(a) The additive is prepared by reacting soybean oil in toluene with hydrogen peroxide and formic acid.

(b) It meets the following specifications:

(1) Epoxidized soybean oil contains oxirane oxygen, between 7.0 and 8.0 percent, as determined by the American Oil Chemists' Society (A.O.C.S.) method Cd 9–57, ''Oxirane Oxygen,'' reapproved 1989, which is incorporated by reference in accordance with 5 U.S.C 552(a) and 1 CFR part 51. Copies are available from the American Oil Chemists' Society, P. O. Box 3489, Champaign, IL 61826–3489, or may be examined at the Division of Petition Control (HFS–215), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 1110 Vermont Ave. NW., suite 1200, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(2) The maximum iodine value is 3.0, as determined by A.O.C.S. method Cd 1–25, ''Iodine Value of Fats and Oils Wijs Method,'' revised 1993, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The availability of this incorporation by reference is given in paragraph (b)(1) of this section.

(3) The heavy metals (as Pb) content can not be more than 10 parts per million, as determined by the ''Heavy Metals Test,'' Food Chemicals Codex, 3d ed. (1981), p. 512, Method II (with a 2-gram sample and 20 microgram of lead ion in the control), which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Box 285, Washington, DC 20055, or may be examined at the Division of Petition Control (HFS–215), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 1110 Vermont Ave. NW., suite 1200, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(c) The additive is used as a halogen stabilizer in brominated soybean oil at a level not to exceed 1 percent.

Dated: June 14, 1995.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 95–15349 Filed 6–23–95; 8:45 am]

BILLING CODE 4160–01–F

21 CFR PART 184

[Docket No. 84G–0257]

Enzyme Preparations From Animal and Plant Sources; Affirmation of Gras Status as Direct Food Ingredients

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is affirming that certain enzyme preparations derived from animal and plant sources are generally recognized as safe (GRAS) for use as direct food ingredients. This action is a partial response to a petition filed by the Ad Hoc Enzyme Technical Committee (now the Enzyme Technical Association). The following enzyme preparations derived from animal sources are affirmed as GRAS in this final rule: Catalase (bovine liver), animal lipase, pepsin, trypsin, and pancreatin (as a source of protease activity). The following enzyme preparations derived from plant sources are affirmed as GRAS in this final rule: Bromelain, ficin, and malt.

DATES: Effective June 26, 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 certain publication listed in 21 CFR 184.1024(b), 184.1034(b), 184.1316(b), 184.1415(b), 184.1443a(b), 184.1583(b), 184.1595(b), and 184.1914(b), effective June 26, 1995.

FOR FURTHER INFORMATION CONTACT: Laura M. Tarantino, Center for Food Safety and Applied Nutrition (HFS–206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3090.

SUPPLEMENTARY INFORMATION:

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I. Introduction

In accordance with the procedures described in § 170.35 (21 CFR 170.35), the Ad Hoc Enzyme Technical Committee (now the Enzyme Technical Association), c/o Miles Laboratories, Inc., 1127 Myrtle St., Elkhart, IN 46514, submitted a petition (GRASP 3G0016) requesting that the following enzyme preparations be affirmed as GRAS for use in food:

(1) Animal-derived enzyme preparations: Catalase (bovine liver); lipase, animal; pepsin; rennet; rennet, bovine; and trypsin.

(2) Plant-derived enzyme preparations: Bromelain; malt; and papain.

(3) Microbially-derived enzyme preparations: *Aspergillus niger*, var. (lipase, catalase, glucose oxidase, and carbohydrase); *Bacillus subtilis*, var. (carbohydrase and protease mixtures); *Rhizopus oryzae* (carbohydrase); and *Saccharomyces* species (carbohydrase).

FDA published a notice of filing of this petition in the **Federal Register** of April 12, 1973 (38 FR 9256), and gave interested persons 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. The petition was amended by notices published in the **Federal Register** of June 12, 1973 (38 FR 15471), proposing affirmation that microbially derived enzyme preparations (carbohydrase, lipase, and protease) from *A. oryzae* are GRAS for use in food; in the **Federal Register** of August 29, 1984 (49 FR 34305), proposing affirmation that the enzyme preparations ficin, obtained from species of the genus *Ficus* (fig tree), and pancreatin, obtained from bovine and porcine pancreas, are GRAS for use in food; and in the **Federal Register** of June 23, 1987 (52 FR 23607), proposing affirmation that the enzyme preparation protease from *A. niger* is GRAS for use in food. In the June 23, 1987, notice, FDA also noted the petitioner's assertion that pectinase enzyme preparation from *A. niger* and lactase enzyme preparation from *A. niger* are included under carbohydrase enzyme preparation from *A. niger*, and that invertase enzyme preparation from *Saccharomyces cerevisiae* and lactase enzyme preparation from *Kluyveromyces marxianus* are both included under carbohydrase enzyme preparation from species of the genus *Saccharomyces*. The agency further noted that, therefore, pectinase enzyme preparation from *A. niger*, lactase enzyme preparation from *A. niger*,

invertase enzyme preparation from *S. cerevisiae*, and lactase enzyme preparation from *K. marxianus* were to be considered part of the petition. Interested persons were given an opportunity to submit comments to the Dockets Management Branch (address above) on each amendment.

After the petition was filed, the agency published, as part of its comprehensive safety review of GRAS substances, two GRAS affirmation regulations that covered three of the enzyme preparations from animal and plant sources included in the petition. These two regulations are: (1) § 184.1685 *Rennet (animal derived)* (21 CFR 184.1685), which was published in the **Federal Register** of November 7, 1983 (48 FR 51151) and includes the petitioned enzyme preparations rennet and bovine rennet; and (2) § 184.1585 *Papain* (21 CFR 184.1585), which was published in the **Federal Register** of October 21, 1983 (48 FR 48805). The agency concludes that rennet, bovine rennet, and papain are already affirmed as GRAS and listed in existing regulations and need not be addressed further.

