FOOD CHEMICAL NEWS

Editor: Louis Rothschild, Jr. *Circulation Director: Shirley Galant*
Managing Editor: Raymond Galant *Assistant Director: Iris M. Schwartz*
Assistant to the Editors: Natalie Pargas *Production Manager: Dorothy Hill*
Assistant Editors: Patricia Mitchell, Nancy Richardson *Assistant Managers: Alice Wilkes, Sonia Rothschild*
Associate Editors: Cathy Cooper, Pam Brogan, Ron Grandon

FDA TIES "UNAVOIDABLE" CONTAMINATION TO ADHERENCE TO GMPs

Under current Food and Drug Administration policy, food contamination with pesticide or industrial chemical residues is considered "unavoidable" when Good Manufacturing Practices have been followed.

In practical terms, this means that a food or feed product which meets tolerances or action levels for residues of "unavoidable" contaminants may legally be marketed -- if the firm involved has followed GMPs.

If, however, the company has not followed GMPs, the residues would be considered "avoidable" contaminants, and the product would be adulterated even if the residue levels were within the tolerances or action levels.

This policy, attempting to differentiate between "unavoidable" and "avoidable" contaminants, was developed in response to questions raised concerning the current polychlorinated biphenyl contamination episode (See FOOD CHEMICAL NEWS, Oct. 1, Pages 46 and 67).

Revised Policy Seems to Meet Broiler Council Objectives

The revised FDA policy seems to meet National Broiler Council objectives. NBC a year ago asked for a redefinition of "avoidable" in regard to an incident in which fish meal contaminated with PCBs was used in feed (See FOOD CHEMICAL NEWS, Oct. 9, 1978, Page 5).

According to an FDA memo of a meeting, the Council asked that the policy be changed "to a position where the avoidability would be determined on the basis of the firm's knowledge and adherence to GMPs." FDA-ers at the 1978 meeting suggested that NBC file a petition.

Earlier this year (See FOOD CHEMICAL NEWS, March 5, Page 6), NBC again asked FDA to change its policy to make determinations of "avoidability" at stages of the food chain. Under the old FDA policy, the agency pointed out, "If the initial contamination was avoidable, then each direct succeeding step in the distribution, manufacturing, and human food production chain also constitutes avoidable contamination." NBC said it would file a petition if necessary.

MONS 006961

FOOD CHEMICAL NEWS (ISSN 0015 6337) is published weekly for $310 per year and $190 for additional subscriptions by Food Chemical News, Inc., 400 Wyatt Building, 777 - 14th Street, N.W., Washington, D.C. 20005. Second class postage

Correspondence between the Broiler Council and FDA has continued on the topic, and the agency has been preparing a response to NBC. The FDA letter to NBC is expected to reflect the recent policy revision.

Question Raised About Mayonnaise, Feed, Meat Meal, Yellow Grease

Questions were raised by FDA's Denver, Seattle, and Minneapolis Districts regarding the status of specific products -- mayonnaise, yellow grease, meat meal, and animal feed which may contain PCBs. The policy attempting to answer the questions was stated by Associate Commissioner for Regulatory Affairs Joseph P. Hile in a Sept. 27 memo to the field.

Noting that "questions regarding enforcement levels" were raised in the PCB incident, Hile said, "Because of this, appropriate offices within the agency have reviewed our existing policies, regulations, and analytical capabilities in order to provide updated regulatory guidance." Taking part in the review were representatives of the Bureau of Food, Bureau of Veterinary Medicine, Executive Director of Regional Operations, General Counsel's Office, and the Regulatory Affairs Office.

Describing the "updated policy" as confirming "existing guidelines" and providing "new guidance where appropriate for this investigation," Hile wrote:

"(1) Human and animal feed for which tolerances have been established are considered violative when they contain PCB at a level above the established tolerances. If a manufacturer, producer or processor could have avoided adding PCB to the food or feed by following current GMP, the established tolerances do not apply. In this case, the lower confirmation level becomes the level for recommending regulatory action. This level currently ranges from 0.2 to 1.5 (p.p.m.) for human foods; is at about 2.0 p.p.m. for meat meal and other feed ingredients of animal origin; and at 0.2 p.p.m. for finished feed.

