From the desk of

GEORGE H. GRIFFIN

XC John Goddard ✓
J. Deily ✓

File

NOV 10 1980

PCB-ARCH-EXT0377983

NOV 7 1980

XC
7.p FRHS
WWW
RWK/TMH

LAW OFFICES
KELLER AND HECKMAN
1150 17TH STREET, N.W.
SUITE 1000
WASHINGTON, D.C. 20036

JOSEPH E. KELLER
JEROME H. HECKMAN
CHARLES M. MEEHAN
WILLIAM H. BORGHESANI, JR.
ROBERT R. TIERNAN
WAYNE V. BLACK
DAVID L. HILL
MARTIN W. BERCOVICI
JOHN S. ELDRED
CAROLE C. HARRIS
MICHAEL F. MORRONE
LARRY S. SOLOMON
JOHN B. DUBECK
CHRISTINE A. MEAGHER
PETER L. DE LA CRUZ *
SHIRLEY S. FUJIMOTO
LAWRENCE P. HALPRIN
DEBORAH SHUR TRINKER
C. DOUGLAS JARRETT
EDWARD L. KORWEK
ROBERT L. FLESHNER **

* OHIO BAR ONLY
** VA. BAR ONLY

TELEPHONE
202-457-1100
CABLE ADDRESS "KELMAN"
WRITER'S DIRECT DIAL NUMBER

202/457-1110

November 3, 1980

TO: SPI Food, Drug and Cosmetic Packaging Materials Committee

Re: Polychlorinated Biphenyls; Current Good Manufacturing Practice Relating to Poisonous and Deleterious Substances in Food, Feed and Food-Packaging Materials Plants; Docket No. 80N-0128; SPI Comments

Ladies and Gentlemen:

In our August 4, 1980, letter we included a copy of draft Comments prepared on behalf of The Society of the Plastics Industry, Inc. (SPI), requested your recommendations regarding possible revisions, and indicated that we would prepare a final version for presentation to the Food and Drug Administration (FDA) before the closing date of November 3, 1980. Our purpose here is to inform you that the comment period has been extended until December 4, 1980, and that an informal public meeting on these proposals will be held on November 7, 1980. We are enclosing a copy of the Federal Register notice to this effect (45 Fed. Reg. 71364, October 28, 1980).

Many of you have written to us and offered helpful suggestions to strengthen the SPI Comments, particularly with regard to the statements dealing with small processors. The final version of the Society's Comments will be suitably amended to reflect these recommendations. A number of you have also sent us copies of your own statements to the Agencies pointing out the costs your companies would incur were the

regulations to be promulgated as proposed. We are sure this will be helpful, and urge those who have not already done so to take advantage of the additional time to write to FDA and inform it of the unnecessary economic burden that will be placed upon you by its excessive proposals regarding food and feed manufacturing plants.

Turning to the new FDA initiative, the background is that several trade associations representing companies in the food and feed industries have recently requested an opportunity to discuss various aspects of the PCB proposals with the three Agencies coordinating this matter (Food and Drug Administration, U.S. Department of Agriculture, and Environmental Protection Agency). In response, an informal public meeting has been set for November 7, 1980, in Room 218-A of the Department of Agriculture's Administration Building, Fourteenth Street and Independence Avenue, S.W., Washington, D.C. In addition, the comment time was extended to December 4, 1980, to provide an opportunity for the public to respond to statements made at the public meeting.

Although SPI is not planning to present a formal statement at this meeting, Dr. Dixler of our office will attend and will be prepared to offer comments from the floor should this be deemed necessary or desirable. As soon as practicable thereafter, we shall report to you regarding the substance of the various presentations and the Agencies' responses.

We trust this letter will serve to bring you up-to-date regarding the status of the subject proposed rulemaking. Should you have any questions or additional suggestions to make, we would be pleased to hear from you.

Cordially yours,

Jerome H. Heckman

Enclosure

DEPARTMENT OF AGRICULTURE

Food Safety and Quality Service

7 CFR Part 2859

9 CFR Parts 308 and 381

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 109, 110, 225, 226, 500, and 509

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 761

Polychlorinated Biphenyls in Food, Feed, Agricultural Pesticide and Fertilizer Facilities

AGENCIES: Food Safety and Quality Service, USDA, Food and Drug Administration; and Environmental Protection Agency.

ACTION: Extension of comment periods; announcement of informal public meeting.

SUMMARY: On May 9, 1980, the Department of Agriculture, the Food and Drug Administration, and the Environmental Protection Agency announced individual proposed regulations affecting the use of PCB-containing equipment in food, feed, agricultural pesticide and fertilizer facilities. This notice extends the comment period on each of these proposals until December 4, 1980. In addition, this notice announces an informal public meeting regarding the three proposals to be held on November 7, 1980.

DATES: Informal public meeting on November 7, 1980, beginning at 10:00 a.m. Requests to appear at the meeting must be received on or before November 5, 1980. Written comments on all three Agency proposals must be received on or before December 4, 1980. (For information on how to make request to make presentations at the meeting, see "For Further Information Contact" section.)

