

Cross Contamination of Feeds Alleged in Letter

A regulatory letter from FDA to Orson E. Pacey Farm, Chalmers, Ind., said that U. S. Department of Agriculture inspectors collected objective samples of swine tissue on three occasions last year, finding sulfamethazine in liver tissue as high as 3.89 p.p.m., in kidney tissue as high as 3.43 p.p.m., and in muscle tissue as high as 0.40 p.p.m. FDA said USDA also found finished feeds had sulfamethazine ranging up to 21.5 p.p.m.

FDA said that Pacey Farm had failed to clean equipment before mixing and before transportation of medicated and nonmedicated feeds, to keep adequate inventory records, and to assay finished medicated feed.

FDA wrote to Sebrea Feed & Grain, Inc., Sebrea, Ky., that work areas were insufficient to provide room for separate storage of medicated feeds and pesticide products, that invoices serving as production records lacked adequate information, and that medicated feeds distributed in bulk were not routinely accompanied by complete labeling. A letter to Big 4 Feed and Implement Co., Scottsville, Ky., said the building work areas were inadequate, that inventory records and production records were inadequate, and that medicated feeds distributed in bulk were not accompanied by complete labeling.

A regulatory letter alleged that Havrakos Candy Co., St. Louis, Mo., was not complying with the Fair Packaging and Labeling Act. The agency said that the net weight statements for Pecan Heavenly Hash and Pecan Bark were not on the lower 30% of the principal display panel of the labels. FDA also said the labels failed to bear the common or usual names of ingredients, since Havrakos Chocolate and Nu-moline are not common or usual names of ingredients.

FDA TAKES CAUTIOUS VIEW OF REPORTS OF TUMORS FROM VCM FEEDING TESTS

The Food and Drug Administration has adopted a cautious approach to reports that Prof. Cesare Maltoni has produced carcinomas in two of 240 rats fed vinyl chloride monomer by tube intubation.

FDA officials will meet with Maltoni, of the Ontology Institute and Tumor Center of the Bologna Hospital in Italy, during his visit to a meeting on occupational cancer hazards at the New York Academy of Sciences March 24-27.

Maltoni reported results of his new work at a meeting last week in Stockholm before the Royal Academy of Science. Using gavage feeding, Maltoni treated rats at levels of 50 p.p.m., 16.65 p.p.m. and 3.30 p.p.m., along with controls. One rat at the highest level died of an angiosarcoma of the thymus while another at the next highest level died of angiosarcoma of the liver. FDA has wired Maltoni for a report of his studies.

Maltoni's discovery of angiosarcoma of the lungs, which was ultimately verified in humans from occupational exposure to polyvinyl chloride, led to proposed Occupational and Safety Health Administration standards for workers.

March 17, 1975

FOOD CHEMICAL NEWS

Although most concern has been centered on inhalation exposure, FDA, nevertheless, has been preparing to regulate use of PVC for food packaging to eliminate potential dangers from VCM migration to food (See FOOD CHEMICAL NEWS, Jan. 20, Page 33).

Canadian Reports Rapid GI Uptake in Feeding Tests of PVC

In another report, R. J. Withey, of Canada's Health Protection Branch, told the annual meeting of the Society of Toxicology last week in Williamsburg, Va., that gastrointestinal uptake of VCM does occur. Reporting on pharmacokinetic studies, Withey, of HPB's Branch of Chemical Safety, suggested that carcinogenic determinations other than by the route of inhalation should be designed.

He said data from the GI uptake must be evaluated to determine potential hazards from very low levels in foodstuffs, citing reports of migration from food packages of 1 to 5 p.p.m. and as much as 10 to 20 p.p.m. in some special packaging.

Withey's work was conducted by intragastric intubation with solutions containing up to 2 mg/ml of aqueous vinyl chloride in rats. He said the uptake of vinyl chloride by this route is extremely rapid, peak concentrations being achieved less than 10 minutes after administration of the dose.

He suggested that effects from VCM could result in multi-system diseases, and noted discovery of tumors, including osteochondroma of the bone. Withey said additional work will be continued in Canada to determine the actual hazards of VCM from food.

Commenting on Maltoni's new report on rat feeding by intubation, Attorney Jerome H. Heckman, General Counsel of the Society of the Plastics Industry, said FDA and the National Institute of Occupational Safety and Health were informed of the data within minutes after he received the reports from Stockholm.

He said the result of Maltoni's "gross feeding studies is not entirely unexpected and it should be pointed out that the amounts of VCM which were force-fed to the test rats have no real relationship to any exposure the public might have to VCM through use of PVC packaging for food, drugs and cosmetics."

For instance, he continued, a human being would have to drink daily some 20,000 bottles of wine to simulate the lowest level of feeding Maltoni has thus far found to induce cancer.

Heckman, of the Washington law firm of Keller & Heckman, said, "We have been told by some FDA toxicologists that they have avoided taking precipitous regulatory action based on preliminary gavage studies..."

Heckman pointed out that SPI is sponsoring pilot work on a more normal type of feeding study and intends to continue the work once FDA issues its long-awaited proposal governing interim PVC usage during testing. He explained:

"It has been, and continues to be, our position that, especially with the newer PVC compounds, migration of VCM from packaging to consumer goods is virtually nil. Further, past exposures from packaging can similarly be regarded as at near zero levels. Most packaging applications have been for film, coatings, and closure linings and even a number of FDA scientists have advised us they are willing to concede migration to be at practically zero level (even on the basis of mathematical calculations based on exaggerated assumptions) where no actual extraction data exists."

Heckman stressed that the position of SPI for the past year-and-a-half has been that FDA should adopt an interim policy on PVC packaging permitting continued use so long as no detectable level of monomer is found in food simulating solvents with exaggerated test methods sensitive to 50 p.p.b.

PVC packaging meeting this criterion, he explained, should not be considered subject to the Food Additives Amendment, at least as far as the monomer is concerned, adding:

"It is completely clear that the law is only intended to cover materials which may reasonably be expected to become food components. In our view, all elements of the PVC packaging industry can meet such a 'no migration' standard, provided FDA is willing to give common sense meaning to the word 'reasonably,' and not succumb to public hysteria."

Even if the present OSHA standard for VCM worker exposure - - 1 p.p.m. in air for an eight hour day - - remains in effect, Heckman said, "an ordinary citizen would have to eat the equivalent of 200 pounds of meat wrapped in PVC daily to have exposure to the same 'safe' level FDA's sister agency has already established."

FDA REVAMPS FOOD ADDITIVE SURVEY PROGRAM

The Food and Drug Administration has revamped its survey program for food additives which is designed to determine whether additives manufactured in this country meet the specifications set forth in the Food Chemicals Codex.

FDA's initial survey program designed to be carried out during fiscal year 1974 (See FOOD CHEMICAL NEWS, July 30, 1973, Page 3) had called for inspection of 216 firms to be done by the Districts, with five samples to be collected and analyzed from each firm.

However, much of FDA's inspection and laboratory resources were diverted to the mushroom crisis, so that there were only 104 inspections, with 460 samples collected, of which only 298 were analyzed, Richard J. Ronk, Director of the Division of Food and Color Additives in FDA's Bureau of Foods, reported at the National Academy of Sciences Symposium on Specifications for Food Chemicals, held in Washington, D.C., March 13.