

PART 404—FEDERAL OLD-AGE, SURVIVORS AND DISABILITY INSURANCE (1950—)

Subpart D—[Amended]

1. The authority citation for subpart D of part 404 continues to read as follows:

Authority: Secs. 202, 203(a) and (b), 205(a), 216, 223, 225, 228(a)–(e), and 702(a)(5) of the Social Security Act (42 U.S.C. 402, 403(a) and (b), 405(a), 416, 423, 425, 428(a)–(e), and 902(a)(5)).

2. Section 404.332 is amended by revising paragraph (b)(4) to read as follows:

§ 404.332 When wife's and husband's benefits begin and end.

* * * * *

(b) * * *

(4) If you are under age 62, there is no longer a child of the insured who is under age 16 or disabled and entitled to child's benefits on the insured's earnings record. (See paragraph (c) of this section if you were entitled to wife's or husband's benefits for August 1981 on the basis of having a child in care.) (If you no longer have in your care a child who is under age 16 or disabled and entitled to child's benefits on the insured's earnings record, your benefits may be subject to deductions as provided in § 404.421.)

* * * * *

3. Section 404.341 is amended by revising paragraph (b)(2) to read as follows:

§ 404.341 When mother's and father's benefits begin and end.

* * * * *

(b) * * *

(2) There is no longer a child of the insured who is under age 16 or disabled and entitled to a child's benefit on the insured's earnings record. (See paragraph (c) of this section if you were entitled to mother's or father's benefits for August 1981.) (If you no longer have in your care a child who is under age 16 or disabled and entitled to child's benefits on the insured's earnings record, your benefits may be subject to deductions as provided in § 404.421.)

* * * * *

4. Section 404.357 is amended by adding a new sentence following the first sentence to read as follows:

§ 404.357 Who is the insured's stepchild?

* * * You also may be eligible as a stepchild if you were conceived prior to the marriage of your natural parent to the insured but were born after the marriage and the insured is not your natural parent. * * *

5. Section 404.361 is revised to read as follows:

§ 404.361 When a natural child is dependent.

(a) *Dependency of natural child.* If you are the insured's natural child, as defined in § 404.355, you are considered dependent upon him or her, except as stated in paragraph (b) of this section.

(b) *Dependency of natural child legally adopted by someone other than the insured.*

(1) Except as indicated in paragraph (b)(2) of this section, if you are legally adopted by someone other than the insured (your natural parent) during the insured's lifetime, you are considered dependent upon the insured only if the insured was either living with you or contributing to your support at one of the following times:

- (i) When you applied;
- (ii) When the insured died; or
- (iii) If the insured had a period of disability that lasted until he or she became entitled to disability or old-age benefits or died, at the beginning of the period of disability or at the time he or she became entitled to disability or old-age benefits.

(2) You are considered dependent upon the insured (your natural parent) if:

- (i) You were adopted by someone other than the insured after you applied for child's benefits; or
- (ii) The insured had a period of disability that lasted until he or she became entitled to old-age or disability benefits or died, and you are adopted by someone other than the insured after the beginning of that period of disability.

6. Section 404.366 is amended by revising the sixth sentence of the introductory text in paragraph (b) to read as follows:

§ 404.366 "Contributions for support," "one-half support," and "living with" the insured defined—determining first month of entitlement.

* * * * *

(b) * * * Ordinarily we consider a reasonable period to be the 12-month period immediately preceding the time when the one-half support requirement must be met under the rules in §§ 404.362(c)(1) and 404.363 (for child's benefits), in § 404.370(f) (for parent's benefits) and in § 404.408a(c) (for benefits where the Government pension offset may be applied). * * *

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7. The authority citation for subpart E of part 404 continues to read as follows:

Authority: Secs. 202, 203, 204(a) and (e), 205(a) and (c), 222(b), 223(e), 224, 225, and 702(a)(5) of the Social Security Act (42 U.S.C. 402, 403, 404(a) and (e), 405(a) and (c), 422(b), 423(e), 425, and 902(a)(5)).

8. Section 404.406 is amended by revising the second sentence to read as follows:

§ 404.406 Reduction of maximum because of retroactive effect of application for monthly benefits.

* * * An application may also be effective (retroactively) for benefits for months before the month of filing (see § 404.603). * * *

[FR Doc. 99-7271 Filed 3-25-99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 173

[Docket No. 96F-0248]

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 limitations 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: The regulation is effective March 26, 1999; written objections and requests for a hearing by April 26, 1999.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Andrew D. Laumbach, Center for Food Safety and Applied Nutrition (HFS-215), 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 22, 1996 (61 FR 37905), FDA announced that a food additive petition (FAP 6A4502) had been filed by Life Technologies, Inc., 8400 Helgerman Ct., Gaithersburg, MD 20874 (now, 9800 Medical Center Dr., Rockville, MD 20850). The petition proposed to amend the food additive regulations in § 173.25(b)(5) *Ion-exchange resins* (21 CFR 173.25(b)(5)) to provide for a change in the temperature and pH limitations for sulphopropyl cellulose

ion-exchange resin for the recovery and purification of proteins for food use.

