

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 58

[DA-93-18]

Grading and Inspection, General Specifications for Approved Plants and Standards for Grades of Dairy Products; General Specifications for Dairy Plants Approved for USDA Inspection and Grading Service

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This document amends the General Specifications for Dairy Plants Approved for USDA Inspection and Grading Service (General Specifications), by revising the requirements for anhydrous milkfat to allow butter to be used as an ingredient and by revising the requirements for butteroil to allow the addition of safe and suitable antioxidants. The action to allow the use of butter was initiated at the request of the American Butter Institute.

EFFECTIVE DATE: January 24, 1995.

FOR FURTHER INFORMATION CONTACT: Duane R. Spomer, Chief, Dairy Standardization Branch, USDA/AMS/Dairy Division, Room 2750-S, P.O. Box 96456, Washington, DC 20090-6456, (202) 720-7473.

SUPPLEMENTARY INFORMATION: This final rule has been reviewed under Executive Order 12778, Civil Justice Reform. This action is not intended to have retroactive effect. This rule would not preempt any State or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule. There are no administrative procedures which must be exhausted prior to any judicial challenge to the provisions of this rule.

The final rule also has been reviewed in accordance with the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.* The Administrator, Agricultural Marketing Service, has determined that this final rule will not have a significant economic impact on a substantial number of small entities because participation in the USDA-approved plant program is voluntary and the amendments will not increase the costs to those utilizing the program.

The Department is issuing this final rule in conformance with Executive Order 12866.

The General Specifications, established in 1975, do not provide for butter to be used as an ingredient in

anhydrous milkfat. This is inconsistent with international standards. The General Specifications also do not provide for the addition of antioxidants to butteroil, which also is permitted in international standards. These restrictions place the domestic manufacturer at a disadvantage when competing in the world market.

In order to enable domestic manufacturers of anhydrous milkfat and butteroil to compete on equal terms with manufacturers from other exporting countries and to amend the General Specifications to more closely align U.S. requirements with international standards, USDA is amending part 58, subpart B, of the grading and inspection regulations concerning dairy products, as follows:

1. *Provide that butter may be used as an ingredient in anhydrous milkfat.* Currently, the General Specifications permit only cream to be used as an ingredient in anhydrous milkfat. This is inconsistent with internationally recognized standards published by the International Dairy Federation and the Codex Alimentarius Commission that allow the use of butter in anhydrous milkfat. These amendments more closely align USDA requirements with internationally recognized standards and allow butter to be used as an ingredient in anhydrous milkfat.

2. *Provide that antioxidants may be added to butteroil.* Currently, the General Specifications do not allow the addition of antioxidants to butteroil. Internationally recognized dairy standards permit this addition to assist in preserving the flavor characteristics of this product. These amendments more closely align USDA requirements with international standards and allow the addition of antioxidants to butteroil, provided the antioxidant used is permitted by standards developed by the Codex Alimentarius Commission and authorized for use by the Food and Drug Administration (FDA). The Standards developed by the Commission may be found in the "Standard A-2 for Milkfat Products¹." Antioxidants which are permitted by the Commission and which may be added to butteroil and the maximum levels allowed are as follows:

| Antioxidant | Maximum level |
|----------------------|---------------|
| Propyl gallate | 100 mg/kg. |

¹"Standards A-2 for Milkfat Products", Joint FAO/WHO Food Standards Program, Codex Committee on Milk and Milk Products. Copies of the Standard may be obtained from the Dairy Division, Agricultural Marketing Service, United States Department of Agriculture, P.O. Box 96456, Washington, DC 20090-6456.

| Antioxidant | Maximum level |
|--|--|
| Butylated hydroxytoluene (BHT)*. | 75 mg/kg. |
| Butylated hydroxyanisole (BHA). | 200 mg/kg. |
| Any combination of propyl gallate, BHA, or BHT*. | 200 mg/kg, but individual limits above not to be exceeded. |
| Natural and synthetic tocopherols. | 500 mg/kg. |
| Ascorbyl palmitate; Ascorbyl stearate. | 500 mg/kg individually or in combination. |
| Dilauryl thiodipropionate. | 200 mg/kg. |
| Antioxidant synergists | |
| Citric acid | Limit by Good Manufacturing Practice (GMP). |
| Sodium citrate | Limit by GMP. |
| Isopropyl citrate mixture; Phosphoric acid; Monoglyceride citrate. | 100 mg/kg individually or in combination. |

*Temporarily endorsed by the Codex Alimentarius Commission.

