

Adoption of the Amendment**§ 71.123 [Amended]**

According by, pursuant to the authority delegated to me, § 71.123 of Part 71 of the Federal Aviation Regulations (14 CFR Part 71), is amended, effective 0901 G.m.t., January 19, 1984, as follows:

V-91 [Amended]

By deleting the words "From Calverton, NY, via" and substituting the words "From INT Calverton, NY, 180° and Hampton, NY, 223° radials; Calverton;" (Secs. 307(a) and 313(a), Federal Aviation Act of 1958 (49 U.S.C. 1348(a) and 1354(a)); (49 U.S.C. 106(g) (Revised, Pub. L. 97-449, January 12, 1983)); and 14 CFR 11.69)

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Issued in Washington, D.C., on November 4, 1983.

B. A. Bancroft,

Acting Manager, Airspace-Rules and Aeronautical Information Division.

[PR Doc. 83-30684 Filed 11-14-83; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Part 133**

[Docket No. 79P-0349]

**Cheese and Cheese Products;
Amendment to Permit Use of
Antimicrobials on Surface of Bulk
Cheeses and To Provide for
Declaration of Animal, Plant, and
Microbial Enzymes as "Enzymes"**

Correction

In FR Doc. 83-28785 beginning on page 49012 in the issue of Monday, October 24, 1983 make the following correction:

On the same page, column two, lines twelve through fifteen, the last sentence

of the SUMMARY should read "FDA concludes that the amendments to the standards will promote honesty and fair dealing in the interest of consumers."

BILLING CODE 1505-01-M

21 CFR Parts 172, 182, and 184

[Docket No. 81N-0313]

GRAS Status of Starter Distillate and Diacetyl

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is affirming that starter distillate and diacetyl are generally recognized as safe (GRAS) as direct human food ingredients. The safety of these ingredients has been evaluated under the comprehensive safety review conducted by the agency.

DATES: Effective December 15, 1983. The Director of the Federal Register approves the incorporation by reference of certain publications in 21 CFR 184.1278 effective on December 15, 1983.

FOR FURTHER INFORMATION CONTACT: Lawrence J. Lin, Bureau of Foods (HFF-335), Food and Drug Administration, 200 C St. SW., Washington, 20204, 202-426-8950.

SUPPLEMENTARY INFORMATION: In the Federal Register of August 6, 1982 (47 FR 34155), FDA published a proposal to affirm that starter distillate and diacetyl are GRAS for use as direct human food ingredients. The proposal was published in accordance with the announced FDA review of the safety of GRAS and prior-sanctioned food ingredients.

In accordance with § 170.35 (21 CFR 170.35), copies of the scientific literature review on starter distillate and diacetyl and the report of the Select Committee on GRAS Substances (the Select Committee) on starter distillate and diacetyl are available for public review in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857. Copies of these documents also are available for public purchase from the National Technical Information Service, as announced in the proposal.

In addition to proposing to affirm the GRAS status of starter distillate and diacetyl, FDA gave public notice that it was unaware of any prior-sanctioned food uses for these ingredients other than for the proposed conditions of use. Persons asserting additional or extended uses in accordance with approvals granted by the U.S. Department of Agriculture of FDA before September 6,

1958, were given notice to submit proof of those sanctions, so that the safety of any prior-sanctioned uses could be determined. That notice was also an opportunity to have prior-sanctioned uses of starter distillate and diacetyl recognized by issuance of an appropriate regulation under Part 181—Prior-Sanctioned Food Ingredients (21 CFR Part 181) or affirmed as GRAS under Part 184 or 186 (21 CFR Part 184 or 186), as appropriate.

FDA also gave notice that failure to submit proof of an applicable prior sanction in response to the proposal would constitute a waiver of the right to assert that sanction at any future time.

No reports of prior-sanctioned uses for starter distillate and diacetyl were submitted in response to the proposal. Therefore, in accordance with the proposal, any right to assert a prior sanction for use of starter distillate or diacetyl under conditions different from those set forth in this final rule has been waived.

No comments were received in response to the agency's proposal on starter distillate and diacetyl. The agency is therefore issuing the proposed regulations as a final rule with minor editorial changes.

In the proposal, FDA stated that it would work with the Committee on Codex Specifications (now known as the Committee on Food Chemicals Codex) of the National Academy of Sciences to develop acceptable specifications for starter distillate used as a direct human food ingredient and would incorporate those specifications into the regulation on this substance when they were developed. To date, however, work on the specifications is still incomplete. Until the specifications are developed, starter distillate for direct food uses must comply with the description in § 184.1848 and be of food-grade purity (21 CFR 184.1(b)(3) and 170.30(h)(1)).

