■ c. Adding ''For the period (MMDDYY) from

3932 to _____ 3933''

and ''Number of months included in this statement

3931''

in the ''Statement of Income (Loss) or Statement of Comprehensive Income, As Applicable'' section in a new line immediately preceding the line reading ''REVENUE''.

■ d. Removing ''B. Additions (including non-conforming capital of $

4263) $ _____ 4260''

and adding in its place ''B. Additions (including non-conforming capital of $

4262) $ _____ 4260''.

■ e. Removing ''(k)(1)—$2,500 capital category as per Rule 15c3–3'' and adding in its place ''(k)(1)—Limited business (mutual funds and/or variable annuities only)'' in the ''Claiming an Exemption from Rule 15c3–3'' section.

■ f. Removing ''3. Other accrued withdrawals'' and adding in its place ''3. Other anticipated withdrawals'' in the ''Other Capital Withdrawals—Recap'' section.

■ g. In the ''Computation of CFTC Minimum Capital Requirements'' section, removing

''v. Enter the sum of Lines A.ii and A.iv. . . . . _____

7455''

and adding in its place:

''v. Amount of uncleared swap margin. . . . . $_____

7446

vi. If the FCM is also registered as a swap dealer, enter 2% of Line A.v. . . . . $_____

7447

vii. Enter the sum of Lines A.ii, A.iv, and A.vi. . . . . $_____

7455''

Note: The text of Part IIC of Form X–17A–5 does not, and this amendment will not, appear in the Code of Federal Regulations.

■ 6. Amend Part IIC of Form X–17A–5 (referenced in § 249.617 of this chapter) by:

■ a. Removing

''2200b'', ''6631b'' and ''6636b''

in Lines 13.B., 13.B.1. and 13.B.2. of the Balance Sheet section and adding in its place

''2200bb'', ''6631bb'' and ''6636bb'', respectively.

b. Removing

''7206b'' and ''7205b''

in Lines 9 and 10 of Column B the Regulatory Capital section and adding in its place

''7206bb'' and ''7205bb'', respectively.

Dated: May 27, 2021.

Vanessa A. Countryman,

Secretary.

[FR Doc. 2021–11572 Filed 6–10–21; 8:45 am]

BILLING CODE 8011–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 130 and 131

[Docket No. FDA–2000–P–0126 (formerly Docket No. 2000P–0685)]

RIN 0910–AI40

Milk and Cream Products and Yogurt Products; Final Rule To Revoke the Standards for Lowfat Yogurt and Nonfat Yogurt and To Amend the Standard for Yogurt

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or we) is issuing a final rule to revoke the standards of identity for lowfat yogurt and nonfat yogurt and amend the standard of identity for yogurt in numerous respects. This action is in response, in part, to a citizen petition submitted by the National Yogurt Association (NYA). The final rule modernizes the yogurt standard to allow for technological advances while preserving the basic nature and essential characteristics of yogurt and promoting honesty and fair dealing in the interest of consumers.

DATES: This rule is effective July 12, 2021. The Director of the Federal Register approves the incorporation by reference of certain publications listed in the rule as of July 12, 2021.

The compliance date of this final rule is January 1, 2024. See section X for further information on the filing of objections.

Submit either electronic or written objections and requests for a hearing on the final rule by July 12, 2021.

ADDRESSES: You may submit objections and requests for a hearing as follows. Please note that late, untimely filed objections will not be considered. Electronic objections must be submitted on or before July 12, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of July 12, 2021. Objections received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic objections in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov*. Follow the instructions for submitting comments. Objections submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your objection will be made public, you are solely responsible for ensuring that your objection does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your objection, that information will be posted on *https://www.regulations.gov.*
- If you want to submit an objection with confidential information that you do not wish to be made available to the public, submit the objection as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper objections submitted to the Dockets Management Staff, FDA will post your objection, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2000–P–0126 for ''Milk and Cream

Products and Yogurt Products; Final Rule to Revoke the Standards for Lowfat Yogurt and Nonfat Yogurt and to Amend the Standard for Yogurt.'' Received objections, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit an objection with confidential information that you do not wish to be made publicly available, submit your objections only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Andrea Krause, Center for Food Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2371, or Joan Rothenberg, Center for Food Safety and Applied Nutrition, Office of Regulations and Policy (HFS–024), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2378.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary

A. Purpose of the Final Rule

We are issuing a final rule to revoke the standards of identity for lowfat yogurt and nonfat yogurt and amend the standard of identity for yogurt in numerous respects. This action is in response, in part, to a citizen petition submitted by the NYA. This action modernizes the yogurt standard to allow for technological advances while preserving the basic nature and essential characteristics of yogurt and promotes honesty and fair dealing in the interest of consumers.

B. Summary of the Major Provisions of the Final Rule

The final rule revokes the standards for lowfat yogurt and nonfat yogurt. Consequently, lowfat yogurt and nonfat yogurt are covered under the general definition and standard of identity in § 130.10 (21 CFR 130.10), which sets out requirements for foods that deviate from other standardized foods due to compliance with a nutrient content claim. The final rule provides a modern yogurt standard to allow for technological advances, preserves but simplifies the basic nature and essential characteristics of yogurt, and promotes honesty and fair dealing in the interest of consumers.

The final rule amends the standard of identity for yogurt by making certain technical changes, permitting reconstituted forms of basic dairy ingredients (cream, milk, partially skimmed milk, and skim milk used alone or in combination) and the use of any optional safe and suitable milk-derived ingredient under certain conditions. The final rule also establishes functional classes of safe and suitable ingredients including cultures, flavoring, color additives, stabilizers, emulsifiers, and preservatives, and replaces the list of nutritive sweeteners with the term ''nutritive carbohydrate sweeteners.'' The final rule permits the optional labeling statement ''contains live and active cultures'' or similar statement if the yogurt contains specified amounts of live and active cultures. For yogurt treated to inactivate viable microorganisms, the final rule requires a statement of ''does not contain live and active cultures'' on the label.

C. Legal Authority

This final rule is issued pursuant to our authority under sections 401, 403(a)(1), 201(n), and 701(e) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 341, 343(a)(1), 321(n), and 371(e)).

Under section 701(e) of the FD&C Act, any action for the amendment or repeal of any definition and standard of identity under section 401 of the FD&C Act for any dairy product (*e.g.,* yogurt) must be begun by a proposal made either by FDA under our own initiative or by petition of any interested persons, showing reasonable grounds therefore, filed with the Secretary. The NYA submitted such a citizen petition on February 18, 2000, requesting that we, among other things, revoke the standards of identity for lowfat yogurt (§ 131.203 (21 CFR 131.203)) and nonfat yogurt (§ 131.206 (21 CFR 131.206)) and amend the standard of identity for yogurt (§ 131.200 (21 CFR 131.200)).

D. Costs and Benefits

Because we are publishing this rule in accordance with the formal rulemaking provisions of 5 U.S.C. 556 and 557, this rule is exempt from the economic

analysis requirements of Executive Order 12866. However, we have examined the economic implications of this rulemaking on small businesses. On a per firm, per year basis, estimated costs are between approximately $0.3 million and $2.7 million per small yogurt manufacturer per year in 2019 dollars discounted at 3 percent and between approximately $0.4 million and $2.7 million per small yogurt manufacturer per year discounted at 7 percent. The rule will likely benefit some manufacturers by modernizing the yogurt standard to allow for technological advances in food processing and to incorporate flexibility in yogurt manufacturing while preserving the basic nature and essential characteristics of yogurt. Because this rule may generate compliance costs for some small firms, we believe that this rule would have a significant economic impact on a substantial number of small entities.

II. Table of Abbreviations/Commonly Used Acronyms in This Document

Abbreviation	What it means
ANPRM	Advance Notice of Proposed Rulemaking.
AOAC International	Association of Official Analytical Collaboration International (formerly Association of Official Agricultural Chemists).
CFR	Code of Federal Regulations.
CFU	Colony Forming Units.
Codex	Codex Alimentarius Commission.
DV	Daily Value.
E.O.	Executive Order.
FD&C Act	Federal Food, Drug, and Cosmetic Act.
FR	Federal Register.
GMP	Good Manufacturing Practice.
ISO	International Organization for Standardization.
NLEA	Nutrition Labeling and Education Act.
NYA	National Yogurt Association.
RACC	Reference Amount Customarily Consumed.
UPC	Universal Product Code.

III. Background

A. Legal Authority

Section 401 of the FD&C Act directs the Secretary to issue regulations fixing and establishing for any food a reasonable definition and standard of identity whenever, in the judgment of the Secretary, such action will promote honesty and fair dealing in the interest of consumers. Section 403(a)(1) of the FD&C Act deems food to be misbranded if its labeling is false or misleading in any particular. Labeling may be misleading due to affirmative representations made or suggested by statement, word, design, device, or any combination thereof; labeling may also be misleading due to failure to reveal facts material in light of such representations (see section 201(n) of the FD&C Act).

Under section 701(e)(1) of the FD&C Act, any action for the amendment or repeal of any definition and standard of identity under section 401 of the FD&C Act for any dairy product (*e.g.,* yogurt) must begin with a proposal made either by FDA under our own initiative or by petition of any interested persons. The NYA submitted a citizen petition on February 18, 2000 (Docket No. FDA–2000–P–0126, formerly Docket No. 2000P–0685), under our procedural regulations in 21 CFR 10.30, requesting, among other things, that we revoke the standards of identity for lowfat yogurt (§ 131.203) and nonfat yogurt (§ 131.206) and amend the standard of identity for yogurt (§ 131.200). In the **Federal Register** of July 3, 2003 (68 FR 39873), FDA issued an advance notice of proposed rulemaking (ANPRM), publishing the proposals in NYA's petition consistent with section 701(e)(1) of the FD&C Act. The ANPRM requested comment on whether the actions proposed in the petition would promote honesty and fair dealing in the interest of consumers. FDA subsequently issued a proposed rule in the **Federal Register** of January 15, 2009 (74 FR 2443) in part to respond to the citizen petition. FDA is now acting pursuant to section 701(e) of the FD&C Act to finalize the rule.

B. History of the Current Standards of Identity for Yogurt, Lowfat Yogurt,and Nonfat Yogurt

In the **Federal Register** of January 30, 1981 (46 FR 9924), we published a final rule establishing standards of identity for yogurt (§ 131.200), lowfat yogurt (§ 131.203), nonfat yogurt (§ 131.206), certain milk products (21 CFR 131.111, 131.112, 131.136, 131.138, 131.144, and 131.146)), and eggnog (21 CFR 131.170)). Interested persons were given until March 2, 1981, to file objections and request a hearing on the final rule. Twenty-one responses were filed objecting to specific provisions of the final rule and, in most cases, requesting a hearing. In response to those objections, we stayed the effective date for provisions regarding certain milk products and eggnog. In addition, we stayed the following provisions in the standards of identity for yogurt, lowfat yogurt, and nonfat yogurt: (1) Provisions that restricted the type of milk-derived ingredients that may be used to increase the milk solids not fat content (§§ 131.200(c)(1), 131.203(c)(1), and 131.206(c)(1) (redesignated as §§ 131.200(d)(1), 131.203(d)(1), and 131.206(d)(1), respectively)); (2) provisions that excluded the use of reconstituted dairy ingredients as basic ingredients (§§ 131.200(a), 131.203(a), and 131.206(a)); (3) provisions that excluded the addition of preservatives (§§ 131.200(c), 131.203(c), and 131.206(c) (redesignated as §§ 131.200(d), 131.203(d), and 131.206(d), respectively)); (4) provisions that set a minimum titratable acidity of 0.9 percent, expressed as lactic acid (§§ 131.200(a), 131.203(a), and 131.206(a)); and (5) § 131.200(a) specifying that the 3.25 percent minimum milkfat level applies after the addition of one or more of the optional sources of milk solids not fat listed in § 131.200(c)(1) (redesignated as § 131.200(d)(1)) (47 FR 41519 at 41523, September 21, 1982).

Due to competing priorities and limited resources, we did not hold a public hearing to resolve these issues, and the effective date for these provisions has been stayed since September 21, 1982. Therefore, these provisions have never been in effect, and yogurt, lowfat yogurt, and nonfat yogurt sold in interstate commerce have

not been required to conform to them. Consequently, yogurt, lowfat yogurt, and nonfat yogurt have varied with respect to the type of milk-derived ingredients used to increase the milk solids not fat content, the use of reconstituted dairy ingredients as basic ingredients, addition of preservatives, level of acidity, and application of the minimum milkfat level. These products have, however, been required to conform to the non-stayed provisions in §§ 131.200, 131.203, and 131.206.

In 1990, the Nutrition Labeling and Education Act (NLEA) (Pub. L. 101–535) amended the FD&C Act and established the circumstances in which claims that describe the nutrient content of food could be made. In response to the NLEA, we published a final rule on January 6, 1993, entitled ''Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definitions of Terms; Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food'' that established definitions for specific nutrient content claims in part 101 (21 CFR part 101) together with principles for their use (58 FR 2302) (the 1993 final rule). At the same time, we published a final rule entitled ''Food Standards: Requirements for Foods Named by Use of a Nutrient Content Claim and a Standardized Term'' (58 FR 2431) that established the general definition and standard of identity in § 130.10 for foods that substitute for a standardized food but deviate from the standard of identity due to compliance with an expressed nutrient content claim defined by FDA regulation, including the expressed nutrient content claims ''no fat'' and ''low fat'' (see § 101.62(b)) and ''light'' or ''reduced calorie'' (see § 101.60(b)).

We noted in the 1993 final rule (58 FR 2302 at 2314) that the common or usual names of certain foods with existing standards of identity include nutrient content claims. Lowfat yogurt and nonfat yogurt are among these foods. We further noted that these foods are exempt under section 403(r)(5)(C) of the FD&C Act from compliance with nutrient content claim definitions established by regulation, provided that the foods were subject to a standard of identity on November 8, 1990. As such, nonfat yogurt and lowfat yogurt are subject to the fat content requirements specified in their respective standards of identity rather than the requirements in § 101.62(b)(1) for ''no fat'' and § 101.62(b)(2) for ''low fat.'' In 1995, we proposed to revoke the standards of identity for lowfat yogurt and nonfat yogurt, along with the standards of identity for other dairy foods, so that the foods would be covered under § 130.10 and subject to the nutrient content claim definitions in part 101 (60 FR 56541). This action was intended to provide for consistency in the nomenclature and labeling of food products.

