PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

99–11–09 Pratt & Whitney: Amendment 39–11180. Docket No. 94–ANE–54. Supersedes AD 94–26–06, Amendment 39-9102.

Applicability: Pratt & Whitney (PW) JT9D–59A, –70A, –7Q, and –7Q3 series turbofan engines, installed on but not limited to Airbus A300 series, Boeing 747 series, and McDonnell Douglas DC–10 series aircraft.

Note 1: This airworthiness directive (AD) applies to each engine identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For engines that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (b) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent diffuser case rupture, an uncontained engine failure, and damage to the aircraft, accomplish the following:

(a) Perform initial and repetitive fluorescent penetrant inspections (FPI) or eddy current inspections (ECI) of diffuser case rear rails for cracks in accordance with the Accomplishment Instructions of PW JT9D (SB) No. 5749, Revision 8, dated October 30, 1998, as follows:

(1) For engines on-wing that have not had the diffuser case rear rail FPI or ECI inspected using the procedures referenced in PW JT9D SB No. 5749, Revision 4, dated May 10, 1993; Revision 5, dated September 29, 1995; Revision 6, dated May 8, 1998; Revision 7, dated August 19, 1998; or Revision 8, dated October 30, 1998; Section 2, Part 1 A (1)–(3), accomplish the following:

(i) Perform an initial on-wing inspection within 25 cycles of the effective date of this AD in accordance with Section 2, Part 2 of PW JT9D SB No. 5749, Revision 8, dated October 30, 1998.

(ii) Thereafter, except as provided in paragraph (a)(4) of this AD, perform on-wing inspections in accordance with the time requirements listed in Section 2, Part 2 of PW JT9D SB No. 5749, Revision 8, dated October 30, 1998.

(2) For engines on-wing that have had the diffuser case rear rail FPI or ECI inspected using the procedures referenced in PW JT9D SB No. 5749, Revision 4, dated May 10, 1993; Revision 5, dated September 29, 1995; Revision 6, dated May 8, 1998; Revision 7, dated August 19, 1998; or Revision 8, dated October 30, 1998; Section 2, Part 1 A (1)–(3), perform initial and repetitive on-wing inspections in accordance with PW JT9D SB 5749, Revision 8, dated October 30, 1998, within the time requirements listed in Section 2, Part 2 of that SB, except as provided in paragraph (a) (4) of this AD.

(3) Remove from service diffuser cases that do not meet the return to service criteria stated in PW JT9D SB No. 5749, Revision 8, dated October 30, 1998, Section 2, Part 2 D, and replace with serviceable parts.

(4) For engines that are overdue for an inspection on the effective date of this AD, accomplish the required inspection within 25 cycles in service of the effective date of this AD.

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Engine Certification Office. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Engine Certification Office.

Note 2: Information concerning the existence of approved alternative methods of compliance with this airworthiness directive, if any, may be obtained from the Engine Certification Office.

(c) Special flight permits may be issued in accordance with §§ 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the aircraft to a location where the requirements of this AD can be accomplished.

(d) The actions required by this AD shall be accomplished in accordance with the following Pratt & Whitney SB:

Document No.	Pages	Revision	Date
5749	1, 2	8	October 30, 1998.
	3	6	May 8, 1998.
	4	7	August 19, 1998.
	5–7	6	May 8, 1998.
	8, 9	8	October 30, 1998.
	10, 11	6	May 8, 1998.
	12	7	August 19, 1998.
	13–18	6	May 8, 1998.
Total pages: 18.			

This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Pratt & Whitney, Publication Department, Supervisor Technical Publications Distribution, M/S 132–30, 400 Main St., East Hartford, CT 06108; telephone (860) 565–7700, fax (860) 565–4503. Copies may be inspected at the FAA, New England Region, Office of Regional Counsel, 12 New England Executive Park, Burlington, MA; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(e) This amendment becomes effective on July 26, 1999.

Issued in Burlington, Massachusetts, on May 18, 1999.

David A. Downey,

Assistant Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 99–13322 Filed 5–25–99; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 184

[Docket No. 79G–0372]

Direct Food Substances Affirmed as Generally Recognized as Safe: Cellulase Enzyme Preparation Derived From Trichoderma Longibrachiatum for Use In Processing Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to affirm that cellulase enzyme preparation derived from *Trichoderma longibrachiatum* (formerly called *Trichoderma reesei*) as generally recognized as safe (GRAS) is for use in processing food. This action is in response to a petition filed by the AAC Consulting Group, Inc., on behalf of Novo Laboratories, Inc.