In the notice of filing, published in the **Federal Register** on July 22, 1996, the agency announced that it was placing the environmental assessment (EA) on display at the Dockets Management Branch for public review and comment. No comments were received. On July 29, 1997, FDA published revised regulations under part 25 (21 CFR part 25), which became effective on August 28, 1997. These regulations established additional categorical exclusions for a number of FDA actions. As a result, such actions would no longer require the submission of an EA. Because the agency had not completed its review of the EA submitted with the petition, the agency evaluated whether a categorical exclusion under revised § 25.32(j) would apply to this rule.

After the filing of the petition on July 22, 1996, FDA determined that the petitioned amendment of the food additive regulations in § 173.25(b)(5) also necessitated an amendment of the provisions in § 173.25(d)(2), that provide extraction requirements for the ion-exchange resin. FDA published an amended filing notice in the **Federal Register** of August 28, 1998 (63 FR 46053), to announce this change. The amended filing notice also contained the agency's determination that the proposed action would not have a significant impact on the human environment, and therefore, that neither an environmental assessment nor an environmental impact statement was required. The notice, however, incorrectly cited the categorical exclusion under § 25.32(i), rather than the exclusion under § 25.32(j).

FDA published a final rule in the **Federal Register** of April 22, 1991 (56 FR 16266), that amended the regulation under § 173.25 to provide for the use of the ion-exchange resin and starting materials used to manufacture the sulphopropyl cellulose ion-exchange resin. The amendment to the regulation was based upon information provided in FAP 6A3905. In the final rule of April 22, 1991, the agency stated that while the sulphopropyl cellulose 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 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 (upper-bound limit of individual lifetime risk no greater than 8×10^{-15}) and PO (upper-bound limit of individual lifetime risk no greater than 1×10^{-14}) that might result from the proposed use of the additive.

As stated previously, FAP 6A4502 was submitted to amend the regulations in § 173.25(b)(5) and (d)(2) by changing the limitations for the temperature, pH, and the extraction requirements for the sulphopropyl cellulose ion-exchange resin. The petitioner did not propose any changes to the provisions under § 173.25(a)(20) for the manufacturing process, involving the starting materials ECH and PO, for the ion-exchange resin.

The agency has reviewed the information in the FAP's 6A3905 and 6A4502, and has determined that the information in FAP 6A4502 does not indicate a change in the manufacturing process. Therefore, the resin composition in FAP 6A4502 does not differ from the resin composition evaluated in the original petition (FAP 6A3905). Moreover, based on its evaluation, the agency finds that the proposed changes to the limitations for the temperature, pH, and the extraction requirements for the ion-exchange resin are expected to reduce the potential level of exposure to the residues of ECH and PO. 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.

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, 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 § 25.32(j) 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.

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

Any person who will be adversely affected by this regulation may at anytime on or before April 26, 1999, 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: 21 U.S.C. 321, 342, 348.

2. Section 173.25 is amended by revising paragraphs (b)(5) and (d)(2) to read as follows:

§ 173.25 Ion-exchange resins.

* * * * *

(b) * * *

(5) The ion-exchange resin identified in paragraph (a)(20) of this section is limited to use in aqueous process

streams for the isolation and purification of protein concentrates and isolates under the following conditions:

(i) For resins that comply with the requirements in paragraph (d)(2)(i) of this section, the pH range for the resin shall be no less than 3.5 and no more than 9, and the temperatures of water and food passing through the resin bed shall not exceed 25 °C.

(ii) For resins that comply with the requirements in paragraph (d)(2)(ii) of this section, the pH range for the resin shall be no less than 2 and no more than 10, and the temperatures of water and food passing through the resin shall not exceed 50 °C.

* * * * *

(d) * * *

(2) The ion-exchange resin identified in paragraph (a)(20) of this section shall comply either with:

(i) The extraction requirement in paragraph (c)(4) of this section by using dilute sulfuric acid, pH 3.5 as a substitute for acetic acid; or

(ii) The extraction requirement in paragraph (c)(4) of this section by using reagent grade hydrochloric acid, diluted to pH 2, as a substitute for acetic acid. The resin shall be found to result in no more than 25 parts per million of organic extractives obtained with each of the following solvents: Distilled water; 15 percent alcohol; and hydrochloric acid, pH 2. Blanks should be run for each of the solvents, and corrections should be made by subtracting the total extractives obtained with the blank from the total extractives obtained in the resin test.