In letters to FDA (Refs. 1 and 2), the petitioner asserted that the enzyme preparation malt (amylase) includes extracts from germinated (malted) barley or ungerminated (unmalted) barley. In addition, certain published references (Refs. 3 and 4) submitted by the petitioner describe the enzyme preparation pancreatin as a substance containing the enzymes amylase, lipase, and protease.

In a notice published in the **Federal Register** of September 20, 1993 (58 FR 48889), the agency announced that the petitioner had requested that the following enzyme preparations be withdrawn from the petition without prejudice to the filing of a future petition: (1) Pancreatin used for its lipase activity, (2) pancreatin used for its amylase activity, and (3) amylase derived from unmalted barley extract. In that notice, the agency stated that, in light of the petitioner's request, any future action by FDA on the petition would not include a determination of the GRAS status of these three enzyme preparations.

This final rule is a partial response to the petition and addresses only enzyme preparations from animal and plant sources. Microbial enzyme preparations will be dealt with separately in a future issue of the **Federal Register**. Furthermore, in accordance with the September 20, 1993, **Federal Register** notice, FDA's determination of the GRAS status of the enzyme preparation malt includes only the enzyme preparation derived from malted barley extracts. Likewise, FDA's determination of the GRAS status of the enzyme preparation pancreatin includes only the use of pancreatin as a protease.

II. Standards for GRAS Affirmation

Pursuant to § 170.30 (21 CFR 170.30) and 21 U.S.C. 321(s), 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 directly or indirectly added to food. The basis of such views may be either scientific procedures or, in the case of a substance used in food prior to January 1, 1958, experience based on common use in food. 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 and ordinarily is based upon published studies, which may be corroborated by unpublished studies and other data and information (§ 170.30(b)). General recognition of safety through experience based on common use in food prior to January 1, 1958, may be determined without the quantity or quality of scientific evidence required for approval of a food additive regulation, and ordinarily is based upon generally available data and information.

For the enzyme preparations from animal and plant sources that are the subject of this document, the Enzyme Technical Association based its request for affirmation of GRAS status on a history of safe food use prior to 1958. In the preamble to a proposed rule amending § 170.30, which was published in the **Federal Register** of July 2, 1985 (50 FR 27294) (final rule published in the **Federal Register** of May 10, 1988 (53 FR 16544)), FDA stated that general recognition of safety through experience based on common use in food requires a consensus on the safety of the substance among the community of experts who are qualified to evaluate the safety of food ingredients.

III. Background

A. Enzymes

Enzymes are proteins or conjugated proteins,[1] produced by plants, animals, and microorganisms, that function as biochemical catalysts (Ref. 5). Further, most enzymes are very specific in their ability to catalyze only certain chemical reactions; this high degree of specificity and strong catalytic activity are the most important functional properties of enzymes (Ref. 6). The practical applications of enzymes used in food processing include the conversion of starch to sugars in brewing, the tenderizing of sausage casings and meat, and the partial hydrolysis (breakdown) of proteins that would otherwise form a haze when beer is chilled (Ref. 7).

B. Enzyme Nomenclature

Enzymes were originally known principally by their trivial (common or historical) names. These trivial names typically were based on one of two methods of nomenclature: (1) By the addition of ''-in'' or ''-ain'' as a suffix to a root indicating the source of the enzyme (e.g., papain from papaya or pancreatin from pancreas); or (2) by the addition of the suffix ''-ase'' to a root indicating the substrate (specific reactant) for the enzyme (e.g., lactase, which acts on the substrate lactose) (Ref. 8). Some proteases, however, have trivial names that are not based on either of these two methods (e.g., trypsin).

In 1956, the Third International Congress of the International Union of Biochemistry (IUB) organized a Commission on Enzymes to devise a systematic strategy for naming enzymes. The system developed by the Commission on Enzymes combined a naming system and a numbering system (Ref. 8). With the exception of most proteases, the systematic name is derived from the names of the substrate, product, and type of reaction.[2] The systematic number is based on the class and subclasses to which the enzyme belongs. The two classes of enzymes in the numbering system relevant to this document are class 1, oxidoreductases (e.g., catalase), which are active in biological oxidation and reduction; and class 3, hydrolases (e.g., glycosidases (carbohydrases), lipases, and proteases), which catalyze the splitting of chemical bonds by the addition of water.

The following examples illustrate the trivial name, functions, and Enzyme Commission (EC) name and number of enzymes that are components of some of the enzyme preparations that are the subject of this document (Refs. 9 through 11).

α-*amylase.* Hydrolysis of α-1,4-glucan bonds in polysaccharides (starch, glycogen, etc.), yielding dextrins and oligo- and monosaccharides (1,4-α-D-glucan glucanohydrolase, EC 3.2.1.1).

Catalase. Decomposition of hydrogen peroxide (H_2O_2), yielding water and

[1] A conjugated protein is a protein that contains a nonamino acid moiety such as a carbohydrate.

[2] In general, proteolytic enzymes are not sufficiently defined to apply short systematic names.

molecular oxygen (H_2O_2:H_2O_2 oxidoreductase, EC 1.11.1.6).

C. Enzyme Preparations That Are the Subject of This Document

1. Introduction

The enzyme preparations that are the subject of this document are derived from animal or plant sources. They contain one or more active enzymes and may also contain diluents, preservatives, antioxidants, and other substances. Table 1 includes characterizing enzyme activities [3] of the animal- and plant-derived enzyme preparations that are the subject of this document, as well as their Chemical Abstracts Service Registry Numbers (CAS Reg. Nos.) and EC numbers as appropriate (Refs. 3, 4, and 9 through 11).

