(1) sanitizers applied to inanimate surfaces and/or in drinking water of animals that do not include any direct or implied claims to control disease.

(2) Primary animal drug usage, FDA having primary jurisdiction, except in those cases in which the drug use is regarded as a not new animal drug - - (a) control of horse bots; (b) oral or parenteral control of cattle grubs; (c) control of demodectic mange mites; (d) oral or parenteral control of fleas or other external parasites; (e) control of ear mites; (f) control of ticks if labeling includes claims for ear mites; (g) aquatic treatments for parasites and/or diseases of fish; and (h) animal drinking water treatments if claims are made for control of animal parasites or diseases.

Jurisdiction by both agencies was indicated for a number of uses, virtually all of which were previously covered by FDA jurisdiction. These were:

(a) Products for oral administration, including liquid feeds and feed supplements, except not articles solely for the control of fecal breeding flies nor solely for sanitizing the drinking water of animals; (b) products administered parenterally; (c) products which are absorbed through the skin surface as in demodectic mange conditions; (d) products introduced into wound or body openings, except for screwworm control, including application to the ear canal, and (e) topical application for systemic action in an animal.

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FOOD PACKAGING CONTROLS CHALLENGED IN PCB CASE

A motion for declaratory judgment in a case involving polychlorinated biphenyls could pose a challenge for all Food and Drug Administration regulation of food packaging materials.

The declaratory judgment motion was one of three legal moves in a case brought against the stayed temporary tolerance of 10 p.p.m. for PCBs in food-packaging paper and paperboard (See FOOD CHEMICAL NEWS, April 27, Page 26).

Natick Paperboard Corporation, Natick, Mass., and Crown Paperboard Company, Inc., Philadelphia, Pa., also asked a temporary restraining order and an injunction. After a quick hearing in U.S. District Court for Massachusetts, the request for a temporary restraining order was rejected. The injunction and declaratory judgment matters are still pending.

FDA stayed the PCB temporary tolerance for paper and paperboard and indicated it would consider granting a public hearing, but at the same time said that paper and paperboard with more than 10 p.p.m. PCBs would be seized.

Natick and Crown, represented by former Massachusetts Governor Endicott Peabody, asked for the TRO and the injunction against seizure of paper food-packaging materials. FDA defeated the TRO plea and has filed a motion to dismiss the injunction request. The agency has argued that the U.S. Supreme Court has ruled that seizure actions cannot be enjoined - - partly because seizures are simply recommended by FDA to the Justice Department.

Of long-range significance is the request for declaratory judgment, in which the two firms argued that food-packaging materials are not subject to regulation. If Crown and Natick should win the declaratory judgment, it might place in jeopardy all of FDA's Subpart F Food Additive Orders for indirect additives.

FDA is expected to argue that PCBs are "food additives" so far as paper and paperboard are concerned - - at least as long as the temporary tolerance is stayed. Thus, food packaging materials could be seized as containing unauthorized food additives if FDA finds more than 10 p.p.m. of PCBs.

Once the temporary tolerance is in effect, however, PCBs in paper become unavoidable poisonous and deleterious substances under §406 of FDA's law. Under FDA's §402 adulteration section, a substance for which a §406 tolerance is in effect cannot be a "food additive."

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FDA TO WORK WITH INDUSTRY ON FOOD ADDITIVE CREDIBILITY PROBLEM

Food and Drug Administration Associate Commissioner for Science Dr. Lloyd B. Tepper has pledged his agency to work with the food industry "toward a common goal wherein the attributes of food chemicals are accurately appraised and fairly presented to the consumer."

In a speech Aug. 29 before the Grocery Manufacturers of America, Tepper predicted that: "The posture of the food industry over the next several years with respect to the utilization of food additives, the credibility of advertising, the adequacy of safety testing, and the level of rapport with consumers and health professionals will surely be reflected in actions on the floor of Congress, and in regulations of Federal agencies."

The FDA-er declined to "predict what will come of suggestions that all foods be required to be 'nutritious' such as drugs are now required to be 'effective.'"

In discussing food advertising, Tepper hit food industry ads which have an anti-additive connotation, as follows:

> "It has become fashionable and evidently commercially useful, even outside the 'natural' or 'organic' food industry, to capitalize upon public doubts with respect to additives in the merchandising of certain foods. Cereals are advertised as having a 'natural taste' not available in processed cereals. Frankfurters are proclaimed to have 'no dried milk - - no cereal - - no soy concentrate.' Reference is made to 'natural protein' as if there were some other kind. There is even natural beer. One must question the long-term utility of propagating and reinforcing an attitude which may ultimately have to change."

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