We deferred action on our proposal to revoke the standards of identity for lowfat yogurt and nonfat yogurt (61 FR 58991, November 20, 1996), citing economic considerations and technical difficulties for the yogurt industry if required to fortify lowfat yogurt and nonfat yogurt in accordance with the nutritional equivalence requirement in § 130.10(b) (61 FR 58991 at 58999). We later withdrew the proposed rule on November 26, 2004 (69 FR 68831).

C. Description of the Proposed Rule

In the **Federal Register** of January 15, 2009 (74 FR 2443), we published a proposed rule to revoke the standards of identity for lowfat yogurt (§ 131.203) and nonfat yogurt (§ 131.206) and amend the standard of identity for yogurt (§ 131.200). The proposal was, in part, in response to a citizen petition submitted by the NYA on February 18, 2000, and our ANPRM (68 FR 39873; July 3, 2003) in which we asked for comments and information concerning the NYA petition (Docket No. FDA–2000–P–0126, formerly Docket No. 2000P–0685).

We proposed to revoke the standards of identity for lowfat yogurt (§ 131.203) and nonfat yogurt (§ 131.206) so that yogurt (under proposed § 130.200) could be modified according to the ''low fat'' and ''no fat'' nutrient content claim definitions in § 101.62(b), thereby bringing lowfat yogurt and nonfat yogurt within the coverage of § 130.10. Consequently, lowfat yogurt and nonfat yogurt would be standardized foods under the general definition and standard of identity, rather than standardized foods under §§ 131.203 and 131.206.

We also proposed numerous changes to the standard of identity for yogurt in § 131.200. In brief, we proposed to modify the description of the standardized food yogurt; define basic dairy, optional dairy, and other optional ingredients used in the manufacture of yogurt; revoke the provisions for optional addition of vitamins A and D and the associated labeling requirements; update or provide the methods of analysis for milk solids not fat, titratable acidity, pH, and live and active cultures; and modify nomenclature, including required and recommended descriptors based on the manufacture of the product.

We further discussed our disagreement with some of the requests in the NYA citizen petition, including the requests to require that yogurt contain a specified amount of live and active cultures; permit the addition of optional milk-derived ingredients after culturing; permit the use of whey protein concentrate as a basic dairy ingredient; require a minimum amount of dairy ingredients; and permit a broad category of safe and suitable ingredients for nutritional or functional purposes (see 74 FR 2443 at 2449 through 2453).

IV. Comments on the Proposed Rule, FDA Responses, and Description of the Final Rule

A. Introduction

We requested comments on the proposed rule by March 31, 2009. We later extended the comment period to April 29, 2009 (Ref. 1). We received over 6,200 comments (including more than 6,000 form letters) from consumers, industry, trade associations, a scientific organization, and academia.

Some comments supported one or more of the proposed requirements. Other comments opposed certain proposed requirements, suggested changes to the proposed requirements, or asked us to clarify the proposed requirements. Comments from several trade associations representing food manufacturers and ingredient suppliers supported the need to modernize the yogurt standard to allow for recent technological advances in food processing and to incorporate flexibility in yogurt manufacturing while preserving the basic nature and essential characteristics of yogurt. However, other comments urged us not to revoke or change the standards of identity for yogurt, expressing concerns that the proposal would reduce the requirements for yogurt, including those provisions regarding nutrition, quality, safety, and labeling.

In this section, we discuss the issues raised in the comments on the proposed rule and our responses, and we describe the final rule. For ease of reading, we preface each comment discussion with a numbered ''Comment,'' and each response with a corresponding numbered ''Response.'' We have numbered each comment to help distinguish among different topics. The number assigned to each comment is for organizational purposes and does not signify the comment's importance or the order in which it was received.

We did not respond to comments outside the scope of this rulemaking, such as comments related to the safety of domestic versus imported ingredients, or country of origin labeling. The final rule is limited to

defining the standard of identity for yogurt and revoking the standards for lowfat yogurt and nonfat yogurt.

B. General Comments

(Comment 1) Several comments requested that we not change the standard of identity for yogurt. The comments asserted that the proposed rule lowers the requirements for yogurt, yields substantially to the NYA petition, and provides yogurt manufacturers too much flexibility in the manufacture of yogurt.

(Response 1) We disagree with the comments. The final rule does not lower the requirements for yogurt, but rather modernizes the yogurt standard to allow for technological advances while preserving the basic nature and essential characteristics of yogurt and promotes honesty and fair dealing in the interest of consumers. Technological advances in food science and technology allow for a wider range of milk-derived ingredients developed with advances in membrane processing technology in the dairy industry. The final rule permits the use of emulsifiers and preservatives to prevent separation, improve stability and texture, and extend the shelf-life of yogurt. The final rule also allows for modern methods for measuring acidity (pH in addition to titratable acidity) and analysis for milkfat, total solids content, milk solids not fat, titratable acidity, and a method to measure the characteristic live and active cultures or microorganisms in yogurt.

As described in our responses to comments 14, 21, 22, and 30, the final rule modifies some requirements to best preserve the integrity and economic value that consumers expect of yogurt. In addition, the final rule provides regulatory clarity, aligns the standard with products on the market, reflects industry practices, and promotes honesty and fair dealing in the interest of consumers:

Although we considered the NYA petition mentioned in section III.C., we also considered multiple factors, such as new processing technology and ingredients before proposing to amend the yogurt standards.

We also disagree that the rule provides yogurt manufacturers too much flexibility in the manufacture of yogurt. Providing flexibility in manufacturing may increase efficiency while maintaining the basic nature and essential characteristics of yogurt in terms of the taste, flavor, and texture expected by consumers. For example, the variety of yogurt products increased greatly over the years, with thicker Greek-style yogurt becoming as popular as regular yogurt. Permitting optional functional dairy ingredients achieves a desired protein content for Greek-style yogurt prior to culturing/fermentation, and allows for manufacturing without the production of the undesirable acid whey that is potentially a disposal problem. This flexibility also allows the use of technological advances without compromising safety or quality.

(Comment 2) Several comments said that the proposed rule would lower the quality and safety standards for yogurt by specifically allowing non-Grade ''A'' dairy ingredients to be used in the manufacture of yogurt.

(Response 2) The comments may have misinterpreted the current standards and proposed rule. The current standards for yogurt (§ 131.200), lowfat yogurt (§ 131.203), or nonfat yogurt (§ 131.206) do not specify the use of either Grade ''A'' or non-Grade ''A'' dairy ingredients in the manufacture of these products. Nor did we propose or discuss the specific use of non-Grade ''A'' dairy ingredients in the manufacture of yogurt in the proposed rule. Thus, there is no change between the current standards and the standard of identity for yogurt in this final rule with respect to the use of non-Grade ''A'' ingredients. The use of safe and suitable milk-derived ingredients as described in the final rule does not lower the value, grade, or safety or attribute requirements for yogurt and its ingredients.

C. Section 131.200(a)—Description

The proposed rule, at § 131.200(a), would require yogurt to contain a minimum of 3.25 percent milkfat, a minimum of 8.25 percent milk solids not fat, and a minimum of 0.7 percent titratable acidity expressed as lactic acid or maximum pH of 4.6, before the addition of bulky flavoring ingredients. The proposed rule also would require yogurt that is labeled with the optional phrase ''contains live and active cultures'' or another appropriate descriptor to contain a minimum of 10^7 colony forming units per gram (CFU/g) of live and active cultures at the time of manufacture with a reasonable expectation of 10^6 CFU/g throughout the manufacturer's assigned shelf life of the food.

(Comment 3) Some comments supported the proposal requiring yogurt to have a minimum milkfat of 3.25 percent and minimum milk solids not fat of 8.25 percent before the addition of bulky flavoring ingredients. However, one comment would replace the minimum 3.25 percent milkfat requirement with a requirement of 3 g of fat (including milkfat and other fat present in the bulky flavoring ingredients) in the finished product per reference amount customarily consumed (RACC). The comment said that requiring 3.25 percent milkfat before the addition of bulky flavoring ingredients can cause inconsistency because the amount of total fat in the finished product can vary depending on the amount and/or type of added flavoring ingredients. The comment suggested that some flavoring ingredients, such as chocolate, nuts, and coconut, can contribute to total fat in the finished product. The comment stated that a fat requirement based on the finished product would also provide manufacturers the flexibility of adding cream after culturing.

(Response 3) As discussed in the proposed rule (74 FR 2443 at 2448), we do not believe it is appropriate to change the minimum milkfat content to 3 g fat per 255 g, or 1.3 percent, because the yogurt standard with the minimum 3.25 percent milkfat requirement appears to be used in the manufacture of full-fat yogurts available in the marketplace and is consistent with the basic nature and essential characteristics of yogurt. According to the U.S. Department of Agriculture (USDA) FoodData Central (2019), the total fat content of ''yogurt, plain, whole milk'' is 3.25 g/100 g serving (3.25 percent) (Ref. 2). This is consistent with the minimum milkfat requirement of the current standard of identity for yogurt.

We emphasize that the minimum fat requirement of 3.25 percent is specifically for milkfat. Allowing fat from nondairy ingredients to count towards the minimum fat level deviates from the basic nature and essential characteristics of yogurt as other types of nondairy fats or oils could contribute to variances in the taste, texture, color, or aroma of yogurt (Refs. 3 and 4).

In addition, as discussed in response 15, we are not allowing the addition of optional dairy ingredients, such as pasteurized cream, after culturing. Therefore, it is appropriate to specify a minimum milkfat level of 3.25 percent before the addition of bulky flavoring ingredients.

(Comment 4) Some comments asked us to clarify whether the phrase ''bulky flavoring ingredients'' in proposed § 131.200(a) has the same meaning as the phrase ''bulky flavors'' used in § 131.200(a). One comment asked us to use the term ''bulky flavors'' in the final rule.

(Response 4) We consider the two terms, ''bulky flavors'' and ''bulky flavoring ingredients,'' to have similar meaning. Examples of bulky flavoring ingredients are fruit and fruit preparations. To be consistent with

most of the dairy standards, we have revised the rule to adopt the term ''bulky flavoring ingredients.''

(Comment 5) Currently, the stayed provisions in §§ 131.200(a), 131.203(a), and 131.206(a) specify that yogurt have a titratable acidity of not less than 0.9 percent, expressed as lactic acid. We stayed this provision of the standard on September 21, 1982 (47 FR 41519 at 41522). Titratable acidity and pH can both be used to measure the acidity of a food product. In the proposed rule (74 FR 2443 at 2449), we proposed that yogurt have either a titratable acidity of not less than 0.7 percent, expressed as lactic acid, or a pH of 4.6 or lower.

Several comments agreed that the stayed requirement of 0.9 percent titratable acidity, expressed as lactic acid, should be changed. One comment supported the minimum titratable acidity of 0.7 percent or maximum pH of 4.6. Other comments would modify the minimum titratable acidity to 0.6 percent measured in the cultured and fermented yogurt before the addition of bulky flavor ingredients.

One comment said that a minimum titratable acidity of 0.7 percent in the proposed rule is still too high for yogurt products with chocolate or delicate fruit flavors. Another comment claimed that a lower acidity requirement helps industry develop ''light'' yogurt products. Other comments pointed out that a minimum 0.6 percent titratable acidity is consistent with the Codex Standard for Fermented Milks (CXS 243–2003) (Ref. 5). Codex Alimentarius (Codex) is an international body established by the Food and Agriculture Organization of the United Nations and the World Health Organization.

Some comments asked us to revise the rule so that the maximum pH of 4.6 applies to finished product within 24 hours after filling. The comments said that, for yogurt that continues to ferment in the final container, such as ''cup set'' and ''warm fill'' yogurt, the product pH continues to drop during the cooling step. The comments also argued that, based on our own safety evaluation, we allow all yogurt products to be filled with an initial pH of 4.80 if the product pH reaches 4.6 or below within 24 hours of filling.

(Response 5) We disagree with the comments that would modify the minimum titratable acidity to 0.6 percent or that a minimum titratable acidity of 0.7 percent is still too high for certain yogurt products. Providing for the measurement of acidity in yogurt as a determination of its pH as well as its titratable acidity will introduce flexibility in the yogurt standard and gives manufacturers the flexibility to choose a method that best suits their product. As we noted in the proposed rule, the NYA citizen petition recommended a maximum pH of 4.6, and we believe that allowing a minimum titratable acidity of 0.7 percent or an equivalent maximum pH of 4.6 is appropriate as it reflects current industry practice and better meets some consumers' taste preferences (74 FR 2443 at 2448).

The final rule's requirement of a minimum titratable acidity of 0.7 percent is similar, but not identical, to requirement or position by Codex. We acknowledge that the Codex Standard established a minimum composition for yogurt of 0.6 percent titratable acidity expressed as percent lactic acid. However, yogurt products produced in compliance with our requirement of 0.7 percent titratable acidity would comply with the Codex Standard with respect to titratable acidity. Based on our observation of chocolate yogurt products and yogurt flavored with a variety of fruit flavors currently on the market that have a 0.7 percent titratable acidity, we do not believe that the differences between our final rule and the position taken by Codex will adversely affect the ability of manufacturers to produce yogurt with chocolate or delicate fruit flavors or ''light'' yogurt products, while maintaining the basic nature and essential characteristics of yogurt.

As for the comments that would revise the rule so that the maximum pH applies to finished products within 24 hours after filling, we view the fill pH as an in-process product characteristic for yogurt products. Requiring a maximum pH of 4.6 in the cultured and fermented yogurt before the addition of bulky flavor ingredients ensures the inhibition of growth and toxin formation of *Clostridium botulinum* (the pathogenic organism responsible for foodborne botulism). The manufacturer controls the condition after filling to ensure that the characterizing bacterial culture continues to ferment the product to produce a yogurt product with a maximum pH of 4.6 before the addition of bulky flavoring ingredients.