TABLE 1.—ENZYME ACTIVITIES, CAS REG. NOS., AND EC NUMBERS ASSOCIATED WITH SOME ENZYME PREPARATIONS

Enzyme preparation	Enzyme activity	CAS Reg. No.	EC No.
Catalase	Catalase	9001–05–2	1.11.1.6
Animal lipase	Lipase	9001–62–1	3.1.1.3
Pepsin	Protease	9001–75–6	3.4.23.1
Trypsin	Protease	9002–07–7	3.4.21.4
Pancreatin [1]	Protease Amylase Lipase	8049–47–6	N/A
Bromelain	Protease	9001–00–7	3.4.22.32
Ficin	Protease	9001–33–6	3.4.22.3
Malt [2]	α-amylase	N/A	3.2.1.1
	β-amylase		3.2.1.2

[1] Pancreatin is identified by a CAS Reg. No. but does not have an EC number.
[2] The α-amylase and β-amylase enzyme activities in malt are identified by EC number, but malt does not have a CAS Reg. No.

2. Animal-Derived Enzyme Preparations

a. *Sources.* The animal-derived enzyme preparations that are the subject of this document are derived from a variety of animal sources. Catalase is obtained from bovine liver (Ref. 9). Animal lipase is obtained from the edible forestomach tissue of calves, kids, or lambs, or from animal pancreatic tissue (Ref. 9). Pepsin is obtained from the glandular layer of hog stomach (Ref. 9). Trypsin is obtained from porcine or bovine pancreas (Ref. 9). Pancreatin is also obtained from porcine or bovine pancreas (Refs. 3 and 4). These source materials for bovine liver catalase, animal lipase, pepsin, trypsin, and pancreatin were described by Tauber in 1949 (Ref. 12) and by Reed, in Kirk and Othmer in 1957 (Ref. 13).

b. *Methods of manufacture.* The animal-derived enzyme preparations that are the subject of this document are produced either as tissue preparations (powders) or aqueous extracts of tissues from edible animals (Refs. 8, 9, 12, and 13). In the tissue preparation method, the animal tissue is ground with processing aids, such as sodium chloride and skim milk powder. In the aqueous extract method, the enzyme preparation may remain in aqueous solution, or it can be precipitated by adding a solvent such as acetone or methyl alcohol. For example, pepsin can be prepared by the aqueous extraction of animal tissue, while animal lipase can be prepared by the tissue preparation method as well as the aqueous extraction method.

c. *Technical effects.* Pre-1958 uses in food of animal-derived enzyme preparations are listed in Table 2, using terminology from the cited reference(s) published before or during 1958.

TABLE 2.—APPLICATIONS OF ANIMAL-DERIVED ENZYMES IN FOOD PRIOR TO 1958

Enzyme preparation	Enzyme activity	Food categories	Technical effect or industry application	References
Pepsin	Protease	Beer	Chillproofing	7, 13, 14, 15
		Condiments	Not reported	15
		Evaporated milk	Stabilization	15
Pancreatin	Protease	Milk	Prevention of oxidation flavor	13, 15
		Milk	Protein hydrolysis	13, 15
		Evaporated milk	Stabilization	15
Trypsin	Protease	Milk	Antioxidant	16
Lipase	Lipase	Italian type cheeses	Flavor production	13, 17, 18
Catalase	Catalase	Milk	Removal of peroxide after sterilization.	13, 15

3. Plant-Derived Enzyme Preparations

a. *Sources.* Bromelain is obtained from the pineapples *Ananas comosus* and *A. bracteatus* L. (Ref. 9). Ficin is obtained from the latex of species of the genus *Ficus* (fig tree) (Ref. 9). Malt is obtained from barley after controlled germination (Ref. 19). These source materials for bromelain, ficin, and malt were described by Tauber in 1949 (Ref. 12) and by Reed in 1957 (Ref. 13).

[3] The activity of a commercial product is a measurement of the rate of the reaction catalyzed by the enzyme of interest in the enzyme preparation, and is usually expressed in activity units per unit weight of the product (Ref. 8). The enzyme preparation is then diluted or concentrated until the activity is within a certain desired range.

b. *Methods of manufacture.* Bromelain is obtained from pineapple juice (pressed from the stems of pineapples that remain after harvesting the fruit) by precipitation with alcohol or ammonium sulfate (Refs. 8, 12, and 13). Ficin is obtained from the latex of a variety of tropical fig trees by precipitation with acetone or alcohol (Refs. 9, 12, and 14).

Malt is produced from germinated barley. The petition describes the following process for the manufacture of malt (Ref. 19). Barley is softened by a series of steeping operations in water at 10 °C to 30 °C until the moisture content of the kernels reaches 40 to 50 percent. The grain is then germinated under controlled conditions for a period of up to 7 days. Reducing substances are added to activate the enzymes. Solids are removed from the extract, which is concentrated, stabilized, and standardized. The resultant syrup is usually a brown, sweet, and viscous liquid with a specific gravity of approximately 1.1 to 1.3 at 25 °C.

c. *Technical effects.* Pre-1958 uses in food of plant-derived enzyme preparations are listed in Table 3, using terminology from the cited reference(s) published before or during 1958.

TABLE 3.—APPLICATIONS OF PLANT-DERIVED ENZYMES IN FOOD PRIOR TO 1958

Enzyme preparation	Enzyme activity	Food categories	Technical effect or industry application	References
Malt	Amylase	Bread	Baking	7, 14, 15
		Beer	Mashing	14, 15
		Precooked baby cereals	Not reported	15
		Breakfast cereals	Not reported	14, 15
		Distilled beverages	Mashing	15
Bromelain	Protease	Beer	Chillproofing	13, 14, 15
		Condiments	Not reported	15
		Milk	Protein hydrolysis	15
		Evaporated milk	Stabilization	15
		Meat	Tenderizing, softening tissue	13, 14, 15, 20
		Sausage casings	Tenderizing	14, 15
		Fish	Condensing fish solubles	15
Ficin	Protease	Meat	Softening	20

IV. Safety Evaluation

A. Pre-1958 History of Use in Food

Enzymes have been used for many years in the production and processing of food, for example, in the baking, dairy, and brewing industries (e.g., see Refs. 7, 13, and 14). The consumption of food produced using these enzymes has produced no evidence of an associated human health hazard.

