helping the passenger repack might unduly burden inspectors, who have to process many passengers, frequently in short periods of time.

Conclusion

After further review of the proposal and careful consideration of the comments received, we have decided to adopt the proposed regulatory changes.

Regulatory Flexibility Act and Executive Order 12866

Based upon the supplementary information set forth above and because the opening and examination of baggage and merchandise is mandated by the statutes cited above, pursuant to the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), it is certified that the amendments will not have a significant economic impact on a substantial number of small entities. Accordingly, the amendments are not subject to the regulatory analysis or other requirements of 5 U.S.C. 603 or 604. This document does not meet the criteria for a ''significant regulatory action'' as specified in Executive Order 12866.

Drafting Information

The principal author of this document was Janet L. Johnson, Regulations Branch. However, personnel from other offices participated in its development.

List of Subjects

*19 CFR Part 123*

Canada, Customs duties and inspection, Freight, International boundaries, Mexico, Motor carriers, Railroads, Reporting and recordkeeping requirements, Vessels.

*19 CFR Part 148*

Airmen, Customs duties and inspection, Foreign officials, Government employees, International organizations, Reporting and recordkeeping requirements, Vessels.

Amendments to the Customs Regulations

For the reasons set forth in the preamble, parts 123 and 148 of the Customs Regulations (19 CFR parts 123 and 148) are amended as set forth below.

## PART 123—CUSTOMS RELATIONS WITH CANADA AND MEXICO

1. The general authority citation for part 123 and the specific authority citation for § 123.63 continue to read as follows:

Authority: 19 U.S.C. 66, 1202 (General Note 20, Harmonized Tariff Schedule of the United States), 1624.

* * * * *

Section 123.63 also issued under 19 U.S.C. 1461, 1462.

* * * * *

2. Section 123.63 is revised to read as follows:

### § 123.63 Examination of baggage from Canada or Mexico.

(a) *Opening vehicle or compartment to examine baggage.* Customs officers are authorized to unlock, open, and examine vehicles and compartments thereof for the purposes of examining baggage under sections 461, 462, 496, 581(a) and 582, Tariff Act of 1930, as amended (19 U.S.C. 1461, 1462, 1496, 1581(a), and 1582) and 19 U.S.C. 482. However, to the extent practical, the Customs officer should ask the owner or operator to unlock such vehicle or compartment first. Where the owner or operator is unavailable or refuses to unlock the vehicle or compartment or where it is not practical to ask the owner or operator to unlock the same, it shall be opened by the Customs officer. If any article is subject to duty, or any prohibited article is found upon opening by the Customs officer, the whole contents and the vehicle shall be subject to forfeiture pursuant to 19 U.S.C. 1462.

(b) *Inspection of baggage.* A Customs officer has the right to inspect all merchandise and baggage brought into the United States from contiguous countries under 19 U.S.C. 1461. He also has the right, under the same statute, to require that owners of such baggage open it or furnish keys for doing so. Where the owner or agent is unavailable or refuses to open the baggage or furnish keys or where it is not practical to ask the owner or agent to open or furnish keys to the same, it shall be opened by the Customs officer. If any article is subject to duty, or any prohibited article is found upon opening by the Customs officer, the baggage shall be subject to forfeiture pursuant to 19 U.S.C. 1462.

## PART 148—PERSONAL DECLARATIONS AND EXEMPTIONS

1. The general authority citation for part 148 is revised to read as set forth below, and the specific authority for § 148.21 will continue to read as follows:

Authority: 19 U.S.C. 66, 1496, 1624. The provisions of this part, except for subpart C, are also issued under 19 U.S.C. 1202 (General Note 20, Harmonized Tariff Schedule of the United States).

Section 148.21 also issued under 19 U.S.C. 1461, 1462.

* * * * *

2. Section 148.21 is revised to read as follows:

### § 148.21 Opening of baggage, compartments, or vehicles.

A Customs officer has the right to open and examine all baggage, compartments and vehicles brought into the United States under Sections 461, 462, 496 and 582, Tariff Act of 1930, as amended (19 U.S.C. 1461, 1462, 1496, and 1582) and 19 U.S.C. 482. To the extent practical, the owner or his agent shall be asked to open the baggage, compartment or vehicle first. If the owner or his agent is unavailable or refuses to open the baggage, compartment, or vehicle, it shall be opened by the Customs officer. If any article subject to duty, or any prohibited article is found upon opening by the Customs officer, the whole contents and the baggage or vehicle shall be subject to forfeiture, pursuant to 19 U.S.C. 1462.

George J. Weise,

*Commissioner of Customs.*

Approved: September 6, 1995.

