to prohibit unauthorized access to the records and to provide for a record of the identity of the persons who access such records and of any modifications made.[27] In addition, assurance must be provided that a computer-generated record will be made readily available in machine-readable media or hard copy to the Commission or DOJ upon request. Moreover, records stored on ''machine readable media must use a format and coding structure'' specified in such a request by the Commission or DOJ.[28]

The Commission recognizes that the development of electronic order-routing systems continues to be in flux. The Commission intends to continue to monitor that process with a view toward providing further guidance by advisory or rule in the future. Among other things, the Commission will evaluate the manner in which electronic order-routing systems may interface with other audit trail recordkeeping practices in place at an exchange.

IV. Conclusion

To the extent that a customer order is prepared and transmitted to and reported from an exchange trading pit by an electronic order-routing system, or a customer order is prepared by an electronic off-floor order management system, and the standards set forth below are satisfied, then the ''written'' record requirements of Commission Regulation 1.35(a–1)(1), (a–1)(2)(i), (a–1)(4), and/or (d) will be deemed satisfied by the electronic record generated by the system. Specifically, such electronic records must:

(1) Include the customer order information required under Commission Regulation 1.35.(a–1)(1), (2)(i), (a–1)(4) and/or 1.35(d);

(2) Include any modification, including any change and/or cancellation, that is made to an order and indicate the time the modification is recorded in the system;

(3) Record all Commission-required and other order-related times, including order entry and exit times, and the time of any modification made to a customer order, including any change and/or cancellation, to the highest level of precision achievable by the operating system, but at least to the second. The times captured must not use a clock that can be modified by the person entering the order;

(4) Be kept in hard copy and/or allowable hard copy substitution media, as provided under Commission Regulation 1.31. The stored records shall be open to inspection by the Commission or DOJ as required under Commission Regulation 1.31 and be made readily available to the Commission or DOJ in machine-readable media or hard copy upon request. Records stored on machine-readable media must use a format and coding structure specified in the Commission request. To the extent that records temporarily are stored in erasable form, appropriate security measures must be implemented by the system operator to prohibit any unauthorized access to the records and to maintain an accurate record of when and by whom records are accessed or modified.

Issued in Washington, DC on February 12, 1997.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 97–4004 Filed 2–19–97; 8:45 am]

BILLING CODE 6351–01–P

[27] Id.

[28] Id. at 27465.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 173

[Docket No. 96F–0184]

Secondary Direct Food Additives Permitted in Food for Human Consumption; Sulphopropyl Cellulose

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for a change in the level of reactants for sulphopropyl cellulose ion-exchange resin for the recovery and purification of proteins for food use. This action is in response to a petition filed by Life Technologies, Inc.

DATES: Effective February 19, 1997; written objections and requests for a hearing by March 21, 1997.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Andrew D. Laumbach, Center for Food Safety and Applied Nutrition (HFS–217), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3071.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of July 3, 1996 (61 FR 34852), FDA announced that a food additive petition (FAP 6A4500) had been filed by Life Technologies, Inc., 8400 Helgerman Ct., Gaithersburg MD 20874. The petition proposed to amend the food additive regulations in § 173.25 (21 CFR 173.25) to provide for a change in the level of the reactants for sulphopropyl cellulose ion-exchange resin for the recovery and purification of proteins for food use. The amendment proposed that the amount of epichlorohydrin plus propylene oxide employed does not exceed 250 percent by weight of the starting quantity of cellulose. The current regulation provides that the amount of epichlorohydrin plus propylene oxide employed does not exceed 61 percent by weight of the starting quantity of cellulose.