ADDRESSES: The informal public meeting will be held at Room 218-A, Department of Agriculture, Administration Building, 14th and Independence Avenue, SW., Washington, DC.

Written comments on the proposals to:

FSQS Proposal: Regulations Coordination Division, Attn: Annie Johnson, Room 2637, South Agriculture Building, Food Safety and Quality Service, Compliance Program, U.S. Department of Agriculture, Washington, DC 20250. Oral comments on poultry products inspection regulations to Mr. Bartie T. Woods, (202) 447-5627.

EPA Proposal: Joni T. Repasch, Technical Information Specialist, Room 447 (TS-793), Office of Toxic Substances, EPA, 401 M Street, SW., Washington, DC 20460, Attn: Docket Number OTS-62003 (PCB/RR-3).

FDA Proposal: Docket Management Branch (HFA-305), Food and Drug Administration, Room 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Those persons interested in making presentations at the meeting should arrange to schedule their presentation by contacting: Penny Gentilly, Deputy Director, Public Participation, Room 1168, South Agriculture Building, Food Safety and Quality Service, U.S. Department of Agriculture, Washington, DC 20250, (202) 447-7804.

For information on the technical aspects of the proposals:

Mr. Bartie T. Woods, Director, Facilities, Equipment and Sanitation Division, Meat and Poultry Inspection Program, U.S. Department of Agriculture, Food Safety and Quality Service, Washington, DC 20250, (202) 447-5627.

Mr. John B. Ritch, Jr., Director, Industry Assistance Office, Office of Toxic Substances (TS-799), Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460, telephone toll free (800) 424-9065 (in Washington, 554-1404).

Mr. F. Leo Kaufman, Bureau of Foods (HFF-214), Food and Drug Administration, Department of Health and Human Services, 200 C Street, SW., Washington, DC 20204, (202) 245-1164.

SUPPLEMENTARY INFORMATION: On May 9, 1980, the Department of Agriculture (USDA), the Environmental Protection Agency (EPA), and the Food and Drug Administration (FDA) issued coordinated proposed rulemakings on the use of PCB-containing equipment or machinery in or around food, feed, food-and-feed-packaging material plants or storage facilities, and in facilities manufacturing, processing, or storing fertilizers or agricultural pesticides (45 FR 30980; 30984; 30989).

Specifically, USDA proposed to require that all equipment or machinery containing liquid PCB at levels greater than 50 parts per million by weight (except capcitors with less than 3 pounds of PCB's) would have to be either removed from the meat, poultry, and egg product plants and establishments under its inspection or drained and flushed so that they no longer contain PCB's in the liquid medium at levels greater than 50 parts per million by weight. In addition, any liquids with PCB's above 50 parts per million could no longer enter or be held on the premises for any reason (45 FR 30980-30983).

FDA proposed to prohibit the use of PCB-containing sealed electrical transformers and capacitors used or stored in or around food, feed, and food-and-feed-packaging materials plants or storage facilities, except for capacitors containing less than 3 pounds of fluid. Such equipment would have to be either replaced or drained and flushed so that the residual PCB's in the replacement fluid would be no more than 50 parts per million by weight. In addition, FDA also proposed that certain raw materials used in human food which are susceptible to PCB contamination be examined and analyzed as necessary to ensure that they comply with FDA tolerance levels for PCB's and other poisonous or deleterious substances (45 FR 30984-30988).

EPA proposed to prohibit the use of PCB Items as defined in 40 CFR 761.2(x), such as PCB large, high, and low voltage capacitors, PCB transformers, PCB-contaminated transformers, PCB heat transfer systems, and PCB hydraulic systems in facilities manufacturing, processing, or storing fertilizers or agricultural pesticides. PCB small capacitors (containing less than 3 pounds of fluid) are not to be regulated by the proposal (45 FR 30989-30993).

Initially, each of these proposals established comment periods for the receipt of information and data—USDA and FDA by July 7, 1980, and EPA by July 8, 1980. Subsequently, each of these comment periods was extended for 120 days—until November 4, 1980, for USDA (45 FR 44317, July 1, 1980), and FDA (45 FR 44325, July 1, 1980), and November 5, 1980, for EPA (45 FR 47168-69, July 14, 1980).

In a letter dated September 17, 1980, the American Frozen Food Institute, on behalf of themselves and other interested trade associations,[1] requested an opportunity to discuss in an informal meeting various aspects of the three

[1] These other interested Associations include: American Feed Manufacturers' Association, American Meat Institute, Biscuit and Cracker Manufacturers' Association of America, Edison Electric Institute, National Agriculture Chemical Association, National Broiler Council, National Coffee Association, National Food Processors Association, National Frozen Pizza Institute, National Soft Drink Association, National Turkey Federation, Potato Chip/Snack Food Association, Utilities Solid Waste Activities Group.

PCB-ARCH-EXT0377986

proposals which they considered common to the three proposals. These issues included potential health risks, the economic impact of the proposals, and the request for special consideration for those companies which have already invested funds in efforts to control PCB's.