FDA provisions relevant to those antioxidants permitted by the Commission are found in 21 CFR parts 172, 182 or 184. The antioxidants permitted by FDA are those contained in these regulations. The antioxidants and levels permitted by FDA are as follows:

| Antioxidant | Maximum level |
|---------------------------------|-----------------|
| Propyl gallate | 0.02% of fat. |
| Butylated hydroxytoluene (BHT). | 0.02% of fat. |
| Butylated hydroxyanisole (BHA). | 0.02% of fat. |
| Tocopherols | Limit by GMP. |
| Ascorbyl palmitate | Limit by GMP. |
| Dilauryl thiodipropionate .. | 0.02% of fat. |
| Antioxidant synergists | |
| Citric acid | Limit by GMP. |
| Sodium citrate | Limit by GMP. |
| Isopropyl citrate | 0.02% of food. |
| Phosphoric acid | Limit by GMP. |
| Monoglyceride citrate | 200 ppm of fat. |

3. *Reduce the amount of moisture permitted in anhydrous milkfat.* Currently, the General Specifications allow a maximum moisture content of 0.15 percent in anhydrous milkfat. International standards developed by the International Dairy Federation and the Codex Alimentarius Commission allow a maximum moisture content of 0.1 percent. These amendments more closely align USDA requirements with international standards by reducing the maximum allowable moisture content to 0.1 percent.

4. Provide for the pasteurization of oil (highly concentrated milkfat) in the manufacture of anhydrous milkfat.

Pasteurization of dairy products ensures the destruction of pathogenic organisms. Currently the General Specifications require that cream be pasteurized during the production of anhydrous milkfat. In some segments of the dairy industry, this pasteurization step occurs when the milkfat in the cream has been concentrated to a level where it is considered to be "oil" rather than cream. These amendments still require pasteurization but allow the manufacturer to pasteurize either cream or oil.

5. Restrict the amount of other butter constituents in anhydrous milkfat.

When butter is used in anhydrous milkfat, the majority of the non-milkfat constituents normally found in butter are removed during manufacture. The non-milkfat constituents removed include protein, ash, and salt. These amendments limit the amount of non-milkfat constituents that are permitted to remain in anhydrous milkfat.

Anhydrous milkfat specifications established by USDA are voluntary specifications that are developed to facilitate the orderly marketing process. Dairy plants are free to choose whether or not to use the specifications. When manufactured or processed dairy products are graded or inspected, the USDA regulations governing the grading or inspection of dairy products are used.

Public Comments

On July 27, 1994, the Department published a proposed rule (59 FR 38136) to amend the General Specifications for Dairy Plants Approved for USDA Inspection and Grading Service. The public comment period closed September 26, 1994. Comments were received from three commenters representing: One dairy processor trade association, one producer of anhydrous milkfat and butteroil, and one exporter of dairy products.

Discussion of Comments

1. One commenter was concerned that certain requirements were inconsistent with international standards. Specifically the USDA requirement for peroxide value was more stringent, the copper requirement was less stringent, and the iron and neutralizer requirements were not specified.

The Department agrees that the Codex Alimentarius requirements for copper and iron content should be included at the levels permitted by Codex Alimentarius standards and has made

appropriate changes to the General Specifications.

The peroxide value requirements have been in effect since 1975. Anhydrous milkfat and butteroil produced in the United States has consistently met the more stringent peroxide values. These requirements do not restrict international trade but rather enhance the quality and stability of U.S. product and its desirability in international trade. Therefore, no changes in peroxide value are being made at this time.

While International Dairy Federation standards allow for trace amounts of neutralizer, Codex Alimentarius standards do not. The Codex Alimentarius standards are the most frequently recognized standards in major trade agreements. Therefore, no changes in neutralizer content are being made at this time.

2. One commenter felt that the value of anhydrous milkfat will decrease because pricing will be based on the butter market rather than the value of sweet cream.

The General Specifications establish quality requirements and provide information that facilitates procurement decisions and enhances trade. The General Specifications do not establish the market value of this product. If users feel that anhydrous milkfat produced from cream will better suit their needs, the General Specifications do not inhibit its availability. Therefore, the changes outlined in the proposed rule are being made at this time.

3. One commenter felt that the use of butter in anhydrous milkfat would result in an inferior product and that an increase in related testing costs would occur.

The anhydrous milkfat quality requirements in the General Specifications do not differentiate product produced from cream versus butter. Furthermore, when butter is used to produce anhydrous milkfat, the General Specifications require that the butter be of either Grade AA or Grade A quality. When cream is used, the General Specifications require its flavor to be comparable to the flavor quality specified for Grade AA or Grade A butter. For these reasons, the Department does not anticipate that increased testing will result.

4. One commenter opposed the change to allow the pasteurization step to occur in a more highly concentrated milkfat product (oil).

Pasteurization is essential in ensuring dairy product safety. For many years, some manufacturers have chosen to pasteurize after the milkfat has been concentrated to a level considered to be an oil. The Department believes that

pasteurization of the oil is essential in ensuring product safety and has revised the General Specifications as outlined in the proposed rule.

5. One commenter requested that the effective date of the changes occur immediately in order to allow manufacturers to take full advantage of available export markets.

The Department agrees that these changes enhance the ability of the U.S. dairy industry to market anhydrous milkfat in the international markets. Therefore, these changes will be made effective upon publication.

