

request, provide Customs with electronic access to certain Passenger Name Record (PNR) information, as defined and described in paragraph (b) of this section. In order to readily provide Customs with such access to requested PNR information, each air carrier must ensure that its electronic reservation/departure control systems correctly interface with the U.S. Customs Data Center, Customs Headquarters, as prescribed in paragraph (c)(1) of this section.

(b) *PNR information defined; PNR information that Customs may request.*

(1) *PNR information defined.* Passenger Name Record (PNR) information refers to reservation information contained in an air carrier's electronic reservation system and/or departure control system that sets forth the identity and travel plans of each passenger or group of passengers included under the same reservation record with respect to any flight covered by paragraph (a) of this section.

(2) *PNR data that Customs may request.* The air carrier, upon request, must provide Customs with electronic access to any and all PNR data elements relating to the identity and travel plans of a passenger concerning any flight under paragraph (a) of this section, to the extent that the carrier in fact possesses the requested data elements in its reservation system and/or departure control system. There is no requirement that the carrier collect any PNR information under this paragraph, that the carrier does not otherwise collect on its own and maintain in its electronic reservation/departure control systems.

(c) *Required carrier system interface with Customs Data Center to facilitate Customs retrieval of requested PNR data.* (1) *Carrier requirements for interface with Customs.* Within the time specified in paragraph (c)(2) of this section, each air carrier must fully and effectively interface its electronic reservation/departure control systems with the U.S. Customs Data Center, Customs Headquarters, in order to facilitate Customs ability to retrieve needed Passenger Name Record data from these electronic systems. To effect this interface between the air carrier's electronic reservation/departure control systems and the Customs Data Center, the carrier must:

(i) Provide Customs with an electronic connection to its reservation system and/or departure control system. (This connection can be provided directly to the Customs Data Center, Customs Headquarters, or through a third party vendor that has such a connection to Customs.);

(ii) Provide Customs with the necessary airline reservation/departure control systems' commands that will enable Customs to:

(A) Connect to the carrier's reservation/departure control systems;

(B) Obtain the carrier's schedules of flights;

(C) Obtain the carrier's passenger flight lists; and

(D) Obtain data for all passengers listed for a specific flight; and

(iii) Provide technical assistance to Customs as required for the continued full and effective interface of the carrier's electronic reservation/departure control systems with the Customs Data Center, in order to ensure the proper response from the carrier's systems to requests for data that are made by Customs.

(2) *Time within which carrier must interface with Customs Data Center to facilitate Customs access to requested PNR data.* Any air carrier which has not taken steps to fully and effectively interface its electronic reservation/departure control systems with the Customs Data Center must do so, as prescribed in paragraphs (c)(1)(i)–(c)(1)(iii) of this section, within 30 days from the date that Customs contacts the carrier and requests that the carrier effect such an interface. After being contacted by Customs, if an air carrier determines it needs more than 30 days to properly interface its automated database with the Customs Data Center, it may apply in writing to the Assistant Commissioner, Office of Field Operations (OFO) for an extension. Following receipt of the application, the Assistant Commissioner, OFO, may, in writing, allow the carrier an extension of this period for good cause shown. The Assistant Commissioner's decision as to whether and/or to what extent to grant such an extension is within the sole discretion of the Assistant Commissioner and is final.

(d) *Sharing of PNR information with other Federal agencies.* Passenger Name Record information as described in paragraph (b)(2) of this section that is made available to Customs electronically may, upon request, be shared with other Federal agencies for the purpose of protecting national security (49 U.S.C. 44909(c)(5)). Customs may also share such data as otherwise authorized by law.

Robert C. Bonner,
Commissioner of Customs.

Approved: June 19, 2002.

Timothy E. Skud,
Deputy Assistant Secretary of the Treasury.
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RAILROAD RETIREMENT BOARD

20 CFR Part 217

RIN 3220–AB46

Application for Annuity or Lump Sum

AGENCY: Railroad Retirement Board.

ACTION: Final rule.

SUMMARY: The Railroad Retirement Board (Board) amends its regulations to permit a spouse application, when filed simultaneously with the employee's application for a disability annuity, to be filed more than three months in advance of the earliest annuity beginning date. These changes bring §§ 217.9 and 217.30 into agreement with the distinction already found in § 218.7.

DATES: Effective June 25, 2002.

FOR FURTHER INFORMATION CONTACT: Marguerite P. Dadabo, Assistant General Counsel, Railroad Retirement Board (312) 751–4945, TTD (312) 751–4701.

SUPPLEMENTARY INFORMATION: Section 217.9 of the regulations of the Board provides for the effective period of an application. This rule amends § 217.9(b) to permit a spouse application, when filed simultaneously with the employee's application for a disability annuity, to be filed more than three months in advance of the earliest annuity beginning date. This rule also makes a conforming amendment to § 217.30 concerning the reasons for denial of an application, and provides greater clarity for such denials.

The Board published the proposed rule on November 29, 2001 (66 FR 59548), and invited comments by January 28, 2002. No comments were received. Accordingly, the proposed rule has been redrafted as a final rule without change.

The Board, with the concurrence of the Office of Management and Budget, has determined that this is not a significant regulatory action under Executive Order 12866. Therefore, no regulatory analysis is required. Information collections associated with § 217.9 have been approved by the Office of Management and Budget under control number 3220–0002.