PCB's are toxic substances which have been identified for regulatory coordination by the Regulatory Development Work Group of the Interagency Regulatory Liaison Group (IRLG). At all stages of these rulemaking proceedings, the agencies have coordinated their activities, whenever possible. After considering the request of the American Frozen Food Institute, the three agencies have individually determined that it is appropriate to conduct a joint public informal meeting on November 7, 1980, to hear presentations and to offer clarifications on certain aspects of the proposed rules to industry and other interested persons. The agencies will welcome all comments and data relevant to their rulemaking efforts. A transcript will be made of this meeting and will be included in the administrative rulemaking records of the three agencies.

In order to include comments and data gathered at the meeting within the rulemaking records of each Agency, and to afford sufficient time following the meeting for interested parties to submit their comments on the record of that proceeding, the comment period on each of the three proposals is being mutually extended by this notice until December 4, 1980. Persons wishing to request a public hearing under the EPA proposal may do so until the end of the public comment period on December 4, 1980. In all other respects, the procedure specified in the proposed rules published by each Agency on May 9, 1980, shall continue to apply.

Done at Washington, DC.

Dated: October 28, 1980.

Donald L. Houston,

Administrator, Food Safety and Quality Service.

Dated: October 21, 1980.

Jere E. Goyan,

Commissioner of Food and Drugs.

Dated: October 22, 1980.

Douglas M. Costle,

Administrator, Environmental Protection Agency.

[FR Doc. 80-33616 Filed 10-27-80; 8:45 am]

BILLING CODE 3410-DM-M

DEPARTMENT OF AGRICULTURE

Food Safety and Quality Service

9 CFR Parts 317 and 381

Net Weight Labeling; Extension of Comment Period

AGENCY: Food Safety and Quality Service, USDA.

ACTION: Proposed rule; extension of comment period.

SUMMARY: On August 8, 1980, the Department published in the Federal Register a document proposing to amend the Federal meat and poultry products inspection regulations to provide more uniform labeling requirements and to prescribe uniform procedures for determining compliance with label statements of net contents of meat and poultry products. In response to several requests for additional time to study the proposal and gather data, the Department is extending the comment period for 60 days.

DATE: Comments must be received on or before January 5, 1981.

ADDRESS: Written comments to: Regulations Coordination Division, Attn: Annie Johnson, Room 2637, South Agriculture Building, Food Safety and Quality Service, U.S. Department of Agriculture, Washington, DC 20250. Oral comments on the poultry products inspection regulations to: Mr. Bill Dennis, (202) 447-3840.

FOR FURTHER INFORMATION CONTACT: Mr. Bill Dennis, Director, Processed Products Inspection Division, Meat and Poultry Inspection Program, Food Safety and Quality Service, U.S. Department of Agriculture, Washington, DC 20250, (202) 447-3840. The Draft Impact Analysis describing the options considered in developing the proposed rule and the impact of implementing each option was published in its entirety as an appendix in the August 8, 1980, proposed rule.

SUPPLEMENTARY INFORMATION:

Significance

The proposal was reviewed under USDA procedures established in Secretary's Memorandum 1955 to implement Executive Order 12044, and was classified "significant."

Background

On August 8, 1980, the Food Safety and Quality Service published in the Federal Register (45 FR 53002-53023) a proposed rule to amend the Federal meat and poultry products inspection regulations to set forth more uniform net weight labeling requirements for federally inspected meat and poultry products and prescribe procedures for determining compliance with these requirements. These proposed regulations would establish objective, numerical standards for determining compliance to insure that consumers receive valid information regarding the actual weight of meat and poultry products and to provide for increased uniformity of regulations at the Federal, State, and local levels. Interested persons were given until November 6, 1980, to comment.

The Food and Drug Administration (FDA) also published a similar proposal relating to non-meat and non-poultry food products (45 FR 53023-53031).

The Department has been requested to extend the comment period for 120 days so data, views, or arguments may be submitted or oral views presented by the American Meat Institute, The Grocery Manufacturers Association, the National Broiler Council and others. The requests stated that additional time was needed in order to gather data and study the proposal. Similar requests were presented to the FDA.

After careful consideration and discussions with the FDA, the Department and FDA have jointly decided that sufficient justification exists to extend the comment period for 60 days. The FDA extension of comment period is published elsewhere in this issue of the Federal Register. In all other aspects, the procedure specified in the proposed rule published on August 8, 1980, shall continue to apply.

Done at Washington, D.C., on: October 21, 1980.

Carol Tucker Foreman,

Assistant Secretary for Food and Consumer Services.

[FR Doc. 80-33503 Filed 10-23-80; 4:56 pm]

BILLING CODE 3410-DM-M

CIVIL AERONAUTICS BOARD

[EDR-408A; Economic Regulations Docket: 38746

14 CFR Parts 221, 296, and 297

Airlines Filing Tariffs Stating Prices as Maximum Amounts

Dated: October 22, 1980.

AGENCY: Civil Aeronautics Board.

ACTION: Proposed rule; extension of comment period.

SUMMARY: The CAB extends the period for public comments on its proposal to allow airlines to file tariffs that state prices as maximum amounts instead of exact amounts, so that any price up to

PCB-ARCH-EXT0377987