In the Federal Register of April 22, 1991 (56 FR 16266), FDA published a final rule that amended the regulation under § 173.25 to provide for the use of the ion-exchange resin and the starting materials used to manufacture the additive. The amendment to the regulation was based upon the information provided in FAP 6A3905. In the final rule of April 22, 1991, the agency stated that while the ion-exchange resin has not been shown to cause cancer, it may contain small amounts of the starting materials epichlorohydrin (ECH) and propylene oxide (PO) as byproducts of its production. Because the chemicals ECH and PO have been shown to cause cancer in test animals, the agency conducted a quantitative risk assessment procedure to calculate the risk from the use of ECH and PO. Based on the results of the risk assessment, the agency concluded in the final rule of April 22, 1991, that there was a reasonable certainty of no harm from exposure to ECH and PO that might result from the proposed use of the additive.

Recently, the agency was advised that the levels of the starting materials for the resin, ECH and PO, that are listed under § 173.25(a)(20) need to be amended. The petitioner discovered that the information in FAP 6A3905 that was used to calculate the levels of ECH and PO in the listings for the regulation contained errors that led to an underestimation of the actual levels of ECH and PO used in the production of the resin. A new petition (FAP 6A4500) was submitted to correct the regulation by listing the actual ratios of the starting materials ECH and PO that are currently being used in the manufacture of the ion-exchange resin.

The agency has reviewed the information in both petitions 6A3905 and 6A4500, and it has determined that

the levels of ECH and PO set out in current § 173.25(a)(20) are in error because those levels do not reflect the levels presently used by industry to manufacture the resin. The information in the present petition establishes that the manufacturing process and the resin composition do not differ from the process and resin composition evaluated in the original petition. Because the composition of the resin is unchanged, the exposure to the residues of ECH and PO remains unchanged. Therefore, the agency concludes that the agency's safety evaluation conducted for the original petition (FAP 6A3905) supports the safety of the amendment to § 173.25 proposed by FAP 6A4500. Accordingly, the agency concludes that a recalculation of a risk assessment performed for the original petition (FAP 6A3905) is not necessary to support this action.

Thus, FDA has evaluated the data in the petition and other relevant material. Based on this information, the agency concludes that: (1) The proposed use of the additive is safe; (2) the additive will achieve its intended technical effect; and that therefore, (3) the regulations in § 173.25 should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has determined under 21 CFR 25.24(a)(9) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Any person who will be adversely affected by this regulation may at any time on or before March 21, 1997, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 173

Food additives.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 173 is amended as follows:

PART 173—SECONDARY DIRECT FOOD ADDITIVES PERMITTED IN FOOD FOR HUMAN CONSUMPTION

1. The authority citation for 21 CFR part 173 continues to read as follows:

Authority: Secs. 201, 402, 409 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348).

2. Section 173.25 is amended by revising paragraph (a)(20) to read as follows:

§ 173.25 Ion-exchange resins.

* * * * *

(a) * * *

(20) Regenerated cellulose, cross-linked and alkylated with epichlorohydrin and propylene oxide, then sulfonated whereby the amount of epichlorohydrin plus propylene oxide employed does not exceed 250 percent by weight of the starting quantity of cellulose.

* * * * *

Dated: February 11, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–4082 Filed 2–19–97; 8:45 am]

BILLING CODE 4160–01–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300453; FRL–5588–1]

RIN 2070–AB78

Zinc Phosphide; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues of phosphine resulting from the use of the rodenticide zinc phosphide in or on the raw agricultural commodities timothy (seed, forage, hay), alfalfa (forage, hay), and clover (forage, hay) in connection with EPA's granting of an emergency exemption to the state of Washington under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of zinc phosphide on timothy or timothy-alfalfa, clover stands. This regulation establishes maximum permissible levels for residues of phosphine in these foods pursuant to section 408(l)(6) of the Federal Food, Drug and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. The tolerances will expire on April 15, 1998.

DATES: This regulation is effective February 20, 1997. The entries in the table expire on April 15, 1998. Objections and requests for hearings must be received by EPA on or before April 21, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300453], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Room M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300453], must also be submitted to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to: Crystal Mall #2, Room 1132, 1921 Jefferson Davis Highway, Arlington, VA.