If the yogurt contains bulky flavoring ingredients, the finished product pH reflects the equilibrium pH of the cultured and fermented yogurt including the bulky flavoring ingredients. Some bulky flavoring ingredients (*e.g.,* fruit preparations) can lower the pH of the cultured and fermented yogurt. Applying the pH requirement to finished product after the addition of these ingredients could indirectly allow the use of acidulants to achieve the desired pH. The yogurt standard does not permit the use of food grade acidulants to meet the acidity or pH requirements (see response 6). To uphold the basic nature and essential characteristics of yogurt while maintaining product safety and attributes, the yogurt standard must ensure that the cultured and fermented yogurt reaches the desired titratable acidity of 0.7 percent or maximum pH of 4.6 solely by the fermentation action of bacterial culture and not through the additions of acidulants or bulky flavoring ingredients like fruit preparations. Thus, we do not agree that the maximum pH of 4.6 should apply only to the finished product.

The final rule, therefore, requires, at § 131.200(a), that yogurt have a titratable acidity of not less than 0.7 percent, expressed as lactic acid, or a pH of 4.6 or lower. We emphasize that both the titratable acidity and the pH requirements apply to yogurt before the addition of bulky flavoring ingredients.

(Comment 6) Several comments stated that the term ''culturing'' as used in § 131.200(a) should only refer to milk fermentation by the characterizing cultures (*Lactobacillus delbrueckii,* subspecies *bulgaricus,* and *Streptococcus thermophilus*) and other additional cultures allowed as optional ingredients. The comments asked us to clarify that ''culturing'' does not refer to the addition of lactic acid or other acidulants in modifying the standard to allow the use of a broad category of safe and suitable ingredients that serve a nutritional or functional purpose.

(Response 6) We agree that ''culturing'' as used in § 131.200(a) refers to milk fermentation by the characterizing cultures (*L. delbrueckii,* subspecies *bulgaricus,* and *S. thermophilus*), and other cultures as described in § 131.200(d)(1). ''Culturing'' does not refer to the addition of lactic acid or other acidulants. Lactic acid or other acidulants are not permitted as other optional ingredients under § 131.200(d).

(Comment 7) A few comments said we should not require yogurt to contain a specified amount of live and active cultures and should permit heat treatment of yogurt after culturing to extend shelf life. However, many comments stated that a unique and defining characteristic of yogurt is the presence of live and active cultures and these live and active cultures provide health benefits. These comments indicated that an important health benefit of live and active cultures in yogurt is their ability to break down lactose to allow lactose intolerant individuals to consume yogurt without uncomfortable side effects. One

comment stated that over 80 percent of the yogurt products sold in the United States in the time around 2009 declared the presence of live and active cultures either on the labels or on company websites. Another comment provided consumer survey results to contend that consumers expect yogurt products to contain live and active cultures. Other comments indicated that the requirement of live and active cultures is consistent with the Codex standard.

Other comments disagreed whether yogurt can be heat-treated after culturing. Some comments strongly opposed heat treatment after culturing and indicated that labeling the resultant product as ''yogurt'' is misleading and deceptive because consumers expect yogurt to contain live and active cultures. Other comments did not object to heat treatment after culturing if the package states that the product does not contain live and active cultures.

Some comments opposed any changes to the heat treatment provisions in the existing yogurt standard. The comments argued that, with extended shelf life, heat-treated yogurt gives consumers an additional option for a healthy dairy product. The comments also claimed that neither the presence nor the number of living bacteria in yogurt has any demonstrated health benefit. Some comments also suggested that some yogurt manufacturers may want to market their yogurt products with the claim ''contains live and active cultures.'' Many comments expressed interest in knowing whether a yogurt product contains live and active cultures.

(Response 7) We analyzed survey data submitted by the NYA and found that, while a majority of respondents expected to find live and active cultures as an ingredient in yogurt, the absence of a discussion in the survey on the response rates raises questions regarding potential bias in the results (Ref. 6). Consequently, we are unable to conclude, based on this survey, that yogurt should necessarily contain live and active cultures or that heat treatment after culturing should be prohibited.

Based on the comments discussing live and active cultures, we believe that many consumers are interested in knowing whether the yogurt products they purchase contains live and active cultures and that this information may impact their purchasing decisions. We therefore conclude that the labeling of yogurt should disclose the absence of live and active cultures rather than the use of heat treatment after culturing. The disclosure statement in § 131.200(f)(1)(ii) has been changed in the final rule to require an accompanying statement of ''does not contain live and active cultures'' on the product label. Thus, the rule permits the treatment of yogurt after culturing to inactivate viable microorganisms and extend shelf life of the product, provided that the label bears this accompanying statement. We discuss the labeling requirements for such treated yogurt in more detail in responses 27, 28, and 29.

We note that, in the future, new technologies other than heat treatment (*e.g.,* high pressure processing) may be used to inactivate viable microorganisms in yogurt and extend yogurt shelf life. Therefore, the final rule, at § 131.200(a), states that, to extend the shelf life of the food, yogurt may be treated after culturing to inactivate viable microorganisms rather than limiting yogurt specifically to heat treatment after culturing to extend the shelf life of the food. Such treated foods require an accompanying statement of ''does not contain live and active cultures'' on the product label.

In a summary and analysis of the consumer survey results submitted by one comment, we did not find that the consumer research results provided evidence that consumers expect all yogurt products to contain live and active cultures (Ref. 6).

Given consumer interest in knowing the presence of live and active cultures in yogurt, manufacturers may wish to affirmatively convey to consumers that live and active cultures are present. Therefore, the final rule, at § 131.200(f)(2), permits the optional labeling statement ''contains live and active cultures'' or another appropriate descriptor if the yogurt product contains a minimum level of live and active cultures as explained further in response 8.

As for the comments regarding the Codex standard, the final rule is consistent with the Codex standard, which also does not require live and active cultures in heat treated yogurt. For yogurt that is not heat treated, the requirement to permit the optional labeling statement ''contains live and active cultures'' is consistent with the Codex standard.

(Comment 8) Many comments supported setting a minimum level of live and active cultures. Some comments provided general support without mentioning any specific levels of live and active cultures. Other comments addressed the issue of what level of live and active cultures must be present when the label bears a statement to this effect. Among these comments, some agreed with our proposed levels of live and active cultures. Some supported the minimum level of 10^7 CFU/g of live and active cultures at the time of manufacture but did not support the inclusion of ''reasonable expectation of 10^6 CFU/g throughout the manufacturer's assigned shelf life of the product.'' One comment stated that manufacturers do not always have control over the storage conditions at retail levels. One comment requested that we not set a minimum level of live and active cultures in the final rule because, for yogurt that is not heat-treated, the provisions on fermentation, minimum titratable acidity, and maximum pH already ensure that the bacterial culture is above 10^7 CFU/g after culturing.

(Response 8) The proposed rule specified a minimum level of live and active cultures of 10^7 CFU/g at the time of manufacture with a reasonable expectation of 10^6 CFU/g through the manufacturer's assigned shelf life of the product. We have included these minimum levels in the final rule under § 131.200(f)(2) for the optional labeling statement ''contains live and active cultures.'' We decline to revise the rule to specify the minimum level of live and active cultures only at the time of manufacture. The time of manufacture is not the point when consumers purchase or consume their yogurt products. Even though manufacturers do not always have full control over the storage conditions at retail level, yogurt products should be properly refrigerated throughout the distribution channel. Studies generally indicate that the characterizing yogurt cultures survive well during cold storage and at lowered pH levels (Refs.7 through 9). One study shows that, when commercial yogurt products were stored at 4 °C, levels of characterizing yogurt cultures remained relatively stable over the study period of 4 weeks, with 1.0 or less log reduction (Ref. 8). Studies also show that, in non-heated yogurt, the mixture of *S. thermophilus* and *L. bulgaricus* is typically well above the minimum 10^6 CFU/g at the end of refrigerated storage, even though some reduction occurred during storage depending on the specific culture used, the storage temperature, and other factors (Refs. 7 through 9). Given these data indicating the minimum of 10^6 CFU/g of live and active cultures will likely exist throughout the shelf life of the food, and to promote honesty and fair dealing in the interest of consumers, the final rule permits the optional labeling statement ''contains live and active cultures'' or another appropriate descriptor if the yogurt product contains a minimum of

10^7 CFU/g of live and active cultures at the time of manufacture with a reasonable expectation of 10^6 CFU/g throughout the manufacturer's assigned shelf life of the product (§ 131.200(f)(2)).

We also do not agree that the provisions of fermentation, minimum titratable acidity, and maximum pH can replace the requirement of the levels of live and active cultures in the finished product. Although the culturing of yogurt is achieved by milk fermentation by the characterizing culture as described in § 131.200(a) and other cultures as described in § 131.200(d)(1) (see response 6), the optional labeling statement ''contains live and active cultures'' or another appropriate descriptor refers specifically to the presence of live and active cultures in the finished product. The minimum level of live and active cultures at the time of manufacturing and a reasonably expected level throughout the assigned shelf life provide a uniform production standard. Therefore, the final rule, at § 131.200(f)(1)(ii), requires that, if the yogurt product is labeled with the phrase ''contains live and active cultures'' or another appropriate descriptor, the yogurt product must contain a minimum of 10^7 CFU/g of live and active cultures at the time of manufacture with a reasonable expectation of 10^6 CFU/g throughout the manufacturer's assigned shelf life of the product.

On our own initiative, for added clarity, we relocated the provisions in proposed § 131.200(a) regarding the minimum number of live and active microorganisms yogurt may contain, to § 131.200(f), ''Nomenclature,'' describing the number of live and active microorganisms necessary for the product to be labeled with the phrase ''contains live and active cultures.''

(Comment 9) One comment opposed heat treatment after culturing and said that, if we permit such practice in the final rule, we should require all non-heat-treated yogurt to contain the proposed minimum levels of live and active cultures regardless of whether any ''live and active cultures'' label claims are made for the product. The comment reasoned that, under the proposed rule, there were at least three classes of yogurt products: (1) Heat-treated yogurt after culturing; (2) yogurt with live and active cultures and labeled with the voluntary live and active cultures claim; and (3) yogurt with live and active cultures but without any live and active cultures claim. The comment said that these different classes of yogurt can create consumer confusion and that, if we allow heat treatment of yogurt, we should require all non-heat-treated yogurt to contain the minimum levels of live and active cultures to reduce consumer confusion.

(Response 9) We disagree that these categories of products will cause consumer confusion. As discussed in responses 7 and 8, it is not evident that consumers always expect yogurt to contain live and active cultures. As such, labeling appears to be a better approach to informing consumers about the absence or presence of live and active cultures. The labeling provisions in § 131.200(f)(1)(ii) and (2) of the final rule will allow consumers to identify products that do not contain live and active cultures (which is a consequence of treatment after culturing) and products that contain a meaningful amount of live and active cultures. The disclosure statements specified in the provisions are required to accompany the name on the principal display panel of the product label and therefore readily inform consumers about the absence or presence of live and active cultures.

(Comment 10) One comment asked us to clarify that nonstandardized products that use yogurt as an ingredient are not required to meet the minimum level of 10^7 CFU/g live and active cultures. The comment gave examples of nonstandardized products, such as frozen yogurt, yogurt-coated cereal, and dried yogurt powder. The comment also asked us to clarify whether foods that do not meet the standard of identity for yogurt can continue to use the descriptive term ''yogurt'' as part of the food's name on the label.

(Response 10) Any food that purports to be or is represented as yogurt, must conform to the definition standard of identity for yogurt and its label must bear the name ''yogurt'' (see 21 U.S.C. 343(g)). Foods that do not purport to be or are not represented as yogurt, are not subject to these requirements. In our experience, products such as frozen yogurt, yogurt-coated cereal, and dried yogurt powder are not represented as and do not purport to be yogurt. Instead, they are nonstandardized foods, and their labels must bear their common or usual names in accordance with section 403(i)(1) of the FD&C Act. Common or usual names are generally established by common usage, though in some cases, common or usual names for nonstandardized foods have been established by regulation (see 21 CFR part 102, subpart B). Because no such regulation for these nonstandardized foods exists, they should be labeled with their common usage names (*e.g.,* ''frozen yogurt), provided that the names do not mislead consumers (see 21 U.S.C. 343(a)(1)).

When ''yogurt'' is used as part of the name of products such as frozen yogurt, yogurt-coated cereal, and dried yogurt powder, we generally expect that yogurt, or a substance derived from yogurt (*i.e.,* yogurt powder) is used as an ingredient in their manufacture. The ingredient must be or be derived from yogurt that complies with § 131.200. For example, we expect that an ingredient used in a yogurt drink is yogurt made in accordance with § 131.200, which is then combined with other ingredients to produce a drink product. The ingredient must be declared by its common or usual name in the ingredient statement on the product label in accordance with section 403(i)(2) of the FD&C Act, and § 101.4(a) and (b).

D. Section 131.200(b)—Basic Dairy Ingredients

The proposed rule, at § 131.200(b), would state that cream, milk, partially skimmed milk, skim milk, and the reconstituted versions of these ingredients may be used alone or in combination as the basic dairy ingredients in yogurt manufacture. The portion of § 131.200(b) that excluded the use of reconstituted versions of the basic ingredients in yogurt was stayed in 1982, so we could not take compliance action against the use of these ingredients until the stay was formally resolved. Although requested by the NYA petition, we did not propose to permit the use of whey protein concentrate as a basic dairy ingredient in yogurt manufacture (see 74 FR 2443 at 2453).

(Comment 11) Some comments opposed the use of reconstituted forms of basic dairy ingredients but did not provide data to support their assertions of any potential safety or technical concerns. Other comments supported the use of reconstituted forms of basic dairy ingredients and stated that these ingredients are already permitted in the manufacture of other standardized dairy foods, have been routinely used by the yogurt industry due to the stay of § 131.200(c), and do not adversely impact the safety or characteristics of yogurt. One comment would allow the use of all types of safe and suitable milk-derived ingredients to meet the minimum required 8.25 percent milk solids not fat.

