Memorandum of Meeting

Date: July 27, 1976

Time: 11:00 a.m.

Location: Commissioner's Conference Room, Bureau of Foods

Attendees: Representing the FDA

Thomas W. Brown, Director, Compliance Coordination & Policy Staff

Charles F. Jelinek, Deputy Associate Director, Office of Technology

Curtis E. Coker, Jr., FDA, Bureau of Foods

L. F. Schneider, Acting District Director, Detroit

E. T. McGarrahan, Chief, Dairy & Lipid Products Branch, DFT/BF

Frank Cordle, Chief, Epidemiology Unit/BF

Herbert Blumenthal, Acting Division Director, Division of Toxicology

J. R. McDowell, Division of Animal Feeds - Animal Feed Safety, Toxicology

Paul E. Corneliussen, Division of Chemical Technology

Helen C. Barry, Field Sciences Branch, EDRO - Scientific Coordin

John Davis, Detroit District Office

William Schwemer, Office of Associate Commissioner for Compliance

Donald Reister, Acting Deputy Director, Bureau of Foods

Representing the State of Indiana MONS 031637

William T. Paynter, Indiana State Board of Health Commissioner

Raymond W. Rizzo, Executive Assistant to the Governor of Indiana

Patrick L. Stevens, Division of Water Pollution Control

H. H. Vaux, Director, Bureau of Food and Drugs, Ind. State Board of Health

W. D. Christen, Hearing Commissioner, Ind. State Board of Healt

The meeting was held at the request of the State of Indiana regarding the Indiana PCB problem of dairy herds with high levels of PCB's resulting from silo coatings.

After welcoming the visitors from Indiana, Mr. Brown stated that the FDA was prepared to listen to them and that we would be responsive to any questions that they might pose.

Mr. Rizzo stated that the State recognized its responsibility regarding the PCB problem and indicated the State intended to do all in its power to assure public health and at the same time to be fair in its actions and to assist in anyway possible the affected farmers whose livelihood had been cut-off. For these reasons the State felt it imperative to discuss the issues involved with the FDA in order to have an understanding of FDA's position and to give FDA an opportunity to understand the position of the State.

Mr. Brown briefly summarized FDA's regulatory position regarding PCB's in milk and some of the reasons for its presence in milk. He specifically mentioned that the FDA has historically found that the primary source of PCB contamination of milk has come about from the use of sealants containing PCB's used in silo construction. He indicated that it was his understanding that the present situation in Indiana has developed because of these PCB contaminated silos.

Mr. Snyder presented a brief discussion of Detroit District's monitoring activities and experiences with the contamination of milk from silos in Ohio, Michigan and Indiana. He said that in December 1975, the State of Indiana reported the presence of PCB's but that it was not until reports of high PCB content of surveillance sampling of silage did the District intensify its PCB contamination survey in Indiana.

Dr. Paynter indicated that the State has been sampling for PCB's in milk since 1971, and that these results have been reported to Detroit District. He said that the Detroit District had not indicated to the State of Indiana there was a regulatory problem in the area of milk contamination until early this year and that, therefore, the State had assumed that the FDA was not overly concerned about the problem since milk commercially available was well below the temporary tolerance of 2.5 ppm. He further stated that the State was under the impression that the FDA did not object to the blending of individual farmers' milk so long as commercially available milk was under the temporary tolerance of 2.5 ppm. He said that, therefore, when the FDA took action against an individual farm producer the State felt that there must have been a switch in FDA's regulatory position.

Mr. Brown reinterated FDA's regulatory position on this matter. He stated that the FDA considers any milk containing 2.5 ppm PCB's to be adulterated and subject to regulatory action. He said that this is applicable to individual farmers, that the FDA had never allowed the blending of milk from several farms at a processor's to arrive at a level below the 2.5 temporary tolerance. He stated that the FDA was not concerned about individual cows on a single farm.

Dr. Blumenthal briefly discussed the toxicological data used by the FDA in establishing the temporary tolerance of 2.5 ppm.

Dr. Paynter stated that public health was the primary concern, but at the same time, the State was concerned about the individual farmers already affected by cut-off and those who in the future may be cut-off. He said that it appears that 20 or so farmers will probably be affected. The State had evidence of several thousand silos of farms throughout the State where the same type problem may arise.

The FDA representatives pointed out that the PCB contaminated silos had been recognized in the late 60's and that the FDA had advised States at that time of the problem, and that the FDA was aware that some States had initiated measures to eliminate the problem, and that the FDA had assumed that all States having such silos would have taken the necessary measures to control the problem by this time. It was stated that the FDA is not familiar with the measures available to correct individual silos to prevent PCB migration into silage, but that we have been informed that procedures had been developed and were available for this purpose. It wes suggested that the State contact Dr. L. B. Willet, Ohio State Univerity, and the USDA for further information in this regard. Mr. Brown told the visitors that he would certainly advise affected farmers and those farmers found to be affected silos not to use the silos for silage until measures have been taken to preclude any further leaching of PCB's into silage from these silos.

Dr. Paynter stated that in monitoring individual farmers milk, the State's surveillance sampling was not used to make a determination of whether to cut-off an individual farmer, but the State would return to a questionable farm to take an official sample. He asked if FDA procedures were the same. Mr. Snyder said that samples collected under FDA surveillance were of sufficier size to make a determination without returning to the farm. He stated that before an individual farmer would be informed that he could not sell his milk in interstate commerce, the FDA performed an original and check analysis of that farmers milk.

Dr. Paynter asked at what point the FDA would allow a farmer to begin selling his milk again after he had been previously cut-off. Mr. Brown stated that only when the farmers milk was shown by sample to be below 2.5 ppm PCB's would a farmer be allowed back on the market. Mr. Snyder said that the FDA would make every effort to sample at reasonable intervals to assure that the farmer was back on the market as soon as possible, and that the FDA would, of course, accept the results of State samples in deciding whether to allow a farmer back on the market.

Dr. Paynter raised the question of whether there was any way to salvage the milk from the farms which were cut-off in order to maintain those farms until they could once again be permitted to sell their milk on the market. As an example, he asked whether the FDA would object to using the affected milk for producing skim milk and discarding the cream.

Mr. Brown stated that the FDA would consider any proposal the State may wish to put forward. He said that the agency would consider the idea of using the milk for the production of skim milk, and that the FDA would advise the State as to the acceptability of this practice as soon as possible.

Following a general discussion of the overall occurrence of PCB's in Indiana, the meeting ended.

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