The petitioner provided generally available information, including published papers and review articles, showing that the animal- and plant-derived enzyme preparations that are the subject of this document were commonly used in food prior to 1958. For example, the pre-1958 food uses shown in Tables 2 and 3 were documented in articles that were published in or before 1958; the cited references demonstrate that the use of these enzyme preparations in a variety of foods was widely recognized by 1958. Therefore, the agency concludes that the enzyme preparations that are the subject of this document were in common use in food prior to January 1, 1958.

B. Corroborating Evidence of Safety

1. The Enzyme Components

A wide variety of enzymes has always been present in human food. Moreover, many naturally occurring enzymes in the cells of animals and plants used for food remain active after cell death. For example, active enzymes are present in fresh fruits and vegetables and are not inactivated unless the fruits or vegetables are cooked (Refs. 6 and 21).

The enzymes that are the subject of this document are naturally occurring proteins that are ubiquitous in living organisms. They are derived from animals and plants that have been used as sources of food, and are identical or substantially similar[4] to enzymes that have been safely consumed as part of the diet throughout human history.

Issues relevant to a safety evaluation of proteins from food sources are potential toxicity and allergenicity. Pariza and Foster (Ref. 6) note that very few toxic agents have enzymatic properties, and those that do (e.g., diphtheria toxin and certain enzymes in the venom of poisonous snakes) catalyze unusual reactions that are not related to the types of catalysis that are common in food processing and that are the subject of this document. Further, the agency has recently noted, in the context of guidance to industry regarding the safety assessment of new plant varieties, that newly introduced enzymes do not generally raise safety concerns (Ref. 22). Exceptions include enzymes that produce substances that are not ordinarily digested and metabolized, or that produce toxic substances. The functions of the enzymes that are the subject of this document are well known; they split proteins, carbohydrates, lipids, or other substances (e.g., hydrogen peroxide) into smaller subunits that do not have toxic properties and that are readily metabolized by the human body.

The agency is not aware of any reports of allergic reactions associated with the ingestion in food of the enzymes that are the subject of this document. There have been, however, some reports of allergies and primary irritations from skin contact with enzymes or inhalation of dust from concentrated enzymes (for example, proteases used in the manufacture of laundry detergents) (Refs. 23 through 25). These reports relate primarily to workers in production plants (Ref. 24) and are not relevant to an evaluation of the safety of ingestion of such enzymes in food.

[4] Enzymes that have the same function and that are identified by the same name and EC number often differ slightly in structure and properties when they are obtained from different sources. For example, the structure of an enzyme isolated from one tissue (such as the liver) of one animal species, may differ slightly from that of the same enzyme isolated from a different tissue from the same species, or from the liver of another animal species. In part because of this variability, the diet routinely contains many thousands of different enzyme protein molecules. The concept of substantial similarity relative to food safety assessment has recently been discussed by several expert groups. For example, a report prepared by an expert group of the Organization for Economic Co-operation and Development (OECD) concluded, in part, ''[I]f a new food or food component is found to be substantially equivalent to an existing food or food component, it can be treated in the same manner with respect to safety. No additional safety concerns would be expected.'' (''Safety Evaluation of Foods Derived by Modern Biotechnology: Concepts and Principles,'' OECD, 1993, Paris).

Moreover, Pariza and Foster (Ref. 6) note that there are no confirmed reports of primary irritations in consumers caused by enzymes used in food processing.

The 1977 report of the Select Committee on GRAS substances concerning the plant enzyme papain (Ref. 23) supports the view that the ingestion of an active protease at levels found in food products is not likely to affect the human gastrointestinal tract, where many proteases already exist at levels adequate to digest food:

> In common with other proteolytic enzymes, papain digests the mucosa and musculature of tissues in contact with the active enzyme for an appreciable period. Because there is no food use of papain that could result in the enzyme preparation occurring in sufficient amount in foods to produce these effects, this property does not pose a dietary hazard.

In summary, the enzyme components of the preparations that are the subject of this document are identical or substantially similar to enzymes that are known to have been safely consumed in the diet; they do not result in the production of toxic substances; and their use in food for many years has not been associated with reports of allergenicity or primary irritation. Therefore, the agency finds that the presence of the enzyme components does not create a basis for concern about the safety of the enzyme preparations.

2. Enzyme Sources and Processing Aids

The agency has concluded that the enzyme components of enzyme preparations do not raise safety concerns; therefore, the relevant safety issue becomes whether the enzyme preparations contain toxic contaminants. Enzyme preparations used in food processing are usually not chemically pure but contain, in addition to the enzyme component, materials that derive from the enzyme source, as well as from the manufacturing methods used to generate the finished enzyme preparation.

In accordance with § 170.30(h)(1), the enzyme preparations affirmed as GRAS in this document must comply with the general requirements and additional requirements for enzyme preparations in the Food Chemicals Codex, 3d ed. (Ref. 9). When the animal-derived enzyme preparations that are the subject of this document are produced in accordance with current good manufacturing practice (CGMP), they are obtained from animal tissues that comply with applicable Federal meat inspection requirements and that are handled in accordance with good hygienic practices (Ref. 9). Similarly, when produced in accordance with CGMP, the plant material used in the production of enzymes consists of components that leave no residues harmful to health in the finished food under normal conditions of use (Ref. 9).

The enzyme preparations may contain substances, such as salts, preservatives, or stabilizers, that are used in their preparation and purification. When used in accordance with CGMP, these processing aids are substances that are acceptable for general use in foods (Ref. 9). As always, any of these substances that are intended to become or become functional components of the enzyme preparation must be GRAS substances or food additives approved for use in the manufacture of enzyme preparations. Therefore, the agency concludes that the presence of added substances and impurities derived from the enzyme source or introduced by manufacturing does not present a basis for concern about the safety of the enzyme preparations.