(Response 11) The comments opposed to reconstituted forms of dairy ingredients did not provide any data nor do we have any information to indicate any technical or safety concern or that use of these ingredients affects the basic nature and essential characteristics of

yogurt or does not comport with consumer expectations about the food. Although the comments provided no data to support that yogurt containing reconstituted forms of dairy ingredients are less acceptable or differ in taste, flavor, or texture to yogurts produced with other basic dairy ingredients, the use of reconstituted forms of dairy ingredients and other optional dairy ingredients in yogurt throughout the marketplace indicates that the basic nature and essential characteristics of yogurt are maintained in producing acceptable and desired yogurt products. Therefore, the final rule includes the reconstituted versions of cream, milk, partially skimmed milk, and skim milk among the basic dairy ingredients in § 131.200(b).

(Comment 12) One comment asked us to expand the list of basic dairy ingredients to include ultrafiltered (UF) milk, its resulting dried products (which were stated to include milk protein concentrate and isolate), and skim milk powder (SMP). The comment described SMP as an ingredient nearly identical to skim milk except for the removal of water and the standardization of protein. The comment stated that allowing UF milk as a basic dairy ingredient for yogurt is consistent with our proposed rule that allows the use of UF milk in standardized cheese and cheese products (70 FR 60751, October 19, 2005). The comment said that the addition of these ingredients does not adversely affect yogurt characteristics or safety.

(Response 12) The current yogurt standard (§ 131.200(c)) lists cream, milk, partially skimmed milk, or skim milk as the basic dairy ingredients. Proposed § 131.200(b) would expand the list by allowing the reconstituted versions of these ingredients. Reconstituted versions are concentrated or dry forms of milk to which water may be added, in a sufficient quantity to reconstitute the dry or concentrated material to fluid form.

The use of fluid UF milk and its dried products as basic ingredients in yogurt is not consistent with the basic nature of yogurt. Fluid UF milk and its dried products are distinctly different from milk and dried milk, respectively. The process of ultrafiltration selectively removes not only water, but also lactose, minerals, and water-soluble vitamins, resulting in a compositionally different ingredient. The use of UF milk also affects the essential characteristics of yogurt, which is a fermented product from milk. The lactose in milk, which is significantly reduced in UF milk, is the substrate for the fermentation process by the bacterial culture in the production of yogurt. In addition, the rationale underlying our 2005 proposal for use of fluid UF milk in standardized cheeses and related cheese products (70 FR 60751) is not applicable to the use of fluid UF milk as a basic ingredient in yogurt because cheese and yogurt have fundamentally different production procedures and are different in their basic nature and essential characteristics. Moreover, the data and evidence the Agency relied on to support its tentative conclusions in the 2005 proposal were specific to standardized cheeses and related cheese products. For these reasons, we decline to revise § 131.200(b) to add fluid UF milk and its dried products for use as basic dairy ingredients in yogurt.

We wish to make clear that the concentrated or dried ingredient used for reconstitution must be such that the reconstituted form does not differ significantly from the respective cream, milk, partially skimmed milk, or skim milk (*i.e.,* has reestablished the same specified water:solids ratio). For example, concentrated milk (§ 131.115) and dry whole milk (§ 131.147) are appropriate ingredients to reconstitute to produce reconstituted milk. Nonfat dry milk (§ 131.125) is an appropriate ingredient to be used with water to produce reconstituted skim milk. Although fluid UF milk, its resulting dried derivatives, and SMP are not basic dairy ingredients under § 131.200(b), if safe and suitable, they can be used in yogurt as optional dairy ingredients under § 131.200(c). Moreover, limiting the basic dairy ingredients to those in § 131.200(b) is consistent with producing yogurt with the taste, flavor, and texture that consumers expect.

(Comment 13) Two comments agreed on limiting the use of whey and whey ingredients only as optional dairy ingredients in § 131.200(c). In addition, one comment strongly opposed the use of whey protein concentrates as a basic dairy ingredient, citing negative impacts on yogurt quality. One comment supported the use of whey protein concentrate and whey protein isolate as basic dairy ingredients in yogurt making, citing their nutritional, functional, and taste properties. However, the comment did not provide data or evidence to support these assertions.

(Response 13) As discussed in the proposed rule (74 FR 2443 at 2453), the use of whey protein concentrates, whey protein isolate, or other similar products as the basic dairy ingredients for yogurt may result in products that are not consistent with the taste, flavor, or texture expected by consumers. There are no new data or information from our own research or provided in the comments to cause us to change this position. Therefore, as noted in response 12, the final rule permits only the use of cream, milk, partially skimmed milk, skim milk, or the reconstituted versions of these ingredients as the basic dairy ingredients in the manufacture of yogurt under § 131.200(b).

E. Section 131.200(c)—Optional Dairy Ingredients

The proposed rule at § 131.200(c) would allow the optional use of other safe and suitable milk-derived ingredients to increase the nonfat solids content of the food, provided that the ratio of protein to total nonfat solids of the food and the protein efficiency ratio of all protein present are not decreased as a result of the use of such ingredients.

Proposed § 131.200(a), would specify that yogurt is a food produced by culturing one or more of the basic dairy ingredients (§ 131.200(b)) and any of the optional dairy ingredients (§ 131.200(c)) with the characterizing bacterial culture. We discussed that any optional safe and suitable milk-derived ingredients can be used to increase the milk solids not fat of the food above the minimum required 8.25 percent (74 FR 2443 at 2450 through 2451).

(Comment 14) The proposed rule, at § 131.200(c), would allow the use of other safe and suitable milk-derived ingredients to increase the nonfat solids content of the food, provided that the ratio of protein to total nonfat solids of the food, and the protein efficiency ratio of all protein present is not decreased as a result of adding such ingredients.

Several comments agreed with the proposed limit on the use of optional dairy ingredients. However, other comments opposed the use of ingredients other than fluid milk in the manufacture of yogurt. Some comments said that, without a defined list of optional safe and suitable milk-derived ingredients, processors would make determinations based on financial advantages rather than consumer preferences.

Many comments strongly opposed the use of milk-derived ingredients such as milk protein concentrate (MPC) and whey products. The comments expressed concerns about the safety and nutritional quality of such ingredients, the adverse effect on yogurt quality, and the negative economic impact on the U.S. dairy farmers. Some comments opposed the use of MPC, which the comments considered to be an inferior, unregulated, and mostly imported dairy ingredient. Further, the comments opposing the use of MPC questioned

whether we performed sufficient evaluations to understand the safety and nutritional quality of MPC. The comment argued that, because MPC is not allowed in other standardized dairy foods, it should not be allowed in yogurt. Some comments indicated that MPC has not been classified as ''generally recognized as safe'' (GRAS) (21 CFR 170.3 and 170.30; sections 201(s) and 409 of the FD&C Act) and that, according to a 2001 report from the U.S. Government Accountability Office, MPC is not nutritionally equivalent to fluid milk (Ref. 10).

(Response 14) Like any other food ingredient, optional milk-derived ingredients (§ 131.200(c)) used in yogurt must be safe and suitable. Section 130.3(d) (21 CFR 130.3) defines safe and suitable ingredients used in the manufacture of standardized foods. The safe and suitable ingredient must perform an appropriate function in the food when used (§ 130.3(d)(1)) and be used at a level no higher than necessary to achieve its intended purpose in that food (§ 130.3(d)(2)).

We disagree with the comments that only permitting the use of fluid milk or establishing a defined list of optional dairy milk-derived ingredients is necessary to manufacture the taste, aroma, appearance, and nutritional characteristics of yogurt. We do not find a technical reason to exclude one or more types of milk-derived ingredients as optional dairy ingredients if the use of these ingredients complies with all our applicable regulations, including § 130.3(d)(1) and (2).

We disagree with comments regarding safety or the GRAS status of MPC. Under FDA's GRAS notification program, a person may notify FDA of a conclusion that a substance is GRAS under the conditions of its intended use in human food (21 CFR part 170, subpart E). FDA has evaluated GRAS notices for certain functional uses of MPC in food, including yogurt, and did not question the notifier's conclusion that these uses are GRAS (Ref. 11). FDA is not aware of any information at this time that calls into question the safety of the use of MPC in yogurt. We note that it is a manufacturer's responsibility to ensure that food ingredients are safe and are otherwise in compliance with all applicable requirements. Furthermore, any optional dairy ingredients, such as MPC, must be ''safe and suitable'' according to our regulations whether they are sourced domestically or imported. This means, in relevant part, that any use must be authorized under section 409 of the FD&C Act or be exempt from regulation as a food additive (§ 130.3(d)).

We likewise disagree with the comment's position that MPC is a substandard ingredient. MPC and other non-milk dairy ingredients can be used as optional ingredients, provided the protein efficiency ratio of all protein present must not be decreased as a result of adding optional ingredients. Milk protein concentrates are made by concentrating fluid skim milk using ultrafiltration and spray drying. Because both casein and whey proteins are concentrated in this process, the ratio of casein to whey protein remains nearly the same as the ratio of these components in fluid milk (Ref. 12). Although the comments provided no data to support that yogurt containing MPC in addition to the required dairy ingredients are less acceptable or differ in taste, flavor, or texture to yogurts produced with other optional dairy ingredients, the longtime use of MPC and other optional dairy ingredients in yogurt throughout the marketplace indicates that the basic nature and essential characteristics of yogurt are maintained in producing acceptable and desired yogurt products.

Regarding the use of imported ingredients, we have programs in place, for example inspecting foods that are imported to the United States from other countries, to make sure they comply with government standards and meet the same safety requirements as foods produced within the United States. In general, a foreign or domestic facility that manufactures, processes, packs, or holds food for consumption in the United States and has to register with FDA under section 415 of the FD&C Act (21 U.S.C. 350d) is subject to the requirements related to preventive controls of the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food rule (21 CFR part 117). Compliance with these regulations helps ensure that imported dairy ingredients, including imported MPC, are as safe as domestically produced dairy ingredients.

The comment stating that the use of MPC or whey products as an optional dairy ingredient in yogurt would have a negative economic impact on U.S. dairy farmers did not provide specific information as to how the use of these ingredients would have a negative economic impact. In addition, we note that Congress did not include economic consequences for industry (such as suppliers or manufacturers) as the statutory basis for establishing standards of identity. Section 401 of the FD&C Act permits FDA to establish food standards, and consequently to amend or revoke them, only when doing so ''promotes honesty and fair dealing in the interest of consumers.''

Regarding the comment concerning MPC's effect on nutritional quality, the use of MPC does not diminish the nutritional quality of yogurt. Under the proposed rule, at § 131.200(c), the ratio of protein to total nonfat solids of the food and the protein efficiency ratio of all protein present in yogurt must not be decreased as a result of adding the optional dairy ingredients. This provision ensures that the milk protein amount and protein quality are not reduced after the addition of optional dairy ingredients and should address the other concerns regarding the use of MPC on nutritional quality. This provision is now codified at § 131.200(c) in the final rule.

Although the proposed rule would require the minimum of 8.25 percent milk solids not fat at § 131.200(a), and as discussed in the preamble (74 FR 2443 at 2448), the proposed rule at § 131.200(c) did not specify this minimum when describing other safe and suitable milk-derived ingredients that may be used to increase the nonfat solids content of the food. Thus, on our own initiative, for added clarity, in § 131.200(c) we specify the minimum of 8.25 percent milk solids not fat above which other safe and suitable milk derived ingredients may be used to increase the milk solids not fat content of the food as required in § 131.200(a).

Additionally, we note that the phrase ''nonfat solids content'' in proposed § 131.200(c) would mean the same as the phrase ''milk solids not fat'' in the proposed § 131.200(a). Therefore, to be consistent in the terms used, we have, on our own initiative, revised § 131.200(c) to use the phrase ''milk solids not fat.''

(Comment 15) One comment said that the addition of optional dairy ingredients after culturing should not be permitted for safety concerns, such as microbial contamination. Other comments asked us to permit the addition of optional dairy ingredients after culturing if the optional dairy ingredients are pasteurized and handled in a manner to prevent post-pasteurization contamination. The comments gave cottage cheese as an example of a standardized food in which optional dairy ingredients may be added after culturing; for example, pasteurized cottage cheese dressing is added to the cultured curd.

One yogurt producer stated that adding pasteurized milk-derived ingredients after culturing would conserve water and energy and would provide production flexibility. The comment stated that characterizing the

yogurt, *e.g.,* by adjustment of the fat content, at the end of the process rather than the beginning, would reduce water usage for cleaning blend storage silos and flushing lines between blends. The comment also stated that energy costs would be reduced because the pasteurizer could operate more efficiently with fewer stoppages for changeovers between blends.

(Response 15) We decline to revise the rule to permit optional dairy ingredients after culturing, regardless of whether the optional dairy ingredients are pasteurized and handled in a manner to prevent post-pasteurization contamination. The goal of the standard of identity is to preserve the basic nature and the essential characteristics of yogurt consistent with consumer expectations. Yogurt has long been considered a cultured dairy product where the dairy ingredients are combined and cultured together. As we explained in response 5, the yogurt standard must ensure that the cultured and fermented yogurt reaches the desired titratable acidity 0.7 or maximum pH of 4.6 solely by the fermentation action of bacterial culture. This ensures not only the taste and texture characteristics of yogurt are developed, but also maintains the product's safety and characteristics. Unlike cottage cheese, adding optional dairy ingredients after culturing is not consistent with the development of yogurt's characteristic flavor and acidity. Because more than 90 different compounds are responsible for the flavor and aroma of fermented yogurt (Ref. 3), it is essential that the dairy ingredients be cultured together.

Likewise, regardless of the potential to conserve water and energy in manufacturing, the addition of pasteurized milk-derived ingredients after culturing at the end of the process, rather than the beginning, may negatively affect the essential characteristic flavor and aroma of yogurt. Therefore, we decline to revise the rule to permit the addition of milk-derived ingredients after culturing.