The agency has previously determined under 21 CFR 25.24(d)(6) (proposed December 11, 1979; 44 FR 71742) that this action is of the type that does not individually or cumulatively have a significant impact on the human environment. FDA has not received any new information or comments that would alter its previous determination.

In accordance with the Regulatory Flexibility Act, the agency has previously considered the potential effects that this rule would have on small entities, including small businesses. In accordance with section 605(b) of the Regulatory Flexibility Act, the agency has determined that no significant impact on a substantial number of small entities would derive

from this action. FDA has not received any new information or comments that would alter its previous determination.

In accordance with Executive Order 12291, the agency has previously considered the potential economic effects of this regulation. As announced in the proposal, the agency has determined that the rule is not a major rule as determined by that Order. FDA has not received any new information or comments that would alter its previous determination.

The agency's findings of no major economic impact and no significant impact on a substantial number of small entities, and the evidence supporting these findings, are contained in a threshold assessment which may be seen in the Dockets Management Branch (address above).

List of Subjects

21 CFR Part 172

Food additives, Food preservatives, Spices and flavorings.

21 CFR Part 182

Generally recognized as safe (GRAS) food ingredients, Spices and flavorings.

21 CFR Part 184

Direct food ingredients, Food ingredients, Generally recognized as safe (GRAS) food ingredients.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(s), 409, 701(a), 52 Stat. 1055, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), Parts 172, 182, and 184 are amended as follows:

PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

§ 172.515 [Amended]

1. In § 172.515 *Synthetic flavoring substances and adjuvants* by removing "Butter starter distillate" from the list of substances in paragraph (b).

PART 182—SUBSTANCES GENERALLY RECOGNIZED AS SAFE

§ 182.60 [Amended]

2. In § 182.60 *Synthetic flavoring substances and adjuvants* by removing "Diacetyl (2,3-butanedione)" from the list of substances.

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

3. In Part 184:

a. By adding new § 184.1278, to read as follows:

§ 184.1278 Diacetyl.

(a) Diacetyl (C₄H₈O₃, CAS Reg. No. 431-03-8) is a clear yellow to yellowish green liquid with a strong pungent odor. It is also known as 2,3-butanedione and is chemically synthesized from methyl ethyl ketone. It is miscible in water, glycerin, alcohol, and ether, and in very dilute water solution, it has a typical buttery odor and flavor.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 368, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(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 as a flavoring agent and adjuvant as defined in § 170.3(o)(12) of this chapter.

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

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

b. By adding new § 184.1848, to read as follows:

§ 184.1848 Starter distillate.

(a) Starter distillate (butter starter distillate) is a steam distillate of the culture of any or all of the following species of bacteria grown on a medium consisting of skim milk usually fortified with about 0.1 percent citric acid: *Streptococcus lactis*, *S. cremoris*, *S. lactis subsp. diacetylactis*, *Leuconostoc citrovorum*, and *L. dextranicum*. The ingredient contains more than 98 percent water, and the remainder is a mixture of butterlike flavor compounds. Diacetyl is the major flavor component, constituting as much as 80 to 90 percent of the mixture of organic flavor compounds. Besides diacetyl, starter distillate contains minor amounts of acetaldehyde, ethyl formate, ethyl acetate, acetone, ethyl alcohol, 2-butanone, acetic acid, and acetoin.

(b) FDA is developing food-grade specifications for starter distillate in cooperation with the National Academy of Sciences. In the interim, this ingredient must be of a purity suitable for its intended use.

(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 as a flavoring agent and adjuvant as defined in § 170.3(o)(12) of this chapter.

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

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

Effective date. This regulation shall be effective December 15, 1983.

(Secs. 201(s), 409, 701(a), 52 Stat. 1055, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348, 371(a)).)

Dated: October 19, 1983.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 83-30372 Filed 11-14-83; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Parts 182 and 184

[Docket No. 80N-0389]

GRAS Status of Calcium Pantothenate, Sodium Pantothenate, and D- Pantothenyl Alcohol

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is affirming that calcium pantothenate is generally recognized as safe (GRAS) as a direct human food ingredient. In addition, FDA is removing sodium pantothenate and D-pantothenyl alcohol from the list of substances that are GRAS. The safety of these ingredients has been evaluated under the comprehensive safety review conducted by the agency.

DATES: December 15, 1983. The Director of the Federal Register approves the incorporation by reference of certain publications at 21 CFR 184.1212 effective on December 15, 1983.

FOR FURTHER INFORMATION CONTACT: Lawrence J. Lin, Bureau of Foods (HFF-335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-426-8950.