* * * * *

Dated: March 17, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

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DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 938

[PA-121-FOR]

Pennsylvania Abandoned Mine Land Reclamation Program; Pennsylvania Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Final rule; approval of amendment.

SUMMARY: OSM is approving, with certain exceptions, a proposed amendment to the Pennsylvania Abandoned Mine Land Reclamation (AMLR) Plan (hereinafter referred to as the AMLR Plan) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA), 30 U.S.C. 1201 *et seq.*, as amended. The proposed amendment adds a new section "F" entitled Government Financed Construction Contracts (GFCC) to authorize the incidental removal of coal and coal refuse at Abandoned Mine Land (AML) sites that would not otherwise be mined and reclaimed under the Title V program, along with relevant statutory provisions authorizing the AMLR Plan amendments. The proposed amendment also includes the Program Requirements and Monitoring Requirements related to the use of GFCC for that purpose. The proposed amendment is intended to improve the efficiency of the Pennsylvania program by allowing the government-financed construction exemption in Section 528 of SMCRA to be applied in cases involving less than 50% financing only in the limited situation where the construction constitutes a government approved and administered abandoned mine land reclamation project under Title IV of SMCRA. The amendment is also intended to authorize the use of excess spoil from a valid, permitted coal mining operation for the reclamation of an abandoned unreclaimed area outside of the permit area.

EFFECTIVE DATE: March 26, 1999.

FOR FURTHER INFORMATION CONTACT: Mr. Robert J. Biggi, Director, Harrisburg Field Office, Third Floor, Suite 3C, Harrisburg Transportation Center (Amtrack) 415 Market Street, Harrisburg, Pennsylvania 17101. Telephone: (717) 782-4036.

SUPPLEMENTARY INFORMATION:

- I. Background on the Pennsylvania Program
- II. Submission of the Proposed Amendment
- III. Director's Findings
- IV. Summary and Disposition of Comments
- V. Director's Decision
- VI. Procedural Determinations

I. Background on the Pennsylvania Program

On July 30, 1982, the Secretary of the Interior conditionally approved the Pennsylvania AMLR Plan. Background on the Pennsylvania AMLR Plan, including the Secretary's findings and the disposition of comments can be found in the July 30, 1982 **Federal Register** (47 FR 33081). Subsequent actions concerning the AMLR Plan amendments are identified at 30 CFR 938.20 and 938.25.

On July 31, 1982, the Secretary of the Interior conditionally approved the Pennsylvania program. Background information on the Pennsylvania program can be found in the July 30, 1982 **Federal Register** (47 FR 33050). Subsequent actions concerning the conditions of approval and program amendments are identified at 30 CFR 938.11, 938.12, 938.15 and 938.16.

II. Description of the Proposed Amendment

By letter dated November 21, 1997 (Administrative Record No. PA-855.00), the Pennsylvania Department of Environmental Protection (PADEP) submitted proposed Program Amendment No. 2 to the Pennsylvania AMLR Plan. In addition, PADEP also submitted the following documents: Introduction; Basis of Authority for the Proposed Amendment; AML Amendment Conformance with 30 CFR Section 884.13; Assistant Counsel's Opinion of Authority for GFCC; PADEP Organization Chart; the Office of Mineral Resources Management Organization Chart; and Public Participation in Part F of the Reclamation Plan (Amendment No. 2). The proposed amendment is intended to improve the efficiency of the Pennsylvania program by allowing the Government-financed construction exemption in Section 528 of SMCRA to be applied in certain cases involving less than 50% government financing. Pennsylvania also proposed to authorize the use of excess spoil from a valid, permitted coal mining operation for the reclamation of an abandoned unreclaimed area outside of the permit area.

OSM announced receipt of the proposed amendment in the December 29, 1997, **Federal Register** (62 FR 67590), and in the same document opened the public comment period and provided an opportunity for a public hearing on the adequacy of the proposed amendment. The public comment period closed on January 28, 1998.

OSM's review of the proposed amendment determined that several items required clarification. As a result, a letter requesting clarification on three items pertaining to placement of excess spoil on Abandoned Mine Lands was sent to Pennsylvania dated June 5, 1998 (Administrative Record No. PA 855.08). Pennsylvania initially responded in its letter dated June 17, 1998, (Administrative Record No. PA 855.09), that it would require additional time to respond to OSM's request, and that it expected to provide a response by July 15. A response was received from Pennsylvania in its letter dated July 7,