(Comment 16) One comment agreed with our proposal to not require a minimum amount of dairy ingredients. Another comment stated that we should set a percentage higher than 51 percent because, according to the comment, yogurt should be mostly made of dairy ingredients.

(Response 16) As explained in the proposed rule, the yogurt standard requires a minimum milkfat of 3.25 percent and a minimum of milk solids not fat of 8.25 percent before the addition of bulky flavoring ingredients (74 FR 2443 at 2447). As noted previously, the 3.25 percent minimum milkfat requirement is consistent with the USDA FoodData Central database for the total fat content of ''yogurt, plain, whole milk'' (3.25 grams/100 gram serving or 3.25 percent) (Ref. 2). With respect to the minimum milk solids not fat, a minimum of 8.25 percent is consistent with the standards found in fluid milk. Both of these minimum requirements contribute to yogurt's characteristic texture. We noted in the proposed rule that the yogurt standard currently requires that the basic ingredients of yogurt be either milk or certain milk-derived ingredients and that yogurt must contain a specified minimum amount of milk solids not fat (74 FR 2443 at 2453). We did not propose to require a minimum amount of dairy ingredients in yogurt because the existing yogurt standard (§ 131.200(a), (b), and (c)) adequately ensures that appropriate amounts of dairy ingredients are used in the manufacture of yogurt (id.). Therefore, we decline to require a minimum percentage amount of dairy ingredients in yogurt.

F. Section 131.200(d)—Other Optional Ingredients

The proposed rule, at § 131.200(d), would allow other optional safe and suitable ingredients in the manufacture of yogurt, specifically cultures in addition to the characterizing bacterial cultures, sweeteners, flavoring ingredients, color additives, stabilizers, emulsifiers, and preservatives. In addition, the proposed rule would revoke the provisions on optional addition of vitamins A and D (74 FR 2443 at 2454).

(Comment 17) Most comments generally supported the use of safe and suitable ingredients, specifically cultures, in addition to the characterizing bacterial cultures. The comments stated that explicitly providing for the use of other optional safe and suitable bacterial cultures provides regulatory clarity for the use of microorganisms such as probiotic strains in yogurt products. One comment also stated that the proposal provides industry flexibility while maintaining the product's basic nature and essential characteristics.

(Response 17) We are finalizing § 131.200(d)(1) without change.

(Comment 18) The proposed rule, at § 131.200(d)(2), would allow the use of ''sweeteners'' (rather than ''nutritive carbohydrate sweeteners'') as an optional ingredient, to permit the use of any safe and suitable sweetening ingredient rather than certain nutritive carbohydrate sweeteners. We explained that the proposed changes would allow consumers to still be informed of the presence of the sweetening ingredient through its declaration by its common or usual name in the ingredient statement of the yogurt (74 FR 2443 at 2452). However, in response to the NYA petition's request for the ''sweetener being declared in the ingredient statement of the food so that non-nutritive sweeteners may be used in yogurt without a specific declaration of its presence in the name of the food,'' we tentatively concluded that there is no basis to make this change (74 FR 2443 at 2451 through 2452).

Several comments supported the change to ''sweeteners,'' stating that there should be no requirement for the declaration of nonnutritive sweeteners in the name of the food because consumers would be adequately informed of the presence of a sweetening ingredient through the declaration by its common or usual name in the ingredient statement of the yogurt. The comments also stated that amending the rule to refer to sweeteners rather than a specific list of nutritive carbohydrate sweeteners would provide manufacturing flexibility, encourage more low-calorie yogurt options for consumers, and be consistent with the sweetener provision in the standard of identity for ice cream and frozen custard (21 CFR 135.110), which refers to ''safe and suitable sweeteners.''

However, other comments opposed a change to ''sweeteners'' as an optional ingredient. Some comments opposed the use of nonnutritive sweeteners in the yogurt standard of identity because of perceived safety concerns, with some opposing the use of specific artificial sweeteners in yogurt. For example, some comments said that people with sensitivities to a specific artificial sweetener would be unaware the product contained the specific artificial sweetener and could be adversely affected. Other comments stated that, if nonnutritive sweeteners are used, they must be labeled in such a way that consumers are adequately and accurately informed. Several comments would require listing nonnutritive sweeteners in the ingredient statement.

(Response 18) We have decided not to revise § 131.200(d)(2) to specify the use of ''sweeteners'' in yogurt rather than ''nutritive carbohydrate sweeteners.'' If we were to amend § 131.200(d)(2) to refer to ''sweeteners,'' then both nutritive carbohydrate sweeteners and nonnutritive sweeteners would be optional ingredients under the yogurt standard. Consequently, manufacturers could use nonnutritive sweeteners in yogurt to reduce calories without

making a nutrient content claim. This is not what we had intended under the regulatory framework of § 130.10 after NLEA was enacted.

We have decided that nonnutritive sweeteners should only be permitted when making a nutrient content claim and therefore when the product is subject to the general definition and standard in § 130.10. As such, products containing nonnutritive sweeteners, but that otherwise comply with the requirements in § 131.200, are not the standardized food ''yogurt'' and are different standardized foods (*e.g.,* ''reduced calorie yogurt'') under § 130.10. The name of each of these foods must be prominently displayed in the statement of identity on the product label in accordance with § 101.3. We note that this approach is consistent with the approach under our current regulations as § 130.10 permits deviations to §§ 131.200, 131.203, and 131.206 in order to comply with a nutrient content claim defined by regulation (*e.g.,* ''reduced calorie'').

We further note that, under this approach, products deviating from § 131.200 due to the use of nonnutritive sweeteners are not required to declare the presence of the nonnutritive sweeteners in the name or statement of identity of the food. Instead, § 130.10 requires them to bear the nutrient content claim achieved by use of nonnutritive sweeteners in the name or statement of identity. We believe this approach will address comments concerning the presence and disclosure of artificial sweeteners while also providing manufacturers flexibility to make modified yogurt products with nonnutritive sweeteners. Unlike the proposed rule, the final rule does not permit the use of nonnutritive sweeteners in yogurt under § 131.200(d)(2). However, under § 130.10, products marketed with a nutrient content claim in the name of the food (*e.g.,* ''reduced calorie yogurt'') will signal to consumers that the food differs from ''yogurt,'' ''lowfat yogurt,'' and ''nonfat yogurt'' and contains nonnutritive sweeteners. Consumers will continue to be informed about the presence of specific nonnutritive sweeteners by their declaration under their common or usual names in the ingredient statement on the label, as required by § 101.4(a).

We have also considered comments concerning safety. We consider the safety of nonnutritive sweeteners as part of the food additive review process or GRAS notification process. There is no evidence to indicate that nonnutritive sweeteners, either as approved food additives or as GRAS substances in yogurt, are unsafe when used in modified yogurt products. We understand that some consumers may have sensitivities to artificial sweeteners. As explained above, the name or statement of identity of the product will put consumers on notice about the presence of artificial sweeteners and the particular sweetener can be confirmed by referencing the ingredient statement.

(Comment 19) Some comments asked us to require prominent declaration or display (*e.g.,* in large type on the principal display panel) of nonnutritive sweeteners on yogurt containers in addition to listing the nonnutritive sweeteners in the ingredient statements.

(Response 19) We do not agree that the name of the nonnutritive sweetener should be prominently displayed on the yogurt containers because, under § 130.10, a yogurt product with nonnutritive sweeteners will bear a nutrient content claim, such as ''reduced calorie,'' in its statement of identity. Section 101.3(d) requires that the statement of identity be presented in bold type on the principal display panel, in a size reasonably related to the most prominent printed matter on such panel, and in lines generally parallel to the base on which the package rests as it is designed to be displayed. The nutrient content claim will signal to consumers the presence of nonnutritive sweeteners and prompt consumers to check the ingredient statements for the types of nonnutritive sweeteners used. Disclosure of nonnutritive sweeteners in the ingredient statement, rather than the name or statement of identity, is consistent with the labeling of other foods made with nonnutritive sweeteners. Nonnutritive sweeteners are declared by their common or usual names in the ingredient statement on the food labels in accordance with § 101.4(a).

In some instances, specific requirements are necessary for the safe use of a nonnutritive sweetener. The conditions for including this information on the label and how and where this information is to be presented on the label are established in the relevant food additive regulations. For example, labels of food that contain aspartame must bear the statement ''PHENYLKETONURICS: CONTAINS PHENYLALANINE,'' either on the principal display panel or on the information panel, in accordance with § 172.804 (21 CFR 172.804).

Other than what is provided in these regulations, we do not see a basis to require disclosure of nonnutritive sweeteners other than in the ingredient statement. Therefore, we decline to require the name of the nonnutritive sweetener be prominently displayed on the yogurt container. However, manufacturers may declare, voluntarily, on the principal display panel that the product is artificially sweetened or is made with nonnutritive sweeteners as long as the declaration is truthful and not misleading.

(Comment 20) One comment opposed the use of high fructose corn syrup (HFCS) in yogurt.

(Response 20) HFCS is a nutritive carbohydrate. HFCS is affirmed as GRAS and can be used in food with no limitation other than current good manufacturing practice (§ 184.1866 (21 CFR 184.1866)). The comment did not provide any data or other information to support prohibiting the use of HFCS in yogurt, so we decline to revise the rule to exclude HFCS as a sweetener.

(Comment 21) The proposed rule would revise § 131.200(d)(5) to permit the use of safe and suitable emulsifiers in addition to stabilizers as optional ingredients in the manufacture of yogurts.

A few comments opposed the use of emulsifiers and questioned the need for these ingredients in yogurt. Other comments supported the use of emulsifiers in yogurt, indicating that this would allow industry more flexibility in formulating products.

(Response 21) There are no data suggesting that emulsifiers pose any safety or characteristic concerns in yogurt, provided they are used within good manufacturing practice as described in 21 CFR 172.5(a) and within limitations specified by our relevant food additive regulations or are GRAS. Therefore, we decline to remove emulsifiers as an optional ingredient in yogurt. However, to clarify that stabilizers and emulsifiers are two different functional classes, we have, on our own initiative, decided to list stabilizers and emulsifiers separately as § 131.200(d)(5) and (6), respectively. We also have renumbered § 131.200(d)(6) as § 131.200(d)(7).

(Comment 22) The proposed rule, at § 131.200(d)(6), would permit preservatives as an optional ingredient in yogurt. Some comments supported permitting the use of safe and suitable preservatives as optional ingredients in the manufacture of yogurt and stated that the use of preservatives should not be limited only to heat-treated yogurt. Other comments opposed the use of any preservatives.

(Response 22) The proposed rule would not limit the use of preservatives to heat-treated yogurt and would, instead, allow the use of preservatives for all types of yogurt. The comments

that opposed the use of preservatives did not provide any data or information to support their opposition, and we do not have any data that indicate that appropriate use of preservatives has an adverse effect on the characteristics of yogurt, particularly in the case of yogurt that is heat-treated after culturing to have an extended shelf-life. Therefore, we decline to revise § 131.200(d)(6) regarding the use of preservatives as an optional ingredient in yogurt, but we have renumbered the section in the final rule as § 131.200(d)(7) (see response 21).

(Comment 23) The proposed rule would revoke § 131.200(b), which provides for optional addition of vitamins A and/or D in yogurt, and revoke § 131.200(f)(1)(iii),which pertains to labeling of yogurt that contains added vitamins A and D. The proposed rule explained, in part, that the provision for the optional fortification of yogurt with vitamins A and D was established in 1981 before the implementation of the NLEA and the adoption of the certain nutrient content and relative claims regulations, including § 101.54. We explained in the proposed rule that we believed it was appropriate to apply the provisions of § 101.54(e) to vitamins A and D fortification of yogurt (74 FR 2443 at 2454).

We invited comment on whether we should retain the current optional vitamin addition provisions of § 131.200(b) and, if so, what the justification for retaining these provisions would be, and the appropriateness of applying § 101.54(e) to yogurt fortified with vitamins A and/or D. One comment agreed with removing the provisions pertaining to optional addition of vitamins A and D.

However, other comments asked us to retain the current optional vitamin fortification provisions and the associated labeling provision. The comments said that, even though such provisions are not consistent with the NLEA and the nutrient content claim regulations, optional vitamins A and D fortification is a longstanding practice for the yogurt industry and is consistent with the standards of identity for other milk products in 21 CFR part 131.

Another comment said we should revise the amounts of vitamins A and D fortification based on percentages of recommended Daily Values (DV) rather than specific levels per quart. The comment recommended we modernize the optional vitamin A addition of not less than 10 percent DV per RACC and optional vitamin D addition of not less than 25 percent DV per RACC in the final rule.

(Response 23) Given the yogurt industry's current fortification practice and apparent consumer acceptance of optional fortification with corresponding ingredient declaration, the final rule does not remove the provisions concerning the optional addition of vitamins A and D. For these reasons, the provisions for optional addition of vitamins A and D remain part of the yogurt standard; however, because the final rule also reorganizes and renumbers the provisions in § 131.200, we have placed the provisions regarding optional vitamin addition in § 131.200(d)(8).

We believe that modernization of the yogurt standard of identity should include bringing the outdated vitamins A and D fortification provisions in conformity with the way in which vitamins are now referenced based on percentages of recommended DV rather than specific levels per quart. Therefore, the final rule, at § 131.200(d)(8), provides for the optional addition of vitamin A if added at not less than 10 percent Daily Value per RACC, and/or the optional addition of vitamin D if added at not less than 25 percent Daily Value per RACC.

In addition, we decline to revoke the labeling requirements associated with optional vitamins A and/or D addition. To inform consumers about the optional addition of vitamins A and/or vitamin D, these requirements remain part of the yogurt standard in § 131.200(f)(1)(iii).