3. Dietary Exposure

Because enzymes are highly efficient catalysts, they are needed in only minute quantities to perform their function. When used in accordance with CGMP, the amounts added to food represent only a minute fraction of the total food mass. The history of common use in food for many years of the enzyme preparations that are the subject of this document has produced no evidence of an associated hazard; further, there is no reason to believe that use of these enzyme preparations at levels needed to perform their functions would raise a safety concern. Therefore, the agency concludes that no limits other than CGMP are needed to ensure safe use.

V. Comments

FDA received seven letters in response to the filing notice and none in response to the amendment notices. Three comments concerned microbially derived enzyme preparations, which will be addressed in a separate document. Of the remaining four comments, one came from a food manufacturer, two from trade associations, and one from a consumer group. Three comments supported the petition for GRAS affirmation of the enzyme preparations included in the petition, stating that these enzyme preparations have a long history of use in foods such as cheese, bread, and corn syrup.

One comment asserted that enzyme preparations should not be considered GRAS, and their use should be declared on the label of foods to warn consumers about hazards inherent in their use. The comment stated that enzyme preparations are rarely purified to any significant degree and contain a variety of cellular constituents and metabolic debris. The comment further argued that, although enzyme preparations are used at low levels and are inactivated after the treatment of food, they may elicit allergic reactions and other biological activities which could be detrimental to human health. In support of this statement, the comment cited a published scientific article (Ref. 26) which reported that enzyme preparations from *B. subtilis* caused temporary weight loss and aggravated infection in mice when injected into the abdominal cavity and caused hemolysis and hemagglutination of sheep erythrocytes in in vitro studies. Because this article concerns microbially derived enzyme preparations injected directly into the abdominal cavity, it is not relevant to this rulemaking, which concerns animal- and plant-derived enzyme preparations consumed by mouth.

The agency also notes that under certain circumstances, applicable regulations already require use of an enzyme preparation in a food to be declared on the label, depending upon the nature of the enzyme preparation's use and technical effect in the food. These regulatory requirements are discussed below.

The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(i)(2)) requires that all ingredients of multi-ingredient foods be listed on the label of the food. By regulation, FDA has exempted certain ingredients that are used only as processing aids from this requirement. Sections 101.100(a)(3)(ii)(a) and (a)(3)(ii)(c) (21 CFR 101.100(a)(3)(ii)(a) and (a)(3)(ii)(c)) provide an exemption from the ingredient listing requirement for processing aids that are added to a food for their technical or functional effect during processing, but are either removed from the food before packaging or are present in the finished food at insignificant levels and do not have any technical or functional effect in the finished food. Although many enzyme preparations are used as processing aids in food (e.g., the use of amylase preparations in the manufacture of glucose syrup and the use of protease preparations in the manufacture of protein hydrolyzates), other enzyme preparations are not used solely as processing aids in the manufacture of foods (e.g., the use of lipase preparations for flavor production in cheeses and the use of protease preparations in tenderizing meat). In these cases, the enzymes remain active

in the finished food product, functioning as an integral part of the food by enhancing body, flavor, and aroma (49 FR 29242, July 19, 1984). Because such effects in the finished food remove the enzymes from the ingredient listing exemption in § 101.100(a)(3)(ii)(c), the use of such enzymes must be declared on the label. Therefore, whether a label declaration is needed for the use of an enzyme preparation in a food will depend upon its function and effect in the food.

VI. Conclusions

The petitioner has provided generally available evidence demonstrating that the enzyme preparations under consideration were in common use in food prior to 1958. As provided for under § 170.30(a) and (c)(1), FDA has determined that this information provides an adequate basis upon which to conclude that the use of these enzyme preparations in food is generally recognized as safe among the community of experts qualified by scientific training and experience to evaluate the safety of food ingredients.

This evidence of common use in food prior to 1958 without any reported adverse effects from consumption is corroborated by the absence of any reports of toxicity resulting from use of the enzyme preparations in food since 1958, by information that the enzymes themselves and the sources from which they are derived are nontoxic, and by evidence that manufacturing will not introduce impurities that will adversely affect the safety of the finished enzyme preparations. Moreover, the enzyme preparations that are the subject of this document are substantially similar to enzymes naturally present in foods that have been safely consumed in the human diet for centuries.

Having evaluated the information in the petition, along with other available information that related to the use of these enzyme preparations, the agency concludes that the following enzyme preparations derived from animal or plant sources are GRAS under conditions of use consistent with CGMP: Bromelain, catalase (bovine liver), ficin, animal lipase, malt, pancreatin (as a source of protease activity), pepsin, and trypsin. The agency is basing its conclusion on evidence of a substantial history of safe consumption of the enzyme preparations in food by a significant number of consumers prior to 1958, corroborated by the other evidence summarized above.

FDA is therefore affirming that the use of the enzyme preparations that are the subject of this document is GRAS with no limits other than CGMP (21 CFR 184.1(b)(1)). The agency further concludes that the general and additional requirements for enzyme preparations in the Food Chemicals Codex, 3d ed. (1981), pp. 107–110, are adequate as minimum criteria for food-grade preparations of these enzymes.

To clarify the identity of each enzyme preparation, the agency is including in §§ 184.1024(a), 184.1034(a), 184.1316(a), 184.1415(a), 184.1443a(a), 184.1583(a), 184.1595(a), and 184.1914(a), the EC number(s) of the enzyme preparation or of the characterizing enzyme activity(ies) for food use of the preparation [5]. In order to make clear that the affirmation of the GRAS status of these enzyme preparations is based on the evaluation of specific uses, the agency is including in §§ 184.1024(c), 184.1034(c), 184.1316(c), 184.1415(c), 184.1443a(c), 184.1583(c), 184.1595(c), and 184.1914(c) the technical effect and the specific substances on which each enzyme preparation acts, although the data show no basis for a potential risk from any foreseeable use of these enzyme preparations.

VII. Environmental Impact

The agency has determined under 21 CFR 25.24(b)(7) 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.

VIII. Economic Impact

FDA has examined the impact of this final rule affirming the GRAS status of enzyme preparations from animal and plant sources under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs Federal agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). The Regulatory Flexibility Act requires Federal agencies to minimize the economic impact of their regulations on small businesses.

