In advising collection of samples, the instructions emphasized use of only those that will assist in the evaluation of the control of the critical points in the process and for the confirmation of inspectional observances of possible violative conditions.

Laboratory analysis was to be made of samples for (1) filth and extraneous matter; and (2) microbiological contamination.

At the conclusion of the pilot program, an evaluation will be made by the Bureau of Foods, in cooperation with EDRO, to:

(1) Identify the critical control points most frequently found to be deficient throughout the selected industry.

(2) Determine the need to extend the HACCP approach to firms producing low-acid foods that are thermally processed and hermetically sealed, as well as other food products, in the remaining Districts.

(3) Determine the need for specific industry educational programs emphasizing certain critical control points or directed at the processing of certain products.

(4) Determine the need for specific programs for training additional FDA personnel in the HACCP technique of inspection.

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FDA DOUBLES PCB TOLERANCES FOR PAPER, INFANT FOOD, CUTS FEED TOLERANCES

The Food and Drug Administration backed up in the face of massive objections to its proposed temporary tolerances for polychlorinated biphenyls in paper and packaging, doubling temporary tolerances for paper, as well as for infant foods, but it tightened the requirements on animal feed.

The agency's final environmental impact statement listing temporary tolerances was placed on display last week at FDA headquarters in Rockville, Md.

The final statement sets temporary tolerances of 10 p.p.m. in paper food packaging material, compared to 5 p.p.m. in the original proposal last spring (See FOOD CHEMICAL NEWS, March 13, Page 36; and March 20, Page 38). The final statement also allows the use of barriers, another change from the proposal and from later FDA statements (See FOOD CHEMICAL NEWS, May 15, Page 42). In the latest statement the agency said:

> "The tolerance for paper food-packaging material shall not apply to such material separated from the packaged food by a functional barrier impermeable to PCB migration."

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FDA's original statement had been greeted by a virtual storm of protest from the packaging industry including charges that the agency was thwarting paper recycling. The Environmental Protection Agency joined in the latter protest,

though it sent its comments in after the close of what had developed into a 90-day comment deadline on the proposal (See FOOD CHEMICAL NEWS, April 10, Page 12; April 24, Page 9; May 1, Page 15; May 8, Page 12; May 15, Page 42; May 22, Page 17; May 29, Page 9; June 5, Page 10; July 3, Page 26; July 24, Page 39; Aug. 7, Page 21; and Oct. 2, Page 11).

FDA also relaxed its tolerances for infant and junior food - - from 0.1 to 0.2 p.p.m.

The tightening of temporary tolerances for animal feeds included reducing from 0.5 p.p.m. to 0.2 p.p.m. the tolerance for complete and finished animal feeds and reducing the tolerances for animal feed components from 5.0 to 2.0 p.p.m.

Other temporary tolerances remained the same as in the original proposal. These were: Milk and Dairy Products (both on a fat basis), 2.5 p.p.m.; Poultry (fat basis) 5.0 p.p.m.; Eggs, 0.5 p.p.m., and fish and shellfish (edible portion), 5.0 p.p.m.

FDA said it would provide on request the analytical methods it will use for enforcing the temporary tolerances.

Other parts of the final document were little changed from the proposal. FDA defended its amendment of the Food Additive Order (§121.2546) for pulp from reclaimed fiber, saying "the amendment and tolerance would not be detrimental to the recycling waste programs." The agency elaborated:

> "The amendment will prohibit the inclusion in the recycling process of pulp that contains any poisonous or deleterious substance which may migrate to food from use in food-packaging. The FDA anticipates that the effect of this amendment will be the exclusion of PCB-containing carbonless copy papers from reclaimed and salvaged fibers. The paper industry is currently following this practice . . . The temporary tolerance applies equally to virgin paper products, which also have been found to contain PCBs, and to recycled paper products."

Final environmental impact statements are placed on public display for 30 days before a final order or regulation can be published in the Federal Register. In other words, if no comments are filed within the next month to change FDA's mind, the temporary tolerances and the amendments to §121.2546 will then be finalized.

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