DATES: This regulation is effective May 26, 1999. 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 in § 184.1250 (21 CFR 184.1250), effective May 26, 1999.

FOR FURTHER INFORMATION CONTACT: Nega Beru, Center for Food Safety and Applied Nutrition (HFS–206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3097.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with the procedures described in § 170.35 (21 CFR 170.35), AAC Consulting Group, Inc. (formerly Arthur A. Checci, Inc.), 7445 Wisconsin Ave., suite 850, Bethesda MD 20814, on behalf of Novo Nordisk BioChem North America, Inc. (formerly Novo Laboratories, Inc.), State Rd. 1003, P.O. Box 576, Franklinton, NC 27525–0576, submitted a petition (GRASP 9G0260) requesting affirmation that cellulase enzyme preparation derived from a nonpathogenic strain of *T. reesei* (later renamed *T. longibrachiatum*) used for processing food is GRAS. Cellulase, the enzyme, is to be distinguished from cellulase enzyme preparation, which contains cellulase as the principal active component, but it also contains other components derived from the production organism and fermentation media. This document will refer to the former as ''cellulase'' and the latter as ''cellulase enzyme preparation.''

In the **Federal Register** of November 27, 1979 (44 FR 67731), FDA published a notice of filing of GRASP 9G0260, and gave interested parties an opportunity to submit comments. FDA received one comment in response to the notice. The comment urged the agency to affirm the GRAS status of the cellulase enzyme preparation without restricting its use in food other than to require that the use of the enzyme be consistent with current good manufacturing practice.

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 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.

In its petition, Novo Nordisk BioChem North America, Inc., relied on scientific procedures, primarily published studies, scientific papers and books, to demonstrate the safety and identity of the cellulase enzyme and the production strain from which it is derived. The petitioner provided published studies documenting that cellulase enzyme preparation derived from nontoxicogenic, nonpathogenic *T. longibrachiatum* is GRAS.

In evaluating this petition, the agency reviewed information concerning: (1) The production organism, (2) the identity and function of the cellulase enzyme, (3) the production and purification of the cellulase enzyme preparation, (4) the use of the cellulase enzyme preparation in the production of food products, and (5) the safety of the enzyme preparation.

III. Safety Evaluation

A. Introduction

Commercial enzyme preparations that are used in food processing typically are not chemically pure, but they contain, in addition to the enzyme component, other components that derive from the production organism and fermentation media, residual amounts of processing aids, and substances used as stabilizers, preservatives or diluents. Issues relevant to a safety evaluation of the enzyme preparation therefore include the safety of the enzyme component, the safety of the enzyme source, and the safety of processing aids and other substances added during the manufacturing process. A safety evaluation of an enzyme preparation also includes consideration of dietary exposure to that preparation.

B. Production Organism

In a submission dated December 7, 1988, the petitioner informed the agency that the International Commission on Taxonomy of Fungi (ICTF) had decided to rename the source organism, a fungus known for its high cellulase productivity, from *T. reesei*, to *T. longibrachiatum* (Ref. 1). The petitioner presented published studies to assess potential pathogenicity of *T. longibrachiatum* in mice, rabbits, and guinea pigs (Ref. 2). No adverse reactions were reported in these studies. The petitioner also included in its petition the results of a search of several scientific data bases including Biological Abstracts, 1977–83; Chemical Abstracts, 1977–83; Scisearch, 1978–83; Medline, 1980–83; and Food Science and Technology Abstracts, 1969–83. The petitioner states that these searches demonstrate that *T. longibrachiatum* is well known and available to the scientific community, and the data bases contain studies in which the microorganism, or enzymes derived from it, were utilized without any evidence of pathogenicity or toxicogenicity being associated with their use. The searches did not identify a single report that *T. longibrachiatum* is the etiological agent of a disease in man or animals. The agency concludes, based upon the published information presented in the petition (Refs. 2 through 6) that the production organism *T. longibrachiatum* has been adequately identified and determined to be nontoxicogenic and nonpathogenic (Ref. 7).