The agency finds that this final rule is not a significant regulatory action as defined by Executive Order 12866. The rule requires no change in current industry practice concerning the manufacture and use of these substances. Compliance costs to firms are therefore estimated to be zero. The substances that are the subject of this document pose no health risks to consumers when used as intended. Costs to consumers are therefore also estimated to be zero.

In accordance with the Regulatory Flexibility Act, FDA also has determined that this final rule will not have a significant adverse impact on a substantial number of small businesses.

[5] The EC number is sufficient to define the characterizing activity in the enzyme preparation. Therefore, FDA is not including the EC systematic name in the regulation.

IX. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Comments of Ad Hoc Enzyme Technical Committee regarding FDA's draft final regulations, entitled ''Enzymes Proposed for Affirmation as GRAS,'' with a letter dated December 21, 1984, from Roger D. Middlekauff, Ad Hoc Enzyme Technical Committee, to Kenneth A. Falci, FDA.
2. Letter dated September 20, 1985, from Roger D. Middlekauff, Enzyme Technical Association, to Lawrence J. Lin, FDA.
3. Monograph on ''Pancreatin,'' U.S. Pharmacopeia, 21st revision, the United States Pharmacopeial Convention, Inc., Rockville, MD, pp. 777–778, 1985.
4. Monograph on ''Pancreatin,'' U.S. Pharmacopeia, 6th supp., the United States Pharmacopeial Convention, Inc., Rockville, MD, pp. 2595–2597, 1987.
5. Morris, W., editor, The American Heritage Dictionary of the English Language, Houghton Mifflin Co., Boston, MA, p. 438, 1976.
6. Pariza, M. W., and E. M. Foster, ''Determining the Safety of Enzymes Used in Food Processing,'' *Journal of Food Protection*, 46:453–468, 1983.
7. Reed, G., ''Industrial Enzymes—Now Speed Natural Processes,'' *Food Engineering*, 24:105–109, 1952.
8. Scott, D., ''Enzymes, Industrial,'' Encyclopedia of Chemical Technology, Mark, H. F. et al., editors, John Wiley and Sons, New York, 3d ed., 9:173–224, 1978.
9. Monograph on ''Enzyme Preparations,'' Food Chemicals Codex, National Academy Press, Washington, DC, 3d ed., pp. 107–110, and 480–481, 1981.
10. IUB, ''Enzyme Nomenclature 1992,'' Academic Press, New York, pp. 116, 307, 346, 388, 399, 402–403, 1992.
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12. Tauber, H., ''The Chemistry and Technology of Enzymes,'' John Wiley and Sons, New York, pp. 25–26, 130–131, 140, 145–151, 163–167, 192–193, and 327–335, 1949.

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14. Underkofler, L. A., and W. J. Ferracone, ''Commercial Enzymes—Potent Catalyzers that Promote Quality,'' *Food Engineering,* 29:123, 125–126, 130, and 133, 1957.
15. Underkofler, L. A., R. R. Barton, and S. S. Rennet, ''Microbiological Process Report—Production of Microbial Enzymes and Their Applications,'' *Applied Microbiology,* 6:212–221, 1958.
16. Smythe, C. V., ''Microbiological Production of Enzymes and Their Practical Applications,'' *Economic Botany,* 5:126–144, 1951.
17. Harper, W. J. and J. E. Long, ''Italian Cheese Ripening. IV. Various Free Amino and Fatty Acids in Commercial Provolone Cheese,'' *Journal of Dairy Science,* 39:129–137, 1956.
18. Long, J. E., and W. J. Harper, ''Italian Cheese Ripening. VI. Effects of Different Types of Lipolytic Enzyme Preparations on the Accumulation of Various Free Fatty and Free Amino Acids and the Development of Flavor in Provolone and Romano Cheese,'' *Journal of Dairy Science,* 39:245–252, 1956.
19. Response of the Enzyme Technical Association to the letter dated June 26, 1986, of Lawrence J. Lin regarding GRASP 3G0016, received with a letter dated October 3, 1986, from Roger D. Middlekauff of the Enzyme Technical Association, to Lawrence J. Lin, FDA.
20. ''List of Chemicals Approved Under Meat Inspection Act Before September 6, 1958, Which are Exempted from the 1958 Food Additives Amendment of the Federal Food, Drug, and Cosmetic Act,'' *Food Drug Cosmetic Law Journal,* 13:834–840, 1958.
21. De Becze, G. I., ''Food Enzymes,'' *Critical Reviews in Food Technology,*'' 1:479–518, 1970.
22. FDA, ''Statement of Policy: Foods Derived from New Plant Varieties,'' 57 FR 22984 at 23005; May 29, 1992.
23. ''Evaluation of the Health Aspects of Papain as a Food Ingredient,'' Select Committee on GRAS Substances, Washington, DC, available through U.S. Department of Commerce, National Technical Information Service, Order No. PB–274–174, 1977.
24. Fulwiler, R. D., ''Detergent Enzymes—An Industrial Hygiene Challenge,'' *American Industrial Hygiene Association Journal,* 32:73–81, 1971.
25. ''Enzyme-containing Laundering Compounds and Consumer Health,'' National Research Council/National Academy of Sciences, National Technical Information Service, Washington, DC, Order No. PB–204–118, 1971.
26. Dubos, R., ''Toxic Factors in Enzymes Used in Laundry Products,'' *Science,* 173:259–260, 1971.

List of Subjects in 21 CFR Part 184

Food ingredients, Incorporation by reference.

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 184 is amended as follows:

PART 184—DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

1. The authority citation for 21 CFR part 184 continues to read as follows:

Authority: Secs. 201, 402, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 371).

2. Section 184.1024 is added to subpart B to read as follows:

§ 184.1024 Bromelain.