Dennis M. O'Connell,

*Acting Deputy Assistant Secretary of the Treasury.*

[FR Doc. 95–25997 Filed 10–19–95; 8:45 am]

BILLING CODE 4820–02–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Food and Drug Administration

## 21 CFR Part 177

**[Docket No. 92F–0493]**

## Indirect Food Additives: Polymers

**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 ethylene-maleic anhydride copolymers containing no more than 2 percent by weight of polymer units derived from maleic anhydride in contact with food at temperatures not to exceed 49 °C (120 °F). This action is in response to a petition filed by Showa Denko K. K.

**DATES:** Effective October 20, 1995; written objections and requests for a hearing by November 20, 1995.

**ADDRESSES:** Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration,

rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Edward J. Machuga, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3085.

**SUPPLEMENTARY INFORMATION:** In a notice published in the Federal Register of February 12, 1993 (58 FR 8290), FDA announced that a food additive petition (FAP 3B4351) had been filed by Showa Denko K. K., Tokyo, Japan, c/o Center for Regulatory Services, 2347 Paddock Lane, Reston, VA 22091. The petition proposed to amend the food additive regulations in 21 CFR part 177 *Indirect Food Additives: Polymers* by adding a new section to provide for the safe use of ethylene-maleic anhydride copolymers containing no more than 2 percent by weight of polymer units derived from maleic anhydride in contact with food at temperatures not to exceed 49 °C (120 °F). However, subsequent to the publication of the filing notice, the agency decided, with concurrence of the petitioner, that the subject additive would be more appropriately regulated in § 177.1520 *Olefin polymers* (21 CFR 177.1520). Therefore, this final rule is amending § 177.1520 to provide for the safe use of ethylene-maleic anhydride copolymers containing no more than 2 percent by weight of polymer units derived from maleic anhydride in contact with food at temperatures not to exceed 49 °C (120 °F).

FDA has evaluated data in the petition and other relevant material. The agency concludes that the proposed use of the food additive is safe and that the regulations in § 177.1520 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 21 CFR 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 carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Any person who will be adversely affected by this regulation may at any time on or before November 20, 1995 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 177

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 177 is amended as follows:

## PART 177—INDIRECT FOOD ADDITIVES: POLYMERS

1. The authority citation for 21 CFR part 177 continues to read as follows:

Authority: Secs. 201, 402, 409, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 379e).

2. Section 177.1520 is amended by adding a new paragraph (a)(6) and in the table in paragraph (c) by adding a new item ''6'' to read as follows:

**§ 177.1520 Olefin polymers.**

* * * * *

(a) * * *

(6) Ethylene-maleic anhydride copolymers (CAS Reg. No. 9006–26–2) containing no more than 2 percent by weight of copolymer units derived from maleic anhydride.

* * * * *

(c) * * *

| Olefin polymers | Density | Melting point (MP) or softening point (SP) (*Degrees Centigrade*) | Maximum extractable fraction (expressed as percent by weight of polymer) in *N*-hexane at specified temperatures | Maximum soluble fraction (expressed as percent by weight of polymer) in xylene at specified temperatures |
|---|---|---|---|---|
| * * | * | * | * | * * |
| 6. Ethylene-maleic anhydride copolymers described in paragraph (a)(6) of this section for use as the adhesive component in multilaminate structures, or as the sealant layer in flexible packaging, in contact with food at temperatures not exceeding 49 °C (120 °F). | 0.92–0.94 ..... | ..... | 1.36 pct at 50 °C. ..... | 2.28 pct at 25 °C. |

* * * * *

Dated: October 4, 1995.

Fred R. Shank,

*Director, Center for Food Safety and Applied Nutrition.*

[FR Doc. 95–25973 Filed 10–19–95; 8:45 am]

**BILLING CODE 4160–01–F**

## 21 CFR Part 184

**[Docket No. 87G–0406]**

## Direct Food Substances Affirmed as Generally Recognized as Safe; Aminopeptidase Enzyme Preparation Derived From Lactococcus Lactis

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending its regulations to affirm that the use of an aminopeptidase enzyme preparation derived from *Lactococcus lactis* (formerly known as *Streptococcus lactis*) in the manufacturing of cheddar cheese and in the preparation of protein hydrolysates is generally recognized as safe (GRAS). This action is in response to a petition filed by Imperial Biotechnology, Ltd.

**DATES:** Effective October 20, 1995. The Director of the Office of the Federal Register approves the incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 of a publication listed in new § 184.1985, effective October 20, 1995.

**FOR FURTHER INFORMATION CONTACT:** Aydin Örstan, Center for Food Safety and Applied Nutrition (HFS–217), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3076.