C. Identity and Function of the Cellulase Enzyme

Cellulase is the accepted name for the enzyme that catalyzes the endohydrolysis of 1,4-beta-glucosidic linkages in cellulose (Ref. 8). The enzyme will also hydrolyze 1,4-linkages in beta-glucans. The enzymatically formed reaction products are mainly glucose and cellobiose, a disaccharide composed of two glucose molecules. According to the recommendations of the International Union of Pure and Applied Chemistry and the International Union of Biochemistry (1972), cellulase has the following designation: Cellulase, E.C. 3.2.1.4 (Ref. 9). FDA concludes that generally available and accepted data and information establish that the cellulase that is the subject of this document is capable of achieving its intended technical effect.

D. Production of Cellulase Enzyme Preparation

The production process for cellulase enzyme preparation from *T. longibrachiatum* is described in GRASP 9G0260 and can be summarized as follows. A pure culture of *T. longibrachiatum* is aseptically grown in a typical culture medium such as one containing potato starch, soybean meal, corn steep liquor, or dextrose. Mineral salts, such as phosphates and sulfates, are included in the medium which also contains an antifoaming agent and a surfactant. The fermentation is conducted at 26 to 32 °C with aeration and maximal agitation. Cell growth and the possible presence of foreign microorganisms are monitored by taking samples before inoculation of the fermenter, every 24 hours during cultivation, and before transfer/harvesting.

After 100 to 170 hours, the culture broth is subjected to flocculation and filtration. The enzyme, which is secreted into the extracellular medium, is separated from the mycelium by action of the flocculating agent. This material is then removed by filtration using a filter aid. The enzyme, which remains in solution, is concentrated by ultrafiltration or vacuum evaporation at 30 to 40 °C. The enzyme suspension is then dried to a powder by spray drying or concentrated in liquid form by vacuum evaporation. The packaged finished product, powder or liquid, is shipped or stored at 4 °C.

The agency finds that the fermentation generating organism is maintained in a manner to avoid contamination and genetic changes, that the fermentation is a pure culture fermentation initially and is monitored for purity periodically during the culture period, and that the filtration step in the purification process would remove any viable production organisms from the final product (Ref. 7). The agency further finds that, because the potential impurities in the cellulase enzyme preparation that may originate from the source or manufacturing process do not raise any basis for concern about the safe use of the preparation, the general requirements for enzyme preparations as described in the ''Food Chemicals Codex,'' 4th ed. (1996) (Ref. 10), which are being incorporated by reference in new § 184.1250 in accordance with 5 U.S.C. 552(a) and 1 CFR part 51, are adequate as minimum criteria for food-grade cellulase enzyme preparation.

E. Use in Food

The function of cellulase enzyme preparation in food production includes uses such as the breakdown of the cellulose in citrus products, removal of fiber from edible oil press cakes, increase in starch recovery from potatoes, extraction of proteins from leaves and grasses, tenderizing fruits and vegetables prior to cooking, extraction of essential oils and flavoring material from plant materials, the preparation of animal feeds, and other uses that are discussed in publications such as the *Handbook of Food Additives* (Refs. 11 and 12) .

The petitioner also presented additional published information that the cellulase enzyme preparation performed its intended technical effect in the production of various food materials. Cellulase enzyme preparation has been shown to be effective in the degradation of vegetable tissues and in the extraction of green tea components, vegetable proteins and starches. Cellulase enzyme preparation is also capable of modifying food materials such as vegetables, rice, and soybeans to markedly influence the digestibility, cooking quality, shape, and the yield of nutrients (Ref. 13).

The agency has considered the estimated dietary exposure to cellulase enzyme preparation from its proposed use (Refs. 14 and 15). Enzymes, including the petitioned cellulase, are used in small quantities in food to accomplish their intended effects. In addition, many food processes that use cellulase also include removal of insoluble solids, a processing step that should remove most of the added enzyme preparation. Nonetheless, in calculating the estimated dietary exposure to cellulase enzyme preparation, the agency made the conservative assumptions that no cellulase enzyme preparation is removed from the food by processing, and all foods that may be treated with cellulase enzyme preparation will be so treated. The agency concludes that the dietary exposure to cellulase enzyme preparation does not present a basis for concern about the safety of its use (Refs. 16 and 17).

F. Safety Studies

The petitioner has provided published studies with the cellulase enzyme preparation, corroborated with unpublished studies, to demonstrate that the enzyme preparation is safe for use in food. The petitioner provided published oral acute toxicity studies with mice, rats, and dogs and oral subchronic studies with rats and dogs (Ref. 2). No significant adverse effects were noted in these studies.