(Comment 24) The proposed rule discussed that the standards of identity for yogurt, lowfat yogurt, and nonfat yogurt do not permit the optional use of any safe and suitable ingredient for a nutritional or functional purpose. We explained that while the NYA petition asked us to revise our regulations to allow for such ingredients and while comments to the ANPRM both favored and opposed the NYA recommendation, we decided that there was not a need for a broad provision to permit any safe and suitable ingredient for a nutritional or functional purpose (74 FR 2443 at 2453).

The comments to the proposed rule were mixed on whether we should add a broad provision permitting the use of any safe and suitable ingredient that serves a nutritional or functional purpose. Some stated that such an approach would help maintain the integrity of yogurt. Other comments said that any safe and suitable ingredient should be allowed to provide flexibility and to promote innovation. One comment was concerned that yogurt bearing nutrient content claims would no longer fall under the standard of identity without a provision that would allow the use of any safe and suitable ingredient for a nutritional or functional purpose. Another comment emphasized that lactic acid and other acidulants as functional ingredients should not be allowed.

(Response 24) As we explained in the proposed rule, our existing regulatory framework governing standardized foods already provides for the addition of substances for a nutritional purpose (74 FR 2443 at 2453). As for the use of ingredients for a functional purpose, the final rule, at § 131.200(c), provides for the use of optional dairy ingredients to increase the nonfat solids content of food under certain conditions. The final rule, at § 131.200(d), also provides for the use of specific functional categories of ingredients such as emulsifiers and stabilizers. We revised § 131.200 to retain the optional addition of vitamins A and/or D. Section 131.200(d)(8) now provides for optional addition of these vitamins as in our current standard of identity for yogurt but has been revised to specify the amounts of added vitamins A and D based on percentages of DV per RACC rather than International Units per quart.

Although § 131.200(c) and (d) permit the use of certain optional ingredients for nutritional or functional purposes in yogurt, lactic acid and other acidulants are not permitted as other optional ingredients under § 131.200(d). Yogurt is produced by culturing the basic dairy ingredients and any optional dairy ingredients with a characterizing lactic acid-producing bacterial culture, and not through the addition of lactic acid or other acidulants (see response 6).

G. Section 131.200(e)—Methods of Analysis

The current standard of identity for yogurt lists the methods of analysis for milkfat content, total solids content, and titratable acidity that are from the ''Official Methods of Analysis of AOAC International,'' 13th Ed. (1980). The proposed rule, at § 131.200(e), would update the referenced methods of analysis to ''Official Methods of Analysis of AOAC International (AOAC Methods),'' 18th edition, 2005. The AOAC Methods have been updated twice since the publication of the proposed rule. The latest version is the 21st edition, 2019. Therefore, on our own initiative, we have revised § 131.200(e) to refer to the 21st edition of the AOAC Methods.

The proposed rule inadvertently deleted the milkfat method of analysis from § 131.200(e). Therefore, on our own initiative, we have revised § 131.200(e) by restoring the method of analysis for milkfat referencing the

updated modified Mojonnier ether extraction method in section 33.2.26 of the AOAC Methods: Official Method 989.05. Thus, we have revised § 131.200(e)(1) by adding paragraph (i) to identify the AOAC Official Method 989.05 for milkfat content and renumbering the remaining paragraphs accordingly.

The proposed rule, at § 131.200(e)(1)(i) and (ii), would establish the methods of analysis for milk solids not fat and for titratable acidity, respectively.

We did not receive comments on these provisions. However, as explained previously, we have renumbered these provisions as § 131.200(e)(1)(ii) and (iii), respectively, because we have restored the inadvertent deletion of the method of analysis for milkfat at § 131.200(e)(1)(i).

Proposed § 131.200(e)(2) would adopt the potentiometric method for pH as described in § 114.90(a) (21 CFR 114.90(a)).

We did not receive comments on the method for pH that indicated a need to change methodology, and we have finalized § 131.200(e)(2) without change.

(Comment 25) Proposed § 131.200(e)(3) would discuss the measurement of live and active cultures and refer to the use of the aerobic plate count method described in Chapter 3 of FDA's Bacteriological Analytical Manual, January 2001 edition (the BAM method) (Ref. 13). Several comments objected to the use of the BAM method. The comments indicated that the BAM method is not appropriate for the accurate enumeration of live and active cultures in yogurt. The comments recommended that, for accuracy and repeatability, live and active cultures should be determined by the method described in the International Organization for Standardization (ISO) 7889/International Dairy Federation (IDF) 117:2003 (ISO 7889/IDF 117:2003), ''Yogurt-Enumeration of characteristic microorganisms—colony count-technique at 37 °C'' (Ref. 14).

(Response 25) We evaluated the BAM method and the ISO 7889/IDF 117:2003 method. We agree that the BAM method is a general reference for determining plate counts and is not designed specifically for the measurement of characterizing cultures in yogurt products. We also agree that the ISO 7889/IDF 117:2003 method, which is specifically designed to measure the characteristic microorganisms in yogurt, is the appropriate method. The ISO 7889/IDF 117:2003 method is also referenced as the appropriate method to enumerate characterizing microorganisms in yogurt in the *Standard Methods for the Examination of Dairy Products* (Ref. 15). Therefore, we have revised § 131.200(e)(3) and replaced the proposed BAM method with the ISO 7889/IDF 117:2003 method incorporated by reference in the final rule.

(Comment 26) One comment said that, for other safe and suitable organisms, individual yogurt manufacturers should bear the responsibility of using validated methods to enumerate such bacteria to substantiate label claims.

(Response 26) We agree that manufacturers using other safe and suitable bacterial cultures have or should have the knowledge to determine the most appropriate method to enumerate these organisms. Therefore, the final rule does not specify methods to measure other safe and suitable bacterial cultures to substantiate label claims.

H. Section 131.200(f)—Nomenclature

The proposed rule would revise § 131.200(f) by: (1) Stating that the word ''sweetened'' must accompany the name of the food wherever it appears on the principal display panel or panels if a ''sweetener'' (rather than a nutritive carbohydrate sweetener) is added without the addition of characterizing flavor; and (2) providing for the optional labeling of ''contains live and active cultures.''

As discussed in responses 18, 19, and 20, we have decided to retain the term ''nutritive carbohydrate sweeteners'' in § 131.200(d)(2) instead of using the term ''sweeteners.'' Likewise, we have decided to retain ''nutritive carbohydrate sweetener'' in § 131.200(f)(1)(i) rather than use the term ''sweetener.'' The requirement in § 131.200(f)(1)(i) continues to apply only to nutritive carbohydrate sweeteners and is not amended under this final rule. Under § 130.10, nonnutritive sweeteners can be used in the manufacture of yogurt products that deviate from the standard of identity for yogurt in order to meet an expressed nutrient content claim defined by regulation (*e.g.,* ''reduced calorie''). The nutrient content claim is part of the name or the statement of identity of the food (*e.g.,* ''reduced calorie yogurt'') and signals to consumers that the food differs from yogurt and contains nonnutritive sweeteners.

As discussed in responses 27, 28, and 29 regarding the labeling of yogurt containing live and active cultures, the final rule revises the proposed nomenclature provisions relating to heat-treated yogurt. Changes in the final rule at § 131.200(a), (b), (c), and (d) necessitate additional changes in § 131.200(f) regarding nomenclature provisions in the final rule.

(Comment 27) Currently, § 131.200(f)(1)(ii) requires that, if the yogurt product is heat-treated after culturing, the parenthetical phrase ''(heat-treated after culturing)'' must follow the name of the food wherever it appears on the principal display panel or panels of the label in letters not less than one-half of the height of the letters used in such name. The proposed rule would revise § 131.200(f)(1)(ii) by requiring the parenthetical phrase ''(heat-treated after culturing)'' to appear after the name of the food if the dairy ingredients have been heat-treated after culturing.

One comment opposed modifying the labeling requirements for heat-treated yogurt. The comment also opposed the requirement of any phrase on the label of heat-treated yogurt that would classify it as one that does not contain live and active cultures, arguing that there is no difference in the effect on the human body between the consumption of yogurt with live and active cultures and those without. Other comments expressed concerns that consumers may not understand the statement ''heat-treated after culturing,'' although one comment did agree with the proposed rule. Another comment cited a consumer survey that evaluated consumer understanding of the phrase ''heat-treated after culturing.'' The comment claimed that the cited survey indicated that the meaning of this phrase is not clear to most consumers and does not inform consumers that the treatment destroys some or all the bacterial cultures.

Many comments opposed heat treatment after culturing but said that, if heat treatment after culturing is allowed, the product should be clearly labeled (see comment 7). One comment would require a statement on the package to indicate that the product ''does not contain live and active cultures.''

(Response 27) As discussed in response 7, many consumers are interested in knowing whether the yogurt product they purchase contains live and active cultures. The term used in the proposed rule ''heat-treated after culturing'' is a description of a manufacturing process and does not directly inform consumers how the manufacturing process affects the properties of finished yogurt product. Apart from the nutritional aspect, the beneficial effect of yogurt or yogurt cultures is reportedly either lost (Ref. 16) or reduced (Refs. 17 to 20) when the

yogurt is heat-treated after culturing. In the proposed rule, we recommended that manufacturers may consider using additional truthful and non-misleading statements, such as ''does not contain live and active cultures,'' in the labeling of their heat-treated yogurt products to help consumers distinguish heat-treated yogurt from traditional yogurt (74 FR 2443 at 2450). We evaluated the consumer survey results and conclude that the survey findings support the belief that many consumers do not understand the meaning of the term ''heat-treated after culturing'' (Ref. 6). We find that the term ''heat-treated after culturing'' does not adequately inform consumers whether the yogurt still contains live and active cultures in the final product. To prevent the labeling of yogurt from being misleading under section 403(a)(1) and 201(n) of the FD&C Act, the phrase ''does not contain live and active cultures'' should appear on the label of yogurt instead of ''heat-treated after culturing'' when the final product does not contain live and active cultures. Therefore, we have revised § 131.200(f)(1)(ii) to require the phrase ''does not contain live and active cultures'' if the dairy ingredients have been treated after culturing to inactivate viable microorganisms.

(Comment 28) One comment stated that new and emerging thermal treatment technologies that are less severe than pasteurization conditions have been used to enhance the sensory profile of a product or for acidity purposes. The comment asked us to clarify that, if these heated yogurt products still contain a minimum of 10^7 CFU/g live and active cultures at the time of manufacture, they do not have to bear the statement indicating that they have been heat-treated or do not contain live and active cultures.

(Response 28) We understand that the impact of a heat treatment will vary depending on heating temperature and holding time. We agree that it would not be appropriate to require heated yogurt products with 10^7 CFU/g live and active cultures to bear the ''does not contain live and active cultures'' statement. As discussed in response 7, we realize that, in the future, new technologies other than heat treatment may be developed to inactivate viable microorganisms and thus extend a product's shelf life. The ''does not contain live and active cultures'' statement should not be limited to only heat-treated yogurt. It would be appropriate for products that have not been heat-treated but have been treated with other alternative technologies to inactivate viable microorganisms, to bear the ''does not contain live and active cultures'' statement to adequately inform consumers. Therefore, we have revised § 131.200(f)(1)(ii) to require that the phrase ''does not contain live and active cultures'' accompany the name of the food if the yogurt has been treated after culturing to inactivate viable microorganisms.

(Comment 29) A few comments requested that we require the statement ''does not contain live and active cultures'' to appear prominently on the label or in the same size, font, and color as the name of the food and in close proximity to the name of the food without intervening material.

(Response 29) Under § 131.200(f)(1)(ii), the phrase ''does not contain live and active cultures'' is required to accompany the name of the food wherever it appears on the principal display panel or panels of the label in letters not less than one-half of the height of the letters used in the name. We do not agree with the comments that the phrase ''does not contain live and active cultures'' must appear in the same size, font, and color as the name of the food. The comments did not demonstrate why use of the same size, font, and color as the name of the food would improve consumer attention to or understanding of the phrase.

I. Revoking the Standards of Identity for Lowfat Yogurt and Nonfat Yogurt

(Comment 30) Some comments supported revoking the standards of identity for lowfat yogurt and nonfat yogurt such that the standardized food yogurt under proposed § 131.200 could be modified to produce lower-fat versions of yogurt under § 130.10. (For purposes of this preamble, ''lower-fat'' versions of yogurt refers to products with less than 3.25 percent minimum fat level specified in § 131.200(a).) Other comments were concerned that there will be no standard of identity for these lower-fat versions of yogurt.

(Response 30) Revocation of § 131.203 and § 131.206 will result in lowfat yogurt and nonfat yogurt being covered under the general definition and standard of identity in § 130.10. This action will provide for consistency in the nomenclature and labeling of ''lowfat'' and ''no fat'' food products and help ensure ''lowfat'' yogurt meets consumer expectations. These foods, along with other lower-fat versions of yogurt, will be standardized foods with a standard of identity under this regulation. Because § 130.10 only permits specific deviations from the standardized food for which a lower-fat version substitutes, many requirements in the yogurt standard of identity will apply to lower-fat versions and will help maintain the basic nature and essential characteristics of these products.

J. Compliance Date

(Comment 31) The proposed rule did not discuss when a final rule would become effective or when the compliance date for a final rule would occur.

One comment requested a 2-year implementation date for necessary label changes after the final rule. The comment indicated that revoking the standards of identity for lowfat yogurt and nonfat yogurt would require these products to be fortified to achieve nutrient equivalency. The comment also stated that the 2-year implementation date is consistent with the Uniform Compliance Date for label changes and will provide enough time for processors to deplete existing packaging inventory, reformulate products, install fortification equipment, and make the necessary label changes. Another comment asked us to align the compliance timeline of the final yogurt rule with that of a then-unpublished final rule to revise our Nutrition and Supplement Facts Label requirements (79 FR 11880, March 3, 2014). The comment said that companies could revise yogurt labels much more efficiently by making a single set of changes in response to both sets of requirements and minimize the economic impact of label changes.

(Response 31) The final rule is effective on July 12, 2021. The compliance date of this final rule is January 1, 2024, consistent with Uniform Compliance Date for final food labeling regulations that are issued in calendar years 2021 and 2022 (see 86 FR 462, January 6, 2021).