**SUPPLEMENTARY INFORMATION:**

I. Background

In accordance with the procedures described in 21 CFR 170.35, Imperial Biotechnology, Ltd., Imperial College Rd., South Kensington, London, SW7 2BT, United Kingdom, submitted a petition (GRASP 8G0335) proposing that aminopeptidase from *L. lactis* be affirmed as GRAS as a direct human food ingredient.

FDA published a notice of filing of this petition in the Federal Register of February 23, 1988 (53 FR 5319), and gave interested parties an opportunity to submit comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857. FDA received no comments in response to that notice.

II. Standards for GRAS Affirmation

Under § 170.30 (21 CFR 170.30), general recognition of safety may be based only on the views of experts qualified by scientific training and experience to evaluate the safety of substances added to food. The basis of such views may be either: (1) Scientific procedures, or (2) in the case of a substance used in food prior to January 1, 1958, experience based on common use in food (§ 170.30(a)). General recognition of safety based upon scientific procedures requires the same quantity and quality of scientific evidence as is required to obtain approval of a food additive regulation and ordinarily is to be based upon published studies, which may be corroborated by unpublished studies and other data and information (§ 170.30(b)). In its petition, Imperial Biotechnology, Ltd., relies on scientific procedures, primarily published scientific papers and books, corroborated by unpublished information, to demonstrate the safety of aminopeptidase enzyme preparation produced from *L. lactis* for use in the manufacturing of cheddar cheese and in the preparation of protein hydrolysates.

III. Identity, Technical Effect, and Production

*A. Identity*

Aminopeptidase enzyme preparation is a mixture of intracellular peptidases derived from the bacterium *L. lactis*. Peptidases are enzymes that cleave peptide bonds to liberate free amino acids or dipeptides (Ref. 1). The natural occurrence of peptidases in the cellular extracts of *L. lactis* and in extracts of cheese made with this organism is documented in the scientific literature (Ref. 2).

For simplicity, the trivial name aminopeptidase is used to describe the enzyme preparation. The Chemical Abstracts Service (CAS) Registry Number for aminopeptidase is 9031–94–1. The Enzyme Commission (EC) numbers of the enzymes present in aminopeptidase enzyme preparation are as follows: aminopeptidase, EC 3.4.11.1; tripeptide aminopeptidase, EC 3.4.11.4; dipeptidase, EC 3.4.13.11; proline dipeptidase, EC 3.4.13.9; dipeptidylpeptide hydrolases (EC 3.4.14.1–3) (Ref. 1). The agency finds that the petitioned preparation meets the requirements for enzyme preparations found in the Food Chemicals Codex, 3d ed. (1981), which is incorporated by reference in new § 184.1985.

*B. Technical Effect*

The progressive breakdown of milk proteins to peptides and amino acids during the ripening of cheese leads to the development of typical cheese texture and flavors. This process is catalyzed by aminopeptidase and other peptidases produced by the bacteria added to milk as starter cultures (Refs. 3 through 6). Also, these enzymes may be extracted from bacterial cultures and used in improving flavor and eliminating the bitterness of protein hydrolysates (Ref. 7), which are used in many foods for a variety of functions, including as formulation aids, leavening agents, stabilizers, thickening agents, nutrient supplements, protein sources, flavorings, and flavor enhancers. The petitioner intends to use the aminopeptidase enzyme preparation to accelerate flavor development during cheddar cheese ripening and to improve the flavor of protein hydrolysates used in various foods.

The petitioner has presented published information demonstrating that peptidase enzymes from *L. lactis* perform their intended technical effect in cheese manufacturing (Ref. 8). Furthermore, the petitioner provided a European patent office publication containing an approved patent application that demonstrates that the aminopeptidase enzyme preparation performs its intended technical effect in the manufacture of protein hydrolysates (Ref. 7). The petitioner also presented unpublished, corroborative studies demonstrating that the aminopeptidase enzyme preparation performs its intended technical effects in the manufacture of cheddar cheese and protein hydrolysates.

*C. Production and Purification*

The production process for aminopeptidase enzyme preparation, described in detail in GRASP 8G0335, may be summarized as follows: *L. lactis*, started from a pure culture, is aseptically grown at 30 °C in stainless steel fermenters in a medium containing lactose, casein hydrolysate, yeast extract, ascorbic acid, disodium hydrogen phosphate, magnesium sulfate, and polypropylene glycol P–2,000 as a defoaming agent. Samples of the medium are removed aseptically at various stages of fermentation and examined microscopically for typical morphology of the production organism and for the presence of contaminating organisms. During fermentation, the pH of the culture is maintained within a range of 6.4–6.6 with sodium hydroxide. Once the maximum cell density of the production organism, as measured by