List of Subjects in 20 CFR Part 217

Claims, Railroad retirement, Reporting and record keeping requirements.

For the reasons set out in the preamble, the Railroad Retirement Board amends title 20, chapter II, part 217 of the Code of Federal Regulations as follows:

PART 217—APPLICATION FOR ANNUITY OR LUMP SUM

1. The authority citation for part 217 continues to read as follows:

Authority: 45 U.S.C. 231d and 45 U.S.C. 231f.

2. Section 217.9, paragraph (b)(1), is amended by adding directly after the words “paragraph (b)(2)”, the words “and paragraph (b)(3)”, and by adding a new paragraph (b)(3) to read as follows:

§ 217.9 Effective period of application.

* * * * *

(b) * * *

(3) *Application for spouse annuity filed simultaneously with employee disability annuity application.* When the qualifying employee's annuity application effective period is determined by the preceding paragraph (b)(2) of this section, a spouse who meets all eligibility requirements may file an annuity application on the same date as the employee claimant. The spouse application will be treated as though it were filed on the later of the actual filing date or the employee's annuity beginning date.

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3. Section 217.30 is amended by removing paragraph (b), redesignating paragraph (c) as paragraph (b), and by adding a new paragraph (c) to read as follows:

§ 217.30 Reasons for denial of application.

* * * * *

(c) The applicant files an application more than three months before the date on which the eligible person's benefit can begin except if the application is for an employee disability annuity or for a spouse annuity filed simultaneously with the employee's disability annuity application.

Dated: June 18, 2002.

By Authority of the Board.

For the Board.

Beatrice Ezerski,

Secretary to the Board.

[FR Doc. 02-15911 Filed 6-24-02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 173

[Docket No. 89F-0452]

Secondary Direct Food Additives Permitted for Direct Addition to Food for Human Consumption; Materials Used as Fixing Agents in the Immobilization of Enzyme Preparations

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 the safe use of dimethylamine-epichlorohydrin and acrylamide-acrylic acid resins, individually or together, as fixing agents for the immobilization of glucose isomerase enzyme preparations. This action is in response to a petition filed by Enzyme Bio-Systems Ltd.

DATES: This rule is effective June 25, 2002. Submit written objections and requests for a hearing by July 25, 2002.

ADDRESSES: Submit written objections and requests for a hearing to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic objections to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT: Rosalie M. Angeles, Center for Food Safety and Applied Nutrition (HFS-206), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 202-418-3107.

SUPPLEMENTARY INFORMATION:

I. Background

In a notice published in the **Federal Register** of November 17, 1989 (54 FR 47828), FDA announced that a food additive petition (FAP 9A4175) had been filed by Enzyme Bio-Systems Ltd., International Plaza, Route 9W, Englewood Cliffs, NJ 07632. The petition proposed to amend the food additive regulations to provide for the safe use of dimethylamine-epichlorohydrin copolymer (DEC) and acrylamide-acrylic acid resin (AAR) as fixing agents for immobilizing glucose isomerase enzyme.

DEC and AAR will be used, individually or together, to immobilize glucose isomerase enzymes for the purpose of converting glucose to a mixture of glucose and fructose for the production of high fructose corn syrup (HFCS). The glucose isomerase

immobilized with the petitioned polymers may be used as a substitute for one or more of the immobilized glucose isomerases currently in use.

In its evaluation of the safety of the petitioned substances, FDA has reviewed the safety of the additives and the chemical impurities that may be present in them resulting from the manufacturing processes. Although the petitioned polymers have not been shown to cause cancer, they may contain minute amounts of carcinogenic impurities resulting from their manufacture. DEC may contain traces of unreacted epichlorohydrin and its degradation product, 1,3-dichloro-2-propanol. AAR may contain minute amounts of the unreacted monomer, acrylamide. These chemical impurities have been shown to cause cancer in test animals. Residual amounts of reactants and their impurities commonly are found as contaminants of chemical products, including food additives.

II. Determination of Safety

Under the general safety standard of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(c)(3)(A)), a food additive cannot be approved for a particular use unless a fair evaluation of the data available to FDA establishes that the additive is safe for that use. FDA's food additive regulations (21 CFR 170.3(i)) define safe as a “reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use.”

The food additives anticancer, or Delaney, clause of the act (21 U.S.C. 348(c)(3)(A)) provides that no food additive shall be deemed safe if it is found to induce cancer when ingested by man or animal. Importantly, however, the Delaney clause applies to the additive itself and not to impurities in the additive. That is, where an additive itself has not been shown to cause cancer, but contains a carcinogenic impurity, the additive is evaluated properly under the general safety standard using risk assessment procedures to determine whether there is reasonable certainty that no harm will result from the intended use of the additive (*Scott v. FDA*, 728 F.2d 322 (6th Cir. 1984)).

III. Safety of the Petitioned Use of the Additives

FDA has estimated that the petitioned use of the additives, DEC and AAR, will result in a daily intake of 210 micrograms per person per day (µg/p/d) and 83 µg/p/d, respectively (Ref. 1).

FDA has evaluated the safety of DEC and AAR under the general safety