Agency Spells Out Suspension Criteria

It was noted that formal cancellation proceedings can be launched after a review of the suspension and that "there should be no obstacle to review of final suspension orders" in a Court of Appeals.

On the same day, EPA ordered suspension of a number of "bait" products (See FOOD CHEMICAL NEWS, March 13, Page 2), spelling out in greater detail than previously its criteria for suspensions.

The expectation that future harm might result from use of a product was one of the most important of these. Such recognition had been urged for new legislation by Harrison Wellford during the recent hearing on pesticide legislation (See FOOD CHEMICAL NEWS, March 13, Page 9). Restating its previous definition of "imminent hazard to the public," EPA also said:

> "The word 'public' is not to be viewed restrictively, and includes fish and wildlife . . . Nor does 'imminent' mean that we are on the 'brink' and that the harm will occur tomorrow or has been documented. It is sufficient that reasonable men can conclude that action taken today will with reasonable certainty lead to a loss in the future and that loss will be irremediable and uncorrectable by subsequent action, and that the benefits from using a chemical, pending the complete statutory review process, are outweighed by the possible harm of use during the period."

Suspended were registrations for cyanide, strychnine, sodium monoacetate (1080) and thallium, the latter because of alleged "bootlegging" from rodenticide uses.

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PCB "GUIDELINES" PROPOSED AS "TEMPORARY TOLERANCES"

The Food and Drug Administration on March 18 proposed upper limits for polychlorinated biphenyls in milk, dairy products, poultry, eggs, feed, feed components, fish, and food packaging materials, as expected (See FOOD CHEMICAL NEWS, March 13, Page 36), but changed the levels from "administrative guidelines" to "temporary tolerances."

This change in strategy would give the upper limits stronger legal standing in court cases, if the "temporary tolerances" withstand challenge. FDA has usually had the burden of establishing that substances present at levels above "guidelines" pose a hazard; a "tolerance" usually has the force of law.

It would not be surprising if there were comments on this point during the 60 days the agency allowed for comments.

In proposing tha temporary tolerance of 5 p.p.m. for PCBs in paper and food-packaging materials, FDA said it would permit "unavoidable PCB residues in these products for a sufficient period of time to provide an opportunity for the orderly elimination of PCB containing raw materials used in the manufacture of food packaging materials."

Noting that the Food Additive Orders for components of paper and paperboard (§121.2526 and §121.2571) do not provide for use of PCBs, FDA said the temporary tolerance "is not to provide for direct uses under the above regulations." It added, "Immediate elimination of all food packaging containing PCBs would disrupt the nation's food packaging and distribution system and is not warranted by the hazard to human health."

FDA Proposes New Section of Regulations for Contamination

The temporary tolerances for PCBs in food, feed, and paper were included in a proposed hew Part 122 of FDA's regulations, covering "Unavoidable Natural, Environmental, or Industrial Contaminants in Food and Food-Packaging Materials." This proposed new section of the regulations would seem to anticipate pending fish inspection legislation which would direct the agency to set limits on hazardous environmental or other contaminants in all foods (See FOOD CHEMICAL NEWS, Dec. 6, Page 43). Other pending legislation, however, would give authority to the Environmental Protection Agency for toxic substances.

§122.1 of the proposed new section would explain that its coverage includes "any poisonous or deleterious substance added to any food where such substance cannot be avoided by good manufacturing practice."

The temporary tolerances were listed under §122.10, and FDA said the tolerances would be in effect "for a sufficient period of time to permit elimination of such residues at the earliest practicable time."

Advance reports of the FDA proposal on PCBs have already brought protests to the agency from the paper industry.. In the Federal Register last week, FDA said there has been "continuing and substantial reduction" of PCB concentrations in paper packaging materials. The Agency said:

> "This problem is being intensively studied by FDA and the paper and food industries.. The studies show that paper for food-packaging materials, where manufactured from recycled paper or virgin stock, may contain PCBs. The source of PCBs in recycled paper is attributed to the use of certain kinds of copying paper and printing ink. While the source of PCBs in virgin stock is not as well defined, it is generally attributed to the presence of PCBs in the equipment, machinery, and water used for manufacturing these materials and to environmental contamination."

