September 28, 1979, by every registered national securities association.

Copies of Form SECO-4-79 (17 CFR 249.504a) will be forwarded to SECO broker-dealers. Copies of the form have been filed with the Office of the Federal Register and additional copies are available on request by contacting William Flanagan, Office of Reports and Information Services, Securities and Exchange Commission, Washington, D.C., 20549.

(Secs. 15 and 23 (15 U.S.C. 78o and 78w).)

By the Commission.

George A. Fitzsimmons,
Secretary.

October 2, 1979.

[FR Doc. 79-30013 Filed 10-4-79; 8:45 am]

BILLING CODE 8010-01-M

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

21 CFR Part 109

[Docket No. 77N-0089]

Unavoidable Contaminants in Food for Human Consumption and Food-Packaging Materials; Polychlorinated Biphenyls (PCB's); Reduction of Tolerances; Confirmation of Effective Date and Partial Stay

AGENCY: Food and Drug Administration

ACTION: Final Rule.

SUMMARY: This document announces that the effective date of the final regulation reducing tolerances for unavoidable residues of the industrial chemicals polychlorinated biphenyls in certain foods is confirmed, except that the provision concerning fish and shellfish is stayed. The stay of the reduced tolerance for fish and shellfish is in effect pending a resolution of the issues raised by an objection filed by the National Fisheries Institute, Inc. A notice specifying the issues, if any, for which a hearing is justified and other pertinent information will be published in the Federal Register at a later date.

EFFECTIVE DATE: The final regulation became effective on August 28, 1979, except the provision concerning fish and shellfish [§ 109.30(a)(7)] is stayed until further notice.

FOR FURTHER INFORMATION CONTACT: Elizabeth Campbell, Bureau of Foods (HFF-312), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C St. SW., Washington, DC 20204, 202-245-3092.

SUPPLEMENTARY INFORMATION: In the Federal Register of June 29, 1979 (44 FR 38330), the agency issued a final regulation reducing tolerances for unavoidable residues of the industrial chemicals polychlorinated biphenyls (PCB's) in several classes of food.

The final regulation provided that the tolerance for PCB's is 1.5 parts per million (ppm) in milk (fat basis), 1.5 ppm for PCB's in dairy products (fat basis), 3 ppm in poultry (fat basis), 0.3 ppm in eggs, and 2 ppm in fish and shellfish (edible portion).

Objection and Request for a Hearing

As provided by law, persons who would be adversely affected by the final regulation were given the opportunity to file written objections on or before July 30, 1979 and, if desired, request a formal, evidentiary hearing on the specific provisions to which they objected.

The agency received over 20 timely objections to the final regulation, all of which dealt with the tolerance for fish and shellfish (§ 109.30(a)(7)). Only one objection, which was submitted by the National Fisheries Institute, Inc. (NFI) in concert with several other organizations, was coupled with a request for the formal hearing provided for in the statute (21 U.S.C. 371(e)(2)). The NFI objection and request for a hearing on § 109.30(A)(7) is based essentially on a contention that the agency grossly underestimated the loss of food that would result from the reduced tolerance for fish and shellfish. According to the Institute, this underestimate resulted in the agency inadequately assessing the "avoidability" of PCB's as a factor in its deliberations as to the correct tolerance level.

Another objection expressed the concern that not all persons interested in fishing had had an opportunity to comment on the final regulation during the 30 days allowed for the filing of objections, and it requested that a hearing be held [in the Great Lakes region, if possible] "to give the people most directly affected a chance to participate." FDA does not interpret this as a request for the formal, trial-type hearing provided for in 21 U.S.C. 371(e)(2), but rather as a request that FDA extend the period for filing objections and hold informal hearings as a mechanism for receiving additional comments and objections on the final regulation. FDA will respond to this request, as well as the points raised in all the other objections it received, in a future Federal Register document announcing the agency's response to NFI's request for a hearing.

Regulation Stayed

By operation of statute (21 U.S.C. 371(e)(2)), the objection and request for hearing filed by NFI, stays the effective date of the revised fish and shellfish tolerance in § 109.30(a)(7) pending resolution of the issues raised in the objection. Because no objections and requests for hearing were received on the other provisions of the reduced tolerance regulation, those other provisions went into effect, as scheduled, on August 28, 1979.

The agency is now in the process of considering whether a hearing is necessary to resolve the issues raised in the NFI objection. A notice stating any issues on which a hearing is justified and setting forth other pertinent information will be published in the Federal Register at a later date. A copy of all the objections is on file in the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857. The NFI objection is identified as OB0015.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 306, 402(a), 408, 701 (a) and (e), 52 Stat. 1045-1046 as amended, 1049 as amended, 1055, 70 Stat. 919 as amended (21 U.S.C. 336, 342,(a) 346, 371 (a) and (e))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), notice is given that § 109.30(a)(1) through (4) and (b) became effective August 28, 1979; an objection and request for a hearing was filed concerning the reduced tolerance for PCB's in fish and shellfish, and § 109.30(a)(7) is thus stayed until further notice.

Dated: September 28, 1979.

Joseph P. Hile,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-30072 Filed 10-3-79; 11:29 am]

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21 CFR Parts 510 and 558

Animal Drugs, Feeds, and Related Products; Cargill, Inc.; Change of Sponsor

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The animal drug regulations are amended to reflect the change of sponsor for a tylosin premix from Neese & Sons, Inc., to Cargill, Inc. A supplemental new animal drug application (NADA) filed by Neese & Sons, Inc., provides for this change.

EFFECTIVE DATE: October 5, 1979.

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