"(2) When no tolerance exists, the finished food is not considered violative when the level of PCB is below the sensitivity (lower limit for confirming the level of PCB) of the official analytical methodology provided current GMPs have been followed. If higher levels of PCB (above the lower confirming level of the methodology) are found in food for which no tolerance has been established, the health significance of those levels must be considered on a case by case basis.

"(3) Regulatory action should be recommended when investigatory evidence shows that current GMPs have not been followed; or, that because ... current widespread publicity or similar information (should have alerted the firm to the problem), a responsible person has not exercised sufficient care to assure that violative raw materials or feeds are not used in the production of food."

Answering specific questions raised by the Districts, Hile said that, "Mayonnaise made under current GMPs with eggs which are later shown to be contaminated with PCBs at levels above the tolerance for eggs is not considered to be violative when the level of PCB in the finished product is below the sensitivity of the analytical methodology for this article."

MONS 006962

The Associate Commissioner said that "yellow grease and meat meal made under GMP's from portions of animals later shown to be contaminated with violative levels of PCBs

are not considered violative when the level of PCB in the finished product is below the established tolerance."

The "same principle," Hile said, "applies to the commingling under current good commercial practices of yellow grease containing violative levels of PCB with other yellow grease containing no PCB." This is one of the few instances in which FDA has formally approved the "blending" of a product containing violative residues with a product with no violative residues in order to come up with a legal product.

Hile wrote that "a finished feed made under current GMPs with meat meal or yellow grease containing violative levels of PCB (greater than 2 p.p.m.) would not be considered adulterated provided the level of PCB in the finished product is below the established tolerance (0.2 p.p.m.)."

The telegram noted that current tolerances for "unavoidable" PCBs are 1.5 p.p.m. in milk (fat basis), 1.5 p.p.m. in manufactured dairy products (fat basis), 3.0 p.p.m. in poultry (fat basis), 0.3 p.p.m. in eggs, 2.0 p.p.m. in feed components of animal origin, 0.2 p.p.m. in finished animal feed for food producing animals, 0.2 p.p.m. in infant and junior foods, and 5.0 p.p.m. in the edible portions of fish and shellfish. Hile noted that a reduction in the PCB tolerance for fish and shellfish to 2.0 p.p.m. "has been stayed upon formal objections" (See FOOD CHEMICAL NEWS, Oct. 1, Page 2).

"SCIENCE COURT" TO MODERATE DELANEY CLAUSE-FOOD SUPPLY CONFLICTS URGED

Use of a "science court" to moderate conflicts between the Delaney clause and the needs of the food supply was suggested recently by Dr. F. J. Francis, President-Elect of the Institute of Food Technologists.

Speaking to the Calorie Control Council's annual meeting Sept. 27-28 in Atlanta, Ga., Francis predicted that the Delaney clause will be modified by legislation and replaced by some form of balanced judgment (See FOOD CHEMICAL NEWS, Oct. 1, Page 2).

Noting that the White House Office of Science and Technology Policy has been considerin the concept of having risk assessment for chemicals done by impartial scientists, Francis said this would amount to a science court. He commented that scientists are more capable to judge scientific evidence than an administrative law judge.

Francis also suggested that use of the Sensitivity of Method (SOM) concept for all components of the food supply could also be a viable way to approach the problem.

The level of acceptable risk is always going to be a social judgment that is too important to leave to scientists, Francis said, adding that it must be done by Congress. He observed that the 1-in-a-million risk level appears to be gaining acceptance.

The IIT President-Elect expressed concern about wide-spread application of the benefit-risk concept, saying it would be "very unfortunate" if it obtains widespread support. If assessment of risk is "primitive," Francis said, assessment of benefits is "prehistoric."

MONS 006963