SUPPLEMENTARY INFORMATION: In the Federal Register of January 14, 1983 (48 FR 1742), FDA published a proposal to affirm that calcium pantothenate is

GRAS for use as a direct human food ingredient. In addition, FDA proposed to remove sodium pantothenate and *D*-pantothenyl alcohol from the list of substances that are GRAS because there is no indication that these substances are currently used in food. The proposal was published in accordance with the announced FDA review of the safety of GRAS and prior-sanctioned food ingredients.

In accordance with § 170.35 (21 CFR 170.35), copies of the scientific literature review on pantothenates and the report of the Select Committee on GRAS Substances (the Select Committee) on pantothenates are available for public review in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857. Copies of these documents also are available for public purchase from the National Technical Information Service, as announced in the proposal.

In addition to proposing to affirm the GRAS status of calcium pantothenate, FDA gave public notice that it was unaware of any prior-sanctioned food ingredient uses for this ingredient other than the proposed conditions of use. Persons asserting additional or extended uses in accordance with approvals granted by the U.S. Department of Agriculture or FDA before September 6, 1958, were given notice to submit proof of those sanctions, so that the safety of any prior-sanctioned use could be determined. That notice was also an opportunity to have prior-sanctioned uses of calcium pantothenate recognized by issuance of an appropriate regulation under Part 181—Prior Sanctioned Food Ingredients (21 CFR Part 181) or affirmed as GRAS under Parts 184 and 186 (21 CFR Part 184 or 186), as appropriate.

FDA also gave notice that failure to submit proof of an applicable prior sanction in response to the proposal would constitute a waiver of the right to assert that sanction at any future time.

No reports of prior-sanctioned uses for calcium pantothenate were submitted in response to the proposal. Therefore, in accordance with the proposal, any right to assert a prior sanction for use of calcium pantothenate under conditions different from those set forth in this final rule has been waived.

No comments were received in response to the agency's proposal on pantothenates. The agency is therefore issuing the proposal as a final rule without change.

The agency has previously determined under 21 CFR 25.24(d)(6) (proposed December 11, 1979; 44 FR 71742) that this action is of a type that does not individually or cumulatively have a

significant impact on the human environment. FDA has not received any new information or comments that would alter its previous determination.

In accordance with the Regulatory Flexibility Act, the agency has previously considered the potential effects that this rule would have on small entities, including small businesses. In accordance with section 605(b) of the Regulatory Flexibility Act, the agency has determined that no significant impact on a substantial number of small entities would derive from this action. FDA has not received any new information or comments that would alter its previous determination.

In accordance with Executive Order 12291, the agency has previously considered the potential economic effects of this final rule. As announced in the proposal, the agency has determined that the rule is not a major rule as determined by that Order. FDA has not received any new information or comments that would alter its previous determination.

The agency's findings of no major economic impact and no significant impact on a substantial number of small entities, and the evidence supporting these findings, are contained in a threshold assessment which may be seen in the Dockets Management Branch (address above).

List of Subjects

21 CFR Part 182

Generally recognized as safe (GRAS) food ingredients, Spices and flavorings.

21 CFR Part 184

Direct food ingredients, Food ingredients, Generally recognized as safe (GRAS) food ingredients, Incorporation by reference.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(s), 409, 701(a), 52 Stat. 1055, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), Parts 182 and 184 are amended as follows:

PART 182—SUBSTANCES GENERALLY RECOGNIZED AS SAFE

§§ 182.8212, 182.8580, and 182.8772
[Removed]

1. Part 182 is amended by removing § 182.8212 *Calcium pantothenate*, § 182.8580 *D-Pantothenyl alcohol*, and § 182.8772 *Sodium pantothenate*.

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

2. Part 184 is amended by adding new § 184.1212, to read as follows:

§ 184.1212 Calcium pantothenate.

(a) Calcium pantothenate $[(C_9H_{16}NO_5)_2Ca]$, CAS Reg. No. of the *D*-isomer, 137-08-6 is a salt of pantothenic acid, one of the vitamins of the B complex. Only the *D*-isomer of pantothenic acid has vitamin activity, although both the *D*-isomer and the *DL*-racemic mixture of calcium pantothenate are used in food. Commercial calcium pantothenate is prepared synthetically from isobutyraldehyde and formaldehyde via 1,1-dimethyl-2-hydroxy-propionaldehyde and pantolactone.

(b) Calcium pantothenate meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 56, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(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 as a nutrient supplement as defined in § 170.3(o)(20) of this chapter.