A published toxicity study with *in utero* exposure, and a teratogenicity study, both conducted with rats, reported no adverse effects at levels up to 5 percent in the diet (Ref. 2). The petitioner also provided published mutagenicity studies involving the Ames test, chromosomal aberration tests, and dominant lethal tests (Ref. 2). There was no evidence of mutagenicity of the cellulase enzyme preparation in any of these tests. Other published studies with the cellulase enzyme preparation provided by the petitioner include an inhalation study in rats; skin and eye irritation tests in rabbits; a skin irritation test in humans; and a skin sensitivity test in guinea pigs and humans. Finally, because certain species of Trichoderma are known to produce substances that inhibit the growth of microorganisms, the petitioner tested the culture broth of *T. longibrachiatum* for antibiotics or toxins; the tests were negative (Ref. 2).

The agency has reviewed the published safety studies in the petition along with other available information. The agency concludes that the published safety data support the use of cellulase enzyme preparation from *T. longibrachiatum* for the enzymatic breakdown of cellulose in processing food (Refs. 16 and 17).

IV. Conclusions

The agency has evaluated all available information and finds, based upon the published information about the identity and function of cellulase, that the enzyme component of cellulase enzyme preparation will achieve its intended technical effect and raises no toxicity concerns. The agency further finds, based upon generally available and accepted information, that when the cellulase enzyme preparation is manufactured in accordance with § 184.1250, the source, *T. longibrachiatum*, and the manufacturing process will not introduce impurities into the preparation that may render its use unsafe. Finally the agency finds that dietary exposure to the cellulase enzyme preparation from the petitioned use does not present a basis for concern about the safe use of the cellulase enzyme preparation. Therefore, the agency concludes, based on the evaluation of published data and information, and based upon scientific procedures (§ 170.30(b)), that use of the cellulase enzyme preparation derived from *T. longibrachiatum* for the enzymatic breakdown of cellulose in processing food is GRAS. Therefore, the agency is affirming that the use of

cellulase enzyme preparation from *T. longibrachiatum* described in the regulation set out below is GRAS (21 CFR 184.1(b)(1)) with no limitations other that current good manufacturing practice.

V. Environmental Effects

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 findings of no significant impact and the evidence supporting these findings, contained in an environmental assessment, may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

VI. Analysis of Impacts

A. Analysis for Executive Order 12866

FDA has examined the impacts of this final rule under Executive Order 12866. Executive Order 12866 directs 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). According to Executive Order 12866, a regulatory action is significant if it meets any one of a number of specified conditions, including having an annual effect on the economy of $100 million, adversely affecting in a material way a sector of the economy, competition, or jobs, or if it raises novel legal or policy issues. FDA finds that this final rule is not a significant regulatory action as defined by Executive Order 12866. In addition, it has been determined that this final rule is not a major rule for the purpose of congressional review.

The primary benefit of this action is to remove uncertainty about the regulatory status of the petitioned substance. No compliance costs are associated with this final rule because no new activity is required and no current or future activity is prohibited by this rule.

B. Regulatory Flexibility Analysis

FDA has examined the impacts of this final rule under the Regulatory Flexibility Act. The Regulatory Flexibility Act (5 U.S.C. 601–612) requires Federal agencies to consider alternatives that would minimize the economic impact of their regulations on small entities. In compliance with the Regulatory Flexibility Act, FDA finds that this final rule will not have a significant impact on a substantial number of small entities.

No compliance costs are associated with this final rule because no new activity is required and no current or future activity is prohibited. Accordingly, under the Regulatory Flexibility Act (5 U.S.C. 605(b)), the agency certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

VII. Paperwork Reduction Act of 1995

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

VIII. Effective Date

As this rule recognizes an exemption from the food additive definition in the Federal Food, Drug, and Cosmetic Act, and from the approval requirements applicable to food additives, no delay in effective date is required by the Administrative Procedure Act (5 U.S.C. 553(d)). The rule will therefore be effective immediately (5 U.S.C. 553(d)(1)).

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. Cannon, P. F., ''International Commission on the Taxonomy of Fungi (ICTF): Name Changes in Fungi of Microbiological Industrial and Medical Importance. Part 2,'' *Microbiological Sciences*, 3(9): 285 to 287, 1986.