Pursuant to 5 U.S.C. 533 it is found and determined that good cause exists for not postponing the effective date of this action until 30 days after publication in the **Federal Register**. U.S. manufacturers are prepared to market anhydrous milkfat in the international markets immediately. Waiting 30 days to make this rule effective would delay this marketing opportunity. Further, considering the comments received, no useful purpose would be served in delaying the effective date. Therefore, this final rule is effective on the date of publication in the **Federal Register**.

List of Subjects in 7 CFR Part 58

Dairy products, Food grades and standards, Food labeling, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 7 CFR Part 58, Subpart B, is amended to read as follows:

PART 58—[AMENDED]

1. The authority citation for 7 CFR Part 58, continues to read as follows:

Authority: Secs. 202–208, 60 Stat. 1087, as amended; 7 U.S.C. 1621–1627, unless otherwise noted.

2. In § 58.305, paragraphs (b) and (c) are revised to read as follows:

§ 58.305 Meaning of words.

* * * * *

(b) *Butteroil*. The food product resulting from the removal of practically all of the moisture and solids-not-fat from butter. It contains not less than 99.6 percent fat and not more than 0.3 percent moisture and not more than 0.1 percent other butter constituents, of which the salt shall be not more than 0.05 percent. Antioxidants permitted to be used are as follows:

| Antioxidant | Maximum level |
|---------------------------------|---------------|
| Propyl gallate | 0.02% of fat. |
| Butylated hydroxytoluene (BHT). | 0.02% of fat. |
| Butylated hydroxyanisole (BHA). | 0.02% of fat. |
| Tocopherols | Limit by GMP. |

| Antioxidant | Maximum level |
|------------------------------|-----------------|
| Ascorbyl palmitate | Limit by GMP. |
| Dilauryl thiodipropionate .. | 0.02% of fat. |
| Antioxidant synergists | |
| Citric acid | Limit by GMP. |
| Sodium citrate | Limit by GMP. |
| Isopropyl citrate | 0.02% of food. |
| Phosphoric acid | Limit by GMP. |
| Monoglyceride citrate | 200 ppm of fat. |

An inert gas may be used to flush air-tight containers before, during, and after filling. Carbon dioxide may not be used for this purpose.

(c) *Anhydrous milkfat.* The food product resulting from the removal of practically all of the moisture and solids-not-fat from pasteurized cream or butter. It contains not less than 99.8 percent fat and not more than 0.1 percent moisture and, when produced from butter, not more than 0.1 percent

other butter constituents, of which the salt shall be not more than 0.05 percent. An inert gas may be used to flush air-tight containers before, during, and after filling. Carbon dioxide may not be used for this purpose.

* * * * *

3. Section 58.325 is revised to read as follows:

§ 58.325 Anhydrous milkfat.

If cream is used in the production of anhydrous milkfat that is eligible for official certification, the anhydrous milkfat shall be made by a continuous separation process directly from milk or cream. The cream used shall be comparable to the flavor quality specified above for U.S. Grade AA or U.S. Grade A butter. The milkfat from cream may then be further concentrated into oil. The cream or oil shall be pasteurized in accordance with the

procedures for cream for buttermaking (§ 58.334a). If butter is used in the production of anhydrous milkfat that is eligible for official certification, the butter used shall conform to the flavor requirements of U.S. Grade AA or U.S. Grade A butter and shall have been manufactured in an approved plant. The appearance of anhydrous milkfat should be fairly smooth and uniform in consistency.

4. Section 58.347 is revised to read as follows:

§ 58.347 Butteroil or anhydrous milkfat.

The flavor shall be bland and free from rancid, oxidized, or other objectionable flavors.

(a) In addition, the finished products shall meet the following specifications when sampled and tested in accordance with §§ 58.336 and 58.337:

| | Butteroil | Anhydrous milkfat |
|--|---|---|
| Milkfat | Not less than 99.6 percent | Not less than 99.8 percent. |
| Moisture | Not more than 0.3 percent | Not more than 0.1 percent. |
| Other butter constituents including salt | Not more than 0.1 percent | Not more than 0.1 percent. |
| Salt | Not more than 0.05 percent | Not more than 0.05 percent. |
| Antioxidants | Those permitted by standards of the Codex Alimentarius Commission and authorized for use by the Food and Drug Administration. | Those permitted by standards of the Codex Alimentarius Commission and authorized for use by the Food and Drug Administration. |
| Free fatty acids | Not more than 0.5 percent (calculated as oleic acid). | Not more than 0.3 percent (calculated as oleic acid). |
| Peroxide value | Not more than 0.1 milliequivalent per kilogram of fat. | Not more than 0.1 milliequivalent per kilogram of fat. |
| Iron content | Not more than 0.2 ppm | Not more than 0.2 ppm. |
| Copper content | Not more than 0.05 ppm | Not more than 0.05 ppm. |

Dated: January 18, 1995.

Lon Hatamiya,
Administrator.

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