(2) The ingredient is used in foods at levels not to exceed current good manufacturing practice. Calcium pantothenate may be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) or with regulations promulgated under section 412(a)(2) of the act.

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

Effective date. This regulation shall be effective December 15, 1983.

(Secs. 201(s), 409, 701(a), 52 Stat. 1055, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348, 371(a))).

Dated October 21, 1983.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 83-30369 Filed 11-14-83; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Parts 182 and 184

[Docket No. 78N-0198]

GRAS Status of Dextrin

AGENCY: Food and Drug Administration.
ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is affirming that dextrin is generally recognized as safe (GRAS) as a direct human food ingredient. The safety of this ingredient has been evaluated under the comprehensive safety review conducted by the agency.

DATES: Effective December 15, 1983. The Director of the Federal Register approves the incorporation by reference of certain publications in 21 CFR 184.1277 effective on December 15, 1983.

FOR FURTHER INFORMATION CONTACT: John Dawson, Bureau of Foods (HFF-335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-426-9463.

SUPPLEMENTARY INFORMATION:

Subsequently, the agency published a tentative final rule in the *Federal Register* of August 20, 1982 (47 FR 36437), in which FDA proposed not to include the levels of use and food categories in the GRAS regulation on dextrin. The tentative final rule provided an opportunity for public comment on this change.

In the *Federal Register* of March 27, 1979 (44 FR 18246), FDA published a proposal to affirm that dextrin is GRAS for use as a direct human food ingredient. The proposal was published in accordance with the announced FDA review of the safety of GRAS and prior-sanctioned food ingredients.

No comments were received in response to the agency's tentative final rule on dextrin. The agency is therefore issuing the tentative final rule as a final rule without change.

The agency has previously determined under 21 CFR 25.24(d)(6) (proposed December 11, 1979; 44 FR 71742) that this action is of the type that does not individually or cumulatively have a significant impact on the human environment. FDA has not received any new information or comments that would alter its previous determination.

In accordance with the Regulatory Flexibility Act, the agency has

previously considered the potential effects that this rule would have on small entities, including small businesses. In accordance with section 605(b) of the Regulatory Flexibility Act, the agency has determined that no significant impact on a substantial number of small entities would derive from this action. FDA has not received any new information or comments that would alter its previous determination.

In accordance with Executive Order 12291, the agency has previously considered the potential economic effects of this regulation. As announced in the tentative final rule, the agency has determined that the rule is not a major rule as determined by that Order. FDA has not received any new information or comments that would alter its previous determination.

The agency's findings of no major economic impact and no significant impact on a substantial number of small entities, and the evidence supporting these findings, are contained in a threshold assessment which may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

List of Subjects

21 CFR Part 182

Generally recognized as safe (GRAS) food ingredients, Spices and flavorings.

21 CFR Part 184

Direct food ingredients, Food ingredients, Generally recognized as safe (GRAS) food ingredients, Incorporation by reference.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(s), 409, 701(a), 52 Stat. 1055, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348, 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) Parts 182 and 184 are amended as follows:

PART 182—SUBSTANCES GENERALLY RECOGNIZED AS SAFE

1. Part 182 is amended:

§ 182.70 [Amended]

a. In § 182.70 *Substances migrating from cotton and cotton fabrics used in dry food packaging* by removing the entry for "Corn dextrin."

§ 182.90 [Amended]

b. In § 182.90 *Substances migrating to food from paper and paperboard products* by removing the entry for "Dextrin".

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

2. By adding new § 184.1277, to read as follows:

§ 184.1277 Dextrin.

(a) Dextrin [(C₆H₁₀O₅)_n·H₂O, CAS Reg. No. 9004-53-9] is an incompletely hydrolyzed starch. It is prepared by dry heating corn, waxy maize, waxy milo, potato, arrowroot, wheat, rice, tapioca, or sago starches, or by dry heating the starches after: (1) Treatment with safe and suitable alkalis, acids, or pH control agents and (2) drying the acid or alkali treated starch.

(b) The ingredient meets the specification of the Food Chemicals Codex, 3d Ed. (1981), p. 96, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(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 as a formulation aid as defined in § 170.3(o)(14) of this chapter; as a processing aid as defined in § 170.3(o)(24) of this chapter; as a stabilizer and thickener as defined in § 170.3(o)(28) of this chapter; and as a surface-finishing agent as defined in § 170.3(o)(30) of this chapter.

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

(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

Effective date. This regulation shall be effective December 15, 1983.

(Secs. 201(s), 409, 701(a), 52 Stat. 1055, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348, 371(a)).)

Dated: October 24, 1983.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 83-30370 Filed 11-14-83; 8:45 am]

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