2. Hjortkjaer, R. K. et al., ''Safety Evaluation of Celluclast TM, an Acid Cellulase Derived From *Trichoderma reesei*,'' *Food Chemical Toxicity*, 21 (1) 55 to 63, 1986.

3. ''Specifications for the Identity and Purity of Some Enzymes and Certain Other Substances'' in the Fifteenth Report of the Joint FAO/WHO Expert Committee on Food Additives; WHO Food Additive Series, No. 2, pp. 3 to 5, 1972 .

4. Rifai, M. A., ''A Revision of the Genus Trichoderma'' in *Mycological Papers*, No. 116, pp. 42 to 44, 1969.

5. Simmons, E. G., ''Classification of Some Cellulase Producing Trichoderma Species'' in *Second International Mycological Congress, Book of Abstracts*, p. 618, 1977.

6. Church, B. D., N. A. Nash, and W. Brosz, ''Use of Fungi Imperfecti in Treating Food Processing Wastes,'' in *Development in Industrial Microbiology*, vol. 13, pp. 30 to 46, 1972.

7. Memorandum from Food and Cosmetics Microbiology Branch, FDA, to GRAS review Branch, FDA, January 10, 1980.

8. King, K. W., and M. I. Vassal, ''Enzymes of the Cellulase Complex,'' in *Cellulase and Their Applications*, edited by R. F. Gould ''Advances in Chemistry Series'' #95, American Chemical Society, Washington, DC, pp. 7 to 25, 1969.

9.''Enzyme Nomenclature,'' recommendations (1972) of the International Union of Pure and Applied Chemistry and the International Union of Biochemistry, American Elsevier, New York, pp. 212 to 213, 1975.

10. ''Monograph on Enzyme Preparations'' in *Food Chemicals Codex*, 4th ed., National Academy Press, Washington, DC, pp. 129 to 134, 1996.

11. Underkofler, L. A., ''Enzymes'' in *CRC Handbook of Food Additives*, edited by T. E. Furia, The Chemical Rubber Co., Ohio, pp. 80 to 82, 1968.

12. Malmos, H., ''Industrial Applications of Cellulase: Enzyme Applications in Food, Pharmaceuticals and Other Industries,'' in *American Institute of Chemical Engineers Symposium Series*, vol. 74, 1976/77, pp. 93–99.

13. Toyoma, N., ''Applications of Cellulases in Japan,'' pp. 359 to 390, in *Cellulases and Their Applications*, edited by R. F. Gould, *Advances in Chemistry Series 195*, American Chemical Society, Washington, DC, 1969.

14. Memorandum from Food and Color Additives Review Section, FDA, to Direct Additives Branch, FDA, February 21, 1989.

15. Memorandum from Food and Color Additives Review Section, FDA, to Direct Additives Branch, FDA, June 22, 1990.

16. Memorandum from Additives Evaluation Branch, FDA, to Direct Additives Branch, FDA, July 11, 1990.

17. Memorandum from Additives Evaluation Branch, FDA, to Direct Additives Branch, FDA, June 29, 1993.

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 SUBSTANCE AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

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

Authority: 21 U.S.C. 321, 342, 348, 371.

2. Section 184.1250 is added to subpart B to read as follows:

§ 184.1250 Cellulase enzyme preparation derived from Trichoderma longibrachiatum.

(a) Cellulase enzyme preparation is derived from a nonpathogenic, nontoxicogenic strain of *Trichoderma*

longibrachiatum (formerly *T. reesei*). The enzyme, cellulase, catalyzes the endohydrolysis of 1,4-beta-glycosidic linkages in cellulose. It is obtained from the culture filtrate resulting from a pure culture fermentation process.

(b) The ingredient meets the general and additional requirements for enzyme preparations in the monograph specifications on enzyme preparations in the ''Food Chemicals Codex,'' 4th ed. (1996), pp. 129 to 134, 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., Box 285, Washington, DC 20055 (Internet ''http://www.nap.edu''), or may be examined at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., rm. 3321, Washington, DC, or at 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 generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used in food as an enzyme as defined in § 170.3(o)(9) of this chapter for the breakdown of cellulose.

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

Dated: May 17, 1999.

L. Robert Lake,

Director, Office of Policy, Planning and Strategic Initiatives, Center for Food Safety and Applied Nutrition.

