- Reed, G., "Enzymes, Industrial," Encyclopedia of Chemical Technology, Kirk, R. E. and D. F. Othmer, editors, Interscience Encyclopedia, Inc., New York, 1st supplemental vol., pp. 294– 312, 1957.
- Underkofler, L. A., and W. J. Ferracone, "Commercial Enzymes—Potent Catalyzers that Promote Quality," *Food Engineering*, 29:123, 125–126, 130, and 133, 1957.
- 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.
- 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.
- 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.
- De Becze, G. I., "Food Enzymes," Critical Reviews in Food Technology," 1:479– 518, 1970.
- FDA, "Statement of Policy: Foods Derived from New Plant Varieties," 57 FR 22984 at 23005; May 29, 1992.
- "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.
- 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.
- 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 \S 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 \S 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: