADA'S FOR LIQUID DES

The Food and Drug Administration proposed March 11 to revoke all New Animal Drug Applications for diethylstilbestrol liquid premixes for use in cattle and sheep feed in 30 days unless a case can be made for a hearing.

The action against the liquid DES premixes was proposed because of the problem of cross-contamination with other liquid feeds, which has led to nearly two dozen seizures since FDA began an intensive investigation of the problem (See FOOD CHEMICAL NEWS, Feb. 21, Page 28). Products of 14 manufacturers have been detected with unpermitted DES residues in liquid feeds.

DES residues detected in liquid feeds have ranged from 2 p.p.b. to 5 p.p.m.

In the Federal Register notice withdrawing the NADAs, FDA named the following companies that hold liquid DES clearances: Rhodia's Hess and Clark, Merck Sharp & Dohme, Dawes Laboratories, Elanco Products, Bresley-Koelling, Inc., Dale Alley Co., and Feed Additives, Inc.

FDA said the evaluation of new information concerning contamination leads to the conclusion that the drugs are not shown to be safe under conditions of use "upon the basis of which applications were approved."