(a) Bromelain (CAS Reg. No. 9001–00–7) is an enzyme preparation derived from the pineapples *Ananas comosus* and *A. bracteatus* L. It is a white to light tan amorphous powder. Its characterizing enzyme activity is that of a peptide hydrolase (EC 3.4.22.32).

(b) The ingredient meets the general requirements and additional requirements for enzyme preparations in the Food Chemicals Codex, 3d ed. (1981), p. 110, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC, or may be examined at the Office of Premarket Approval (HFS–200), Food and Drug Administration, 200 C St. SW., Washington, DC, and the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as GRAS as a direct food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an enzyme as defined in § 170.3(o)(9) of this chapter to hydrolyze proteins or polypeptides.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

3. Section 184.1034 is added to subpart B to read as follows:

§ 184.1034 Catalase (bovine liver).

(a) Catalase (bovine liver) (CAS Reg. No. 9001–05–2) is an enzyme preparation obtained from extracts of bovine liver. It is a partially purified liquid or powder. Its characterizing enzyme activity is catalase (EC 1.11.1.6).

(b) The ingredient meets the general requirements and additional requirements for enzyme preparations in the Food Chemicals Codex, 3d ed. (1981), p. 110, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, 2101 Constitution Ave., NW., Washington, DC 20418, or may be examined at the Office of Premarket Approval (HFS–200), Food and Drug Administration, 200 C St., SW., Washington, DC, and the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as GRAS as a direct food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an enzyme as defined in § 170.3(o)(9) of this chapter to decompose hydrogen peroxide.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

4. Section 184.1316 is added to subpart B to read as follows:

§ 184.1316 Ficin.

(a) Ficin (CAS Reg. No. 9001–33–6) is an enzyme preparation obtained from the latex of species of the genus *Ficus*, which include a variety of tropical fig trees. It is a white to off-white powder. Its characterizing enzyme activity is that of a peptide hydrolase (EC 3.4.22.3).

(b) The ingredient meets the general requirements and additional requirements for enzyme preparations in the Food Chemicals Codex, 3d ed. (1981), p. 110, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, 2101 Constitution Ave., NW., Washington, DC 20418, or may be examined at the Office of Premarket Approval (HFS–200), Food and Drug Administration, 200 C St., SW., Washington, DC, and the Office of the Federal Register, 800 North Capitol St., NW., suite 700, Washington, DC.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as GRAS as a direct food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an enzyme as defined in § 170.3(o)(9) of this chapter to hydrolyze proteins or polypeptides.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

5. Section 184.1415 is added to subpart B to read as follows:

§ 184.1415 Animal lipase.

(a) Animal lipase (CAS Reg. No. 9001–62–1) is an enzyme preparation obtained from edible forestomach tissue of calves, kids, or lambs, or from animal pancreatic tissue. The enzyme preparation may be produced as a tissue preparation or as an aqueous extract. Its characterizing enzyme activity is that of a triacylglycerol hydrolase (EC 3.1.1.3).

(b) The ingredient meets the general requirements and additional requirements for enzyme preparations in the Food Chemicals Codex, 3d ed. (1981), p. 110, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, 2101 Constitution Ave., NW., Washington, DC 20418, or may be examined at the Office of Premarket Approval (HFS–200), Food and Drug Administration, 200 C St., SW., Washington, DC, and the Office of the Federal Register, 800 North Capitol St., NW., suite 700, Washington, DC.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as GRAS as a direct food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an enzyme as defined in § 170.3(o)(9) of this chapter to hydrolyze fatty acid glycerides.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

6. Section 184.1443a is added to subpart B to read as follows:

§ 184.1443a Malt.

(a) Malt is an enzyme preparation obtained from barley which has been softened by a series of steeping operations and germinated under controlled conditions. It is a brown, sweet, and viscous liquid or a white to tan powder. Its characterizing enzyme activities are α-amylase (EC 3.2.1.1.) and β-amylase (EC 3.2.1.2).

(b) The ingredient meets the general requirements and additional requirements for enzyme preparations in the Food Chemicals Codex, 3d ed. (1981), p. 110, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, 2101 Constitution Ave., NW., Washington, DC 20418, or may be examined at the Office of Premarket Approval (HFS–200), Food and Drug Administration, 200 C St., SW., Washington, DC, and the Office of the Federal Register, 800 North Capitol St., NW., suite 700, Washington, DC.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as GRAS as a direct food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an enzyme as defined in § 170.3(o)(9) of this chapter to hydrolyze starch or starch-derived polysaccharides.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

7. Section 184.1583 is added to subpart B to read as follows:

§ 184.1583 Pancreatin.

(a) Pancreatin (CAS Reg. No. 8049–47–6) is an enzyme preparation obtained from porcine or bovine pancreatic tissue. It is a white to tan powder. Its characterizing enzyme activity that of a peptide hydrolase (EC 3.4.21.36).

(b) The ingredient meets the general requirements and additional requirements in the Food Chemicals Codex, 3d ed. (1981), p. 110, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of Premarket Approval (HFS–200), Food and Drug Administration, 200 C St. SW., Washington, DC, and the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as GRAS as a direct food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an enzyme as defined in § 170.3(o)(9) of this chapter to hydrolyze proteins or polypeptides.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

8. Section 184.1595 is added to subpart B to read as follows:

§ 184.1595 Pepsin.

(a) Pepsin (CAS Reg. No. 9001–75–6) is an enzyme preparation obtained from the glandular layer of hog stomach. It is a white to light tan powder, amber paste, or clear amber to brown liquid. Its characterizing enzyme activity is that of a peptide hydrolase (EC 3.4.23.1).

(b) The ingredient meets the general requirements and additional requirements for enzyme preparations in the Food Chemicals Codex, 3d ed. (1981), p. 110, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of Premarket Approval (HFS–200), Food and Drug Administration, 200 C St. SW., Washington, DC, and the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as GRAS as a direct food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an enzyme as defined in § 170.3(o)(9) of this chapter to hydrolyze proteins or polypeptides.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

9. Section 184.1914 is added to subpart B to read as follows:

§ 184.1914 Trypsin.