As expected, FDA proposed amending the Food Additive Order (§121.2546) for pulp from reclaimed fiber. In the clearances for industrial waste from the manufacture of paper and paperboard and for salvage from used paper and paperboard, FDA proposed excluding "that which bears or contains any poisonous or deleterious substance which is retained in the recovered pulp and that migrates to the food." The clearance for salvage had already banned use of paper and paperboard which may have been used for shipping or handling any poisonous or deleterious substance which may be retained in the pulp.

Discussing the problem of PCBs in animal and poultry feeds, FDA said:

> "The survey results available to date show that less than 5% of the animal feeds sampled contain PCBs. Levels range from no detectable contamination to a maximum PCB level of 0.6 p.p.m. It appears that complete animal feeds are not a significant source of PCBs for food-producing animals and that PCB contamination of feeds for food-producing animals can generally be attributed to avoidable industrial accidents and practices."

As expected, FDA issued a §3 proposal governing processing of feed to preclude direct or accidental PCB contamination of food or packaging materials. Similar rules were proposed for food plants under a new §128.4 in the new part of the regulations dealing with contaminants. The proposed rules deal with paints, equipment, utensils, heat exchange units, food or feed contact surfaces, and use of packaging materials containing more than 5 p.p.m. PCBs.

The temporary tolerances proposed last week are 2.5 p.p.m. in milk on a fat basis, 0.1 p.p.m. in infant and junior foods, 2.5 p.p.m. in dairy products on a fat basis, 5 p.p.m. in poultry on a fat basis, 0.5 p.p.m. in eggs, 0.5 p.p.m. in finished animal feed, 5 p.p.m. in animal feed components, 5 p.p.m. in the edible portion of fish, and 5 p.p.m. in food packaging material.

Tolerances usually are based upon data submitted to FDA demonstrating the safe level of a substance. FDA conceded last week that "knowledge of the toxicological effects of PCBs is limited at this time."

Regarding acute toxicity, FDA said PCBs are classed as being "of moderate acute toxicity," noting that DDT has a higher acute toxicity than PCBs.

However, the agency said that chronic toxicity, including mutagenicity and teratogenicity, is not "well defined and thus . . . potentially of greater concern." Noting that chronic toxicity is being studied by government, industry and the scientific community (See story, Page 5), FDA said, "Preliminary reports and observations indicate that it would be prudent to reduce and, wherever possible, eliminate long-term, low-level human exposure to PCBs."

Summarizing the results of its survey, FDA said that "the current dietary level of PCBs is not considered an immediate hazard to the public health," but added that the sources and levels should be "significantly reduced or eliminated so as to minimize the overall long-term human exposure to PCBs."

The agency noted that "no authorization has been granted under the Federal Food, Drug and Cosmetic Act for any use of PCBs which results, either directly or indirectly, in PCBs becoming a component or otherwise affecting the characteristics of food for man or other animals."

FDA noted that some investigations have shown PCB residues in freshwater fish and some other foods of animal origin.

The agency noted that any disposal of PCBs should be accomplished by "appropriate high temperature degradation or other appropriate means" to avoid environmental contamination.

Transformation of the PCB "administrative guidelines" into "temporary tolerances" raises a number of questions. One involves the ease with which FDA will be able to revise the upper limits.

FDA is planning to publish in the Federal Register its "administrative guidelines" for filth, mold, and other contaminants in food products - - probably next week. The PCB document raises the question of whether these upper limits also will be transformed into "temporary tolerances."

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FTC LOOKS AT THE BIG BOYS FIRST

The "bigger" the product and its advertising, the harder the Federal Trade Commission will look at it, the agency told Congress in its annual report for fiscal 1971.

In the consumer protection area, FTC said, its criteria for review of business practices will include:

- - "The relative importance of products in terms of the proportion of consumer retail spending involved;

- - "The numbers of consumers affected;

- - "Advertising intensity relative to total sales of the product;

- - "The prevalence of consumer complaints; and

- - "The existence of health and safety factors."

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