We decline to align the compliance date with that for the final Nutrition and Supplement Facts Label regulations. We note that the compliance date for the final Nutrition and Supplement Facts Label regulations is January 1, 2020, for manufacturers with $10 million or more in annual food sales and January 1, 2021, for manufacturers with less than $10 million in annual food sales (83 FR 19619, May 4, 2018). Thus, these compliance dates for the Nutrition and Supplement Facts Label regulation have already passed.

K. Amendments in 21 CFR 130.10

Revoking the standards of identity for lowfat yogurt and nonfat yogurt brings these foods under the coverage of the general definition and standard in § 130.10. For foods covered under the general definition and standard,

§ 130.10(b) requires nutrients to be added to restore nutrient levels so that the product is not nutritionally inferior to the standardized food as defined in 21 CFR parts 131 to 169. As discussed in the proposed rule, lowfat yogurt and nonfat yogurt have a lower vitamin A content than yogurt and therefore would be required under § 130.10(b) to be fortified with vitamin A to the same level as yogurt.

(Comment 32) One comment supported nutritional equivalence of lowfat yogurt and nonfat yogurt with yogurt under § 130.10(b), noting that the requirement would make these foods consistent with other foods modified under the general definition and standard. Another comment opposed mandatory fortification of lowfat yogurt and nonfat yogurt with vitamin A based on the costs of compliance for industry.

(Response 32) Requiring vitamin A fortification of lower-fat yogurt products under § 130.10(b) would not necessarily make these products consistent with other modified dairy foods. FDA has not enforced § 130.10(b) with respect to vitamin A fortification of lower-fat milk products covered under the general definition and standard (see *South Mt. Creamery, LLC* v. *United States FDA,* 438 F. Supp. 3d 236 (2020)). Moreover, as noted in the proposal, the contribution of yogurt to daily vitamin A intake is not expected to be altered significantly if the nutritional equivalency requirement in § 130.10(b) were to apply to lowfat yogurt and nonfat yogurt. Although yogurt consumption has increased in recent years, the contribution of vitamin A that would result from fortification of lower-fat yogurt products remains insignificant (Ref. 21). Thus, in light of our enforcement policy regarding vitamin A fortification of lower-fat milk products and the lack of public health impact from vitamin A fortification of yogurt, we are amending § 130.10(b) to exempt lower-fat yogurt products from vitamin A fortification.

This final rule revises § 130.10(b) to provide for the exemption. Manufacturers may choose to fortify lowfat yogurt and nonfat yogurt with vitamin A to the level in yogurt; however, they are not required to do so. If they choose to fortify with vitamin A under § 130.10(b), then vitamin A must be declared in the ingredient statement.

L. Incorporation by Reference

The final rule incorporates two references. As we explained in part IV.G, FDA is incorporating by reference three methods from the ''Official Methods of Analysis of AOAC International,'' 21st edition (2019). You may purchase a copy of the material from AOAC INTERNATIONAL, 2275 Research Blvd., Suite 300, Rockville, MD 20850–3250, USA, 301–924–7077 ext. 170. *https://www.aoac.org/official-methods-of-analysis-21st-edition-2019/.* The AOAC Methods have undergone rigorous scientific review and validation to determine the performance characteristics for the intended analytical application and fitness for purpose. Each of the following three methods includes specific instructions for performing the chemical analysis of a substance in a particular matrix.

- AOAC Official Method 947.05, Acidity of Milk Titrimetric Method, 21st edition, 2019, Vol. 1.
- AOAC Official Method 989.05, Fat in Milk Modified Mojonnier Ether Extraction Method, 21st edition, 2019, Vol. 1.
- AOAC Official Method 990.21, Solids-Not-Fat in Milk by Difference between Total Solids and Fat Contents, 21st edition, 2019, Vol. 1.

Also, FDA is incorporating by reference the International Organization for Standardization 7889:2003(E)/International Dairy Federation 117:2003(E) (ISO 7889:2003(E)|IDF 117:2003(E)), Yogurt—Enumeration of Characteristic Microorganisms—Colony-Count Technique at 37 °C, First edition, 2003–02–01. You may purchase a copy of the material from the International Organization for Standardization, ISO Central Secretariat, Chemin de Blandonnet 8, CP 401, 1214 Vernier, Geneva, Switzerland. +41 22 749 01 11. *central@iso.org.* ISO 7889|IDF 117:2003 specifies a method for the enumeration of characteristic microorganisms in yogurt by means of the colony-count technique at 37 degrees Celsius. The method is applicable to yogurts in which both characteristic microorganisms (*L. delbrueckii* subspecies *bulgaricus* and *S. thermophilus*) are present and viable.

V. Economic Analysis of Impacts

This rule is issued in accordance with the formal rulemaking provisions of 5 U.S.C. 556 and 557, and is, therefore, exempt from the economic analysis requirements of Executive Order (E.O.) 12866 and E.O. 13563. We have examined the economic implications of this rulemaking on small businesses.

Regulatory Flexibility Analysis

The Regulatory Flexibility Act (5 U.S.C. 601–612) requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this rule may generate compliance costs for some small firms, we believe that this rule would have a significant economic impact on a substantial number of small entities and is therefore subject to a final regulatory flexibility analysis (5 U.S.C. 604). The following analysis, in conjunction with the remainder of the preamble, constitutes our final regulatory flexibility analysis.

One requirement of the Regulatory Flexibility Act is a succinct statement of any objectives of the rule. As stated previously in the preamble, with this rule, we intend to amend the yogurt standard of identity and revoke the lowfat yogurt and nonfat yogurt standards of identity to promote honesty and fair dealing in the interest of consumers. The amendments are intended to modernize the current yogurt standard and allow for lowfat yogurt and nonfat yogurt to be covered under the general definition and standard to permit flexibility and provide for technological advances in yogurt production, while preserving the basic nature and essential characteristics of yogurt, lowfat yogurt, and nonfat yogurt consistent with consumer expectations and protecting consumer interests.

This rule would affect yogurt manufacturing firms in the Standard Industrial Classification (SIC) code 20260208 (''Yogurt Manufacturing''). The equivalent North American Industry Classification System (NAICS) code is 311511 (''Fluid Milk Manufacturing''). The Small Business Administration (SBA) defines a small business in NAICS code 311511 as a business with 500 or fewer employees. This rule will not affect firms that manufacture products such as frozen yogurt, dried yogurt-style mixes, or products that contain yogurt as an ingredient.

We searched the Dun and Bradstreet database for U.S. firms in SIC code 20260208 (''Yogurt Manufacturing'') and identified 450 firms. To exclude firms not engaged in the manufacture of yogurt, we performed an internet search of the name of each firm and identified frozen yogurt manufacturers. After excluding frozen yogurt manufacturers, we estimate that there are approximately 31 U.S. yogurt manufacturers, of which approximately 9, or 29 percent (= 31×0.29), are small businesses per SBA definition.

We expect that three provisions of the final rule may require some small firms to change their current activity. The other provisions of the final rule provide additional flexibility to firms beyond that available under current requirements. For this analysis, we estimate costs for those provisions that may require some small firms to change

their current practices. We do not estimate costs for changing manufacturing practices in ways that would be newly permitted by the final rule as costs of the final rule.

The three provisions that we estimate will require some small firms to change their current practices are:

1. The requirement that yogurt have either a titratable acidity of not less than 0.7 percent expressed as lactic acid or a pH of 4.6 or lower (''Acidity Requirement'').

2. The requirement that yogurt bearing optional labeling statements such as ''contains live and active cultures'' must contain a minimum of 10^7 CFU/g of live and active cultures at the time of manufacture with a reasonable expectation that the yogurt will contain live and active cultures at a level of 10^6 CFU/g through the manufacturer's assigned shelf life of the product, as well as the requirement that yogurt that is treated after culturing bear on its label the statement ''does not contain live and active cultures'' (''Claims Requirements'').

3. The revocation of the standards of identity for lowfat yogurt (§ 131.203) and nonfat yogurt (§ 131.206) (''Standards of Identity Revocation'').

The following analysis estimates the costs of each provision to small manufacturers.

1. The Acidity Requirement

The final rule requires that yogurt have either a titratable acidity of not less than 0.7 percent expressed as lactic acid or a pH of 4.6 or lower. We stated that we believed that all or nearly all yogurt currently on the market had a titratable acidity above the then-proposed minimum cutoff of 0.7 percent, usually in the range of 1.0 to 1.3 percent, and a pH level below the proposed maximum level of 4.6, usually ranging from 4.1 to 4.3. At the time, we estimated that the proposed acidity requirements would generate minimal or no compliance costs. We received no comments on this.

In the final rule, we require that yogurt have either a titratable acidity of not less than 0.7 percent expressed as lactic acid or a pH of 4.6 or lower. We still believe that all or nearly all yogurt currently on the market has a titratable acidity above the minimum cutoff of 0.7 percent titratable acidity, usually ranging from 1.0 to 1.3 percent, and a pH level below the proposed maximum level of 4.6, usually ranging from 4.1 to 4.3. We estimate that the Acidity Requirement would generate minimal or no compliance costs.

2. The Claims Requirements

Yogurt manufacturers who want to include the optional statement ''contains live and active cultures'' or similar claims on labels will be required to show that their yogurt contains at least 10^7 CFU/g of live and active cultures at the time of manufacture of the yogurt using analytical testing methods. Otherwise, such a claim cannot be made. In addition, yogurt products that are treated to inactivate viable microorganisms after culturing but do not currently bear the claim ''does not contain live and active cultures'' will be required to add this claim to labels. This was modified for clarity as the proposed rule would require yogurt products that are heat-treated after culturing to bear the claim ''heat-treated after culturing'' on their label and it would advise, but not require, that such yogurt products also bear the claim ''does not contain live and active cultures'' on their label.

Based on an analysis of yogurt UPCs using the online grocery shopping platform Peapod®, approximately 85 percent of yogurt UPCs currently make a ''contains live and active cultures'' or similar claim. Approximately 15 percent of yogurt UPCs make no such claims. We estimate that approximately 1,972 UPCs manufactured by small yogurt manufacturers, or equivalently 8 small yogurt manufacturers, will be affected by the Claims Requirement related to the ''contains live and active cultures'' or similar claim (''Claims Requirement A'') and approximately 348 UPCs manufactured by small yogurt manufacturers, or equivalently 1 small yogurt manufacturer, will be affected by the Claims Requirement related to the ''does not contain live and active cultures'' claim (''Claims Requirement B'').

Based on further analysis of yogurt UPCs using Peapod®, 56 percent of yogurt UPCs that make a ''contains live and active cultures'' or similar claim also make a claim that they meet the NYA standard for live and active cultures. The NYA's standard of at least 10^8 CFU/g at the time of manufacture is higher than our standard of at least 10^7 CFU/g. We estimate that approximately 1,105 of the 1,972 UPCs that are affected by Claims Requirement A and are manufactured by small yogurt manufacturers will only need to incur analytical testing costs related to this Claims Requirement.

We do not know how many of the remaining 868 small manufacturer yogurt UPCs that are affected by Claims Requirement A meet this Claims Requirement. Therefore, we conservatively estimate that none do, so that some of these UPCs will need to incur analytical testing costs and reformulation costs to prove that they meet the 10^7 live and active cultures standard. Others will need to incur relabeling costs associated with removing the ''contains live and active cultures'' or similar claims from labels. As we are not aware of data on these proportions, we estimate an even split between these possibilities, with approximately 434 UPCs incurring analytical testing and reformulation costs and approximately 434 UPCs incurring relabeling costs. Finally, we do not know how many of the 348 small manufacturer yogurt UPCs that do not make any kind of a ''contains live and active cultures'' or similar claim undergo heat treatment after culturing and would be subject to Claims Requirement B. Therefore, we conservatively estimate that all undergo heat treatment after culturing and estimate the relabeling costs associated with adding the phrase ''does not contain live and active cultures'' to their labels.

We estimate analytical testing costs using information on formula and UPC counts from 2014 Nielsen Scantrack data, as well as information gathered on published prices from various testing laboratories. This information was gathered by RTI International as part of its development of the FDA Labeling Cost Model. We estimate that the total number of yogurt formulas is approximately 6,070 and the total number of yogurt UPCs is approximately 8,002, yielding a formula-to-UPC ratio of 0.759 (6,070/8,002 = 0.759). The total number of UPCs that will require analytical testing is approximately 1,539 and the total number of formulas subject to analytical testing is approximately 1,167. Analytical tests designed to detect pathogens in food cost between $25.72 and $60.81 in 2019 dollars per formula. These costs represent an estimate of the costs of measuring the amount of CFU/g in yogurt. We estimate that two samples per formula are tested and that labor costs to prepare samples are approximately $29.58 and shipping costs related to shipping the samples to the testing laboratory are approximately $70.81 in 2019 dollars. Therefore, we estimate analytical testing costs to be between approximately $177,206 and $259,105 per year.

The number of small yogurt UPCs that will reformulate related to Claims Requirement A is approximately 434 and the total number of formulas subject to reformulation is approximately 329. We estimated reformulation costs by

multiplying the number of formulas by estimates of per-formula costs. We obtain per-formula cost estimates from the FDA Reformulation Cost Model (Ref. 22), which allows the incorporation of a variety of potential reformulation costs associated with idea generation, product research and process development, coordinating activities, product testing, packaging development, market testing, and production/manufacturing. We estimate that the addition of live and active cultures to yogurt batches represents a critical minor ingredient with functional effects, yielding per-formula reformulation costs ranging from approximately $28,530 to $289,845 in 2019 USD. We estimate that some manufacturers will be able to coordinate a required reformulation with a scheduled reformulation, resulting in lower reformulation costs than if they were unable to coordinate. However, the extent to which manufacturers can undertake such coordination depends on the compliance period. For a 24-month compliance period, we estimate that 20 percent of reformulations can be coordinated with a scheduled reformulation. Combining this information, we estimate one-time reformulation costs related to the Claims Requirement to be between approximately $7.5 million and $76.3 million in 2019 dollars. Annualized over 10 years and discounted at 3 percent, reformulation costs range from approximately $855.1 thousand to $8.7 million per year in 2019 dollars. Annualized over 10 years at 7 percent, reformulation costs range from approximately $1.0 million to $10.2 million per year.