(a) Trypsin (CAS Reg. No. 9002–07–7) is an enzyme preparation obtained from purified extracts of porcine or bovine pancreas. It is a white to tan amorphous powder. Its characterizing enzyme activity is that of a peptide hydrolase (EC 3.4.21.4).

(b) The ingredient meets the general requirements and additional requirements for enzyme preparations in the Food Chemicals Codex, 3d ed. (1981), p. 110, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of Premarket Approval (HFS–200), Food and Drug Administration, 200 C St. SW., Washington, DC, and the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good

manufacturing practice. The affirmation of this ingredient as GRAS as a direct food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an enzyme as defined in § 170.3(o)(9) of this chapter to hydrolyze proteins or polypeptides.

(2) The ingredient is used in food at levels not to exceed current good manufacturing practice.

Dated: June 14, 1995.

Fred. R, Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 95–15239 Filed 6–23–95; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF EDUCATION

34 CFR Parts 75, 200, 201, 364, 365, 366, 367, 386, 388, 396, 403, 405, 406, 607, 641, 647, and 682

Announcement of Effective Dates

AGENCY: Department of Education.

ACTION: Notice of effective dates.

SUMMARY: Prior to its amendment by the Improving America's Schools Act of 1994 (IASA), section 431(d) of the General Education Provisions Act (GEPA) required that most Department of Education regulatory documents be published in the **Federal Register** for forty-five (45) calendar days, or longer if Congress took certain adjournments, before they became effective. Since future congressional adjournments could not be predicted with certainty when a document was published, the Department could not announce a specific effective date at the time of publication. This notice announces the effective dates for certain regulatory documents subject to the delayed effective date requirement of section 431(d) prior to its amendment.

DATES: For effective dates, see **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: Kenneth C. Depew, Division of Regulations Management, Office of the General Counsel, U.S. Department of Education, Room 5112, FB–10, 600 Independence Avenue SW., Washington, DC 20202–2241; telephone: (202) 401–8300.

Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern time, Monday through Friday.

SUPPLEMENTARY INFORMATION: GEPA section 431(d) was amended by the IASA, Pub. L. 103–382, enacted October 20, 1994. Section 431 was also redesignated as section 437. As a consequence of the new legislation, regulations of the Department are no longer subject to a 45-day delayed effective date. This notice announces the effective dates for those regulations subject to the previous statutory requirement for the delayed effective date. In the future, as a result of the new legislation, it will not be necessary for the Department to publish a special announcement of effective dates.

The effective date provision for each of the regulatory documents included in the notice stated that the effective date would be announced in a notice published in the **Federal Register**. Accordingly, this notice announces the following effective dates:

1. 34 CFR Part 682, final regulations for the Federal Family Education Loan Program, published May 17, 1994 (59 FR 25744).
   DATES: *Effective date:* July 1, 1994.
2. 34 CFR Part 75, final regulations for Direct Grant Programs, published June 10, 1994 (59 FR 30258).
   DATES: *Effective date:* July 25, 1994.
3. 34 CFR Part 386, final regulations for Rehabilitation Training: Rehabilitation Long-Term Training, published June 16, 1994 (59 FR 31060).
   DATES: *Effective date:* July 31, 1994.
4. 34 CFR Part 641, final regulations for the Faculty Development Fellowship Program, published July 1, 1994 (59 FR 34198).
   DATES: *Effective date:* August 15, 1994.
5. 34 CFR Parts 403, 405, and 406, final regulations for the State Vocational and Applied Technology Education Program, National Tech-Prep Education Program, and State-Administer Tech-Prep Education Program, published July 28, 1994 (59 FR 38512).
   DATES: *Effective date:* September 21, 1994.
6. 34 CFR Part 388, final regulations for State Vocational Rehabilitation Unit In-Service Training, published August 5, 1994 (59 FR 40176).
   DATES: *Effective date:* September 21, 1994.
7. 34 CFR Parts 200 and 201, final regulations for the Chapter 1 Program in Local Educational Agencies and Chapter 1—Migrant Education Program, published August 10, 1994 (59 FR 41168).
   DATES: *Effective date:* September 24, 1994.
8. 34 CFR Parts 364, 365, 366, and 367, final regulations for State Independent Living Services Program and Centers for Independent Living Program: General Provisions, State Independent Living Services, Centers for Independent Living, and Independent Living Services for Older Individuals Who Are Blind, published August 15, 1994 (59 FR 41908).
   DATES: *Effective date:* September 29, 1994.
9. 34 CFR Part 607, final regulations for the Strengthening Institutions Program, published August 15, 1994 (59 FR 41914).
   DATES: *Effective date:* September 29, 1994.
10. 34 CFR Part 647, final regulations for the Ronald E. McNair Postbaccalaureate Achievement Program, published August 25, 1994 (59 FR 43986).
    DATES: *Effective date:* November 7, 1994.
11. 34 CFR Part 396, final regulations for Training Interpreters for Individuals Who Are Deaf and Individuals Who Are Deaf-Blind, published October 14, 1994 (59 FR 52218).
    DATES: *Effective date:* November 28, 1994.

Dated: June 21, 1995.

Judith A. Winston,

General Counsel.

[FR Doc. 95–15559 Filed 6–23–95; 8:45 am]

BILLING CODE 4000–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[AD–FRL–5225–9]

National Emission Standards for Hazardous Air Pollutants for Source Categories: Gasoline Distribution (Stage I)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; correction.

SUMMARY: This document makes clarifications and corrects errors in the regulatory text of the final rule for National Emission Standards for Gasoline Distribution Facilities (Bulk Gasoline Terminals and Pipeline Breakout Stations) which appeared in the **Federal Register** on December 14, 1994 (59 FR 64303).

EFFECTIVE DATE: December 14, 1994.

FOR FURTHER INFORMATION CONTACT: For general and technical information concerning the final rule, contact Mr. Stephen Shedd, Waste and Chemical