[FR Doc. 99–13151 Filed 5–25–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 914

[SPATS No. IN–144–FOR]

Indiana Regulatory Program

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

ACTION: Final rule; clarification.

SUMMARY: The Office of Surface Mining Reclamation and Enforcement (OSM) is clarifying its decision and responses to comments it received on an amendment to the Indiana regulatory program (Indiana program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The amendment concerned revisions to and additions of statutes pertaining to other State and Federal laws and permit revisions. At the request of the Indiana Department of Natural Resources (IDNR), we are providing clarification of our decision findings and responses to comments for two provisions relating to permit revisions that we disapproved in a previous final rule decision document dated March 16, 1999 (64 FR 12890). This clarification supplements our previous findings made in section III. Director's Findings and our responses to comments made in section IV. Summary and Disposition of Comments of that final rule document, but does not affect our decision made in section V. Director's Decision.

EFFECTIVE DATE: May 26, 1999.

FOR FURTHER INFORMATION CONTACT: Andrew R. Gilmore, Director, Indianapolis Field Office, Office of Surface Mining Reclamation and Enforcement, Minton-Capehart Federal Building, 575 North Pennsylvania Street, Room 301, Indianapolis, Indiana 46204–1521. Telephone (317) 226–6700. Internet: INFOMAIL@indgw.osmre.gov.

SUPPLEMENTARY INFORMATION: On March 16, 1999, we published a final rule approving, with certain exceptions, a May 14, 1998, amendment to the Indiana program. The amendment concerned revisions to Indiana Code (IC) 14–8 and several sections of IC 14–34 made by the Indiana House Enrolled Act No. 1074 (HEA 1074). By letter dated May 12, 1999, the IDNR asked us to clarify our disapproval of two revisions to the Indiana Code that were included in HEA 1074. The IDNR was concerned that the language we used in the preamble discussion of the disapproved revisions would have an adverse impact on the existing approved Indiana program. This final rule clarifies the preamble discussion of our final decision and our responses to the comments received on these two revisions. First, we disapproved IC 14–34–5–7–7(a), which defined a permit revision. Second, we disapproved IC 14–34–5–8.2(4), which added a guideline that would require Indiana to approve postmining land use changes, with specified exceptions, as nonsignificant permit revisions.

IC 14–34–5–7(a), Definition of Permit Revision

As proposed, this provision would define a permit revision as a change in mining or reclamation operations from the approved mining and reclamation plans that adversely affect the permittee's compliance with state statutes and regulations. In the March 16, 1999, **Federal Register** notice disapproving this provision, we cited three problems with the proposed language. The discussion of those three problems is not intended to affect the currently approved regulation at 310 IAC 12–3–121(a)(1) cited by the Indiana Coal Council (ICC) in their comments of June 26,1998, in support of the proposed change (Administrative Record No. IND–1617). The portion of this regulation cited by the ICC requires revisions to permits for changes in surface coal mining or reclamation operations described in the original application and approved under the original permit, when such changes constitute a significant departure from the method of conduct of mining or reclamation operations contemplated by the original permit. In addition to the portion cited by the ICC, the regulation at 310 IAC 12–3–121(a)(1) goes on to state that changes which constitute a significant departure shall include, but not be limited to, those that could result in an operator's inability to comply with applicable requirements (emphasis added). The proposed statutory change we disapproved would have been in conflict with the current regulation in that it would have imposed a limitation inconsistent with this previous approved regulation. However, we do not intend for our disapproval of IC 14–34–5–7(a) to impact the current discretion that Indiana has within its approved program to determine when a revision is required.

IC 14–34–5–8.2(4) Post-Mining Land Use as Nonsignificant Permit Revisions

As proposed, this provision would classify a revision as nonsignificant that involved a land use change other than those listed in IC 14–34–5–8.1(8). Section 8.1(8) listed, as significant revisions, residential land uses, commercial or industrial land uses, recreational land uses, and developed water resources meeting the size criteria of 30 CFR 77.216(a). In a letter faxed to us on December 21, 1998, responding to our concerns regarding this provision, the IDNR indicated that it interpreted this provision to mean that Indiana would retain discretion to determine that land use changes other than those listed in IC 14–34–8.1(8) could be significant revisions (Administrative Record No. IND–1627). However, we disapproved this proposed revision because we feel that it is clear on its face that the proposed change would remove such discretion. We went on to explain