We previously estimated that 434 small yogurt UPCs will undergo relabeling related to removing their ''contains live and active cultures'' or similar claims and 348 small yogurt UPCs will relabel related to the addition of the phrase ''does not contain live and active cultures'' to their label, for a total of 782 small yogurt UPCs affected by relabeling under the Claims Requirement. We estimate the one-time cost of changing all yogurt labels using the FDA Labeling Cost Model. The removal and addition of claims is a major label change. Using the Labeling Cost Model and using a 24-month compliance period, the estimated one-time labeling cost lies between approximately $4.9 million and $12.4 million in 2019 dollars. Annualized over 10 years at 3 percent, relabeling costs range from approximately $558.3 thousand to $1.5 million per year. Annualized over 10 years at 7 percent, relabeling costs range from approximately $633.7 thousand to $1.7 million per year.

In total, for a 24-month compliance period, we estimate that the Claims Requirement would cost small yogurt manufacturers between approximately $1.6 million and $10.4 million per year in 2019 dollars, or between $0.2 million and $1.2 million per small yogurt manufacturer per year, discounted at 3 percent. We estimate that costs are between approximately $1.8 million and $12.1 million per year in 2019 dollars, discounted at 7 percent. Costs per small yogurt manufacturer are between approximately $0.2 million and $1.3 million per year. These estimates are summarized in table 1.

TABLE 1—ANNUAL COSTS TO SMALL FIRMS OF THE CLAIMS REQUIREMENT

[Millions 2017$]

	Discount rate (%)	Low ($)	High ($)
Annual Analytical Testing Costs	.....	$0.2	$0.3
Annual Reformulation Costs	3	0.9	8.7
	7	1.0	10.2
Annual Labeling Costs	3	0.6	1.5
	7	0.6	1.7
Annual Costs	3	1.6	10.4
	7	1.8	12.1
Annual Costs Per Small Firm	3	0.2	1.2
	7	0.2	1.3

Notes: 24-month compliance period. One-time reformulation and labeling costs are annualized over 10 years.

3. The Standards of Identity Revocation for Lowfat Yogurt and Nonfat Yogurt

We are revoking the standards of identity for lowfat yogurt (§ 131.203) and nonfat yogurt (§ 131.206). The revocation will result in lowfat yogurt and nonfat yogurt being covered under the general definition and standard of identity in § 130.10. Section 130.10 sets out requirements for foods that substitute for a standardized food but that deviate from the standard due to compliance with an expressed nutrient content claim defined by FDA regulation.

Under § 131.203 and § 131.206, lowfat yogurt must contain not less than 0.5 percent milkfat nor more than 2 percent milkfat, and nonfat yogurt must contain less than 0.5 percent milkfat. If the fat content of yogurt is modified to meet the expressed nutrient content claims, ''low fat'' and ''no fat'' in § 101.62(b), lowfat yogurt must contain less than or equal to 3 grams of fat per RACC, and nonfat yogurt must contain less than 0.5 grams per RACC. The RACC for yogurt is 170 grams. In other words, when yogurt is modified to comply with the expressed nutrient content claims ''low fat'' and ''no fat,'' the resultant products are standardized foods under § 130.10, and as such, ''lowfat yogurt'' must contain less than or equal to 1.76 percent (= 3g/170g) milkfat and ''nonfat yogurt'' must contain less than 0.29 percent (= 0.5g/170g) milkfat. As acknowledged by comments we received, once this final rule is in effect, some lowfat yogurt and nonfat yogurt products that currently meet the milkfat content requirements in §§ 131.203 and 131.206 will have to be reformulated to meet the fat content requirements for ''low fat'' and ''no fat'' under § 101.62(b). For example, a lowfat yogurt product with 2 percent milkfat will need to be reformulated to contain no more than 1.33 percent milkfat to comply with § 101.62(b) and be covered as a standardized food under § 130.10.

To estimate the percentage of lowfat yogurt and nonfat yogurt products affected by the Standards of Identity Revocation, we use data from the USDA's National Nutrient Database for Standard Reference (Ref. 2). We estimate that approximately 21 percent of lowfat yogurts and 19 percent of nonfat yogurts are affected by the Standards of Identity Revocation and will need to reformulate to reduce the fat content of their yogurts to meet the 1.76 percent and 0.29

percent thresholds. We estimate that there are approximately nine small yogurt manufacturers. Using data from the International Dairy Foods Association, we estimate that 52 percent of yogurt sales are of lowfat yogurt and 43 percent are of nonfat yogurt. We estimate that the number of small lowfat yogurt manufacturers affected by the Standards of Identity Revocation is approximately one and the number of small nonfat yogurt manufacturers affected by the Standards of Identity Revocation is approximately one. We estimate that there are 8,002 yogurt UPCs and that small yogurt manufacturers comprise roughly 29 percent of all yogurt manufacturers. We estimate that the number of small lowfat yogurt and nonfat yogurt manufacturer UPCs affected by the Standards of Identity Revocation are approximately 350 and approximately 200, respectively, for a total of 550 UPCs.

We estimate reformulation costs using the FDA Reformulation Cost Model (Ref. 22). Using the yogurt formula-to-UPC ratio of 0.759, we estimate that the total number of small yogurt manufacturer formulas subject to reformulation is approximately 417. We estimate reformulation costs by multiplying the estimated number of formulas by estimates of per-formula costs obtained from the FDA Reformulation Cost Model. We estimate that yogurt manufacturers that need to reduce the fat content of their yogurt will substitute lower fat milk for higher fat milk in the production process and that this is a critical minor ingredient with functional effects, yielding per-formula reformulation costs ranging from approximately $28,530 to $289,845 in 2019 dollars. For a 24-month compliance period, we estimate one-time reformulation costs related to the Standards of Identity Revocation to be between approximately $11.9 million and $120.9 million in 2019 dollars. Annualized over 10 years at 3 percent, reformulation costs range from approximately $1.4 million to $13.8 million per year. Annualized over 10 years at 7 percent, reformulation costs range from approximately $1.6 million to $16.1 million per year.

Because small yogurt manufacturers must change the fat content of their lowfat yogurt and nonfat yogurt, they also must change the amount of fat declared on the Nutrition Facts Label. Using the FDA Labeling Cost Model, we estimate the one-time cost of this minor label change to be between approximately $1.4 million and $4.1 million in 2019 dollars for small yogurt manufacturers. Annualized over 10 years, labeling costs for small yogurt manufacturers are estimated to be between approximately $161.3 thousand and $471.4 thousand per year, discounted at 3 percent. Labeling costs for small yogurt manufacturers are estimated to be between approximately $188.6 thousand and $551.1 thousand per year, discounted at 7 percent.

In total, for a 24-month compliance period, we estimate that revoking the standards of identity for lowfat yogurt and nonfat yogurt would cost small yogurt manufacturers between approximately $1.4 million and $13.8 million per year in 2019 dollars, or between approximately $1.6 million and $16.1 million per small yogurt manufacturer per year, discounted at 3 percent. Discounted at 7 percent, we estimate that costs are between approximately $1.8 million and $16.6 million per year. Per small yogurt manufacturer range between approximately $1.5 million and $16.9 million per year. These estimates are summarized in table 2.

TABLE 2—ANNUAL COSTS TO SMALL FIRMS OF STANDARDS OF IDENTITY REVOCATION

[Millions 2019$]

	Discount rate (%)	Low ($)	High ($)
Annual Reformulation Costs	3	$1.4	$13.8
	7	1.6	16.1
Annual Labeling Costs	3	0.2	0.5
	7	0.2	0.6
Annual Costs	3	1.5	14.2
	7	1.8	16.6
Annual Costs Per Small Firm	3	1.5	14.5
	7	1.8	16.9

Notes: 24-month compliance period. One-time reformulation and labeling costs are annualized over 10 years.

4. Summary of Costs

The total cost of the final rule to small yogurt manufacturers for a 24-month compliance period is approximately $3.7 million to $25.1 million per year in 2019 dollars, discounted at 3 percent. Discounted at 7 percent, estimated annual total costs are between approximately $4.2 million and $29.2 million. On a per firm per year basis, estimated costs are between approximately $0.4 million and $2.8 million per small yogurt manufacturer per year in 2019 dollars, discounted at 3 percent. Discounted at 7 percent, estimated annual total costs are between approximately $0.5 million and $3.2 million per small yogurt manufacturer. These estimates are summarized in table 3.

TABLE 3—ANNUAL COSTS TO SMALL FIRMS OF FINAL YOGURT RULE

[Millions 2019$]

	Discount rate (%)	Low ($)	High ($)
Annual Cost of Claims Requirements	3	$1.6	$10.4
	7	1.8	12.1
Annual Cost of Standards of Identity Revocation	3	1.5	14.2
	7	1.8	16.6
Annual Cost of Final Yogurt Rule	3	3.1	24.6
	7	3.6	28.8

TABLE 3—ANNUAL COSTS TO SMALL FIRMS OF FINAL YOGURT RULE—Continued

[Millions 2019$]

	Discount rate (%)	Low ($)	High ($)
Annual Cost of Final Yogurt Rule Per Small Firm	3	0.3	2.7
	7	0.4	3.2

Notes: 24-month compliance period.

5. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4) (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $158 million, using the most current (2020) Implicit Price Deflator for the Gross Domestic Product. We do not expect this rule to result in any 1-year expenditure that will meet or exceed this amount.

We estimate that the annual costs of the final rule to small yogurt manufacturers will be between approximately $3.1 million to $24.6 million, discounted at 3 percent in 2019 dollars. At a 7 percent discount rate, we estimate that the annual costs of the final rule will be between $3.6 and $28.8 million. Based on our analysis, we do not expect the final rule to reach the current UMRA threshold of $158 million. We also do not expect the estimated costs of the rule to be disproportionately incurred by any State, local, or tribal government.

The full analysis of economic impacts is available in the docket for this final rule and at *https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations.*

VI. Federalism

We have analyzed the final rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive Order requires agencies to ''construe * * * a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.''

Section 403A of the FD&C Act (21 U.S.C. 343–1) is an express preemption provision. Section 403A(a) of the FD&C Act provides that: ''* * * no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce—(1) any requirement for a food which is the subject of a standard of identity established under section 401 that is not identical to such standard of identity or that is not identical to the requirement of section 403(g). * * *''

The final rule makes changes to the standards of identity for yogurt, lowfat yogurt, and nonfat yogurt. The final rule has preemptive effect under section 403A(a)(1) of the FD&C Act in that it precludes States from issuing any requirements for yogurt that are not identical to the requirements of the final rule. Section 403A(a)(1) of the FD&C Act displaces both State legislative requirements and State common law duties (*Riegel* v. *Medtronic,* 128 S. Ct. 999 (2008)). In addition, as with any Federal requirement, if a State law requirement makes compliance with both Federal law and State law impossible, or would frustrate Federal objectives, the State requirement would be preempted. See *Geier* v. *American Honda Co.,* 529 U.S. 861 (2000); *English* v. *General Electric Co.,* 496 U.S. 72, 79 (1990); *Florida Lime & Avocado Growers, Inc.,* 373 U.S. 132, 142–43 (1963); *Hines* v. *Davidowitz,* 312 U.S. 52, 67 (1941).

VII. Analysis of Environmental Impact

We have determined under 21 CFR 25.32(a) 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. Paperwork Reduction Act of 1995

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

IX. Consultation and Coordination With Indian Tribal Governments

We have analyzed this rule in accordance with the principles set forth in Executive Order 13175. We have determined that the rule does not contain policies that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. Accordingly, we conclude that the rule does not contain policies that have tribal implications as defined in the Executive Order and, consequently, a tribal summary impact statement is not required.

X. Objections

This rule is effective as shown in the **DATES** section, except as to any provisions that may be stayed by the filing of proper objections. If you will be adversely affected by one or more provisions of this regulation, you may file with the Dockets Management Staff (see **ADDRESSES**) either electronic or written objections. You must separately number each objection, and within each numbered objection you must specify with particularity the provision(s) to which you object, and the grounds for your objection. Within each numbered objection, you must specifically state whether you are requesting a hearing on the particular provision that you specify in that numbered objection. If you do not request a hearing for any particular objection, you waive the right to a hearing on that objection. If you request a hearing, your objection must include a detailed description and analysis of the specific factual information you intend to present in support of the objection in the event that a hearing is held. If you do not include such a description and analysis for any particular objection, you waive the right to a hearing on the objection.

Any objections received in response to the regulation may be seen in the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *https://www.regulations.gov.* We will

publish notice of the objections that we have received or lack thereof in the **Federal Register**.

XI. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at *https://www.regulations.gov.* References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction, or they are available as published articles and books. Please contact either person identified in the **FOR FURTHER INFORMATION CONTACT** section to schedule a date to inspect references without asterisks. Some may be available at the website address, if listed. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. FDA Office for Policy & Planning to the Division of Dockets Management Memorandum, ''Extension of Comment Period on Docket No. FDA–2000–P–0126 (Formerly Docket No. 2000P–0685) (Milk and Cream Products and Yogurt Products; Proposal to Revoke the Standards for Lowfat Yogurt and Nonfat Yogurt and to Amend the Standard for Yogurt),'' March 31, 2009. Document ID: FDA–2000–P–0126–0070.
2. *United States Department of Agriculture, Agricultural Research Service, FoodData Central, 2020, available at: *https://fdc.nal.usda.gov/.*
3. Routray, W. and H.N. Mishra, ''Scientific and Technical Aspects of Yogurt Aroma and Taste: A Review,'' *Comprehensive Reviews in Food Science and Food Safety,* 10(4): 208–220, 2011.
4. Cheng, H., ''Volatile Flavor Compounds in Yogurt: A Review,'' *Critical Reviews in Food Science and Nutrition,* 50:938–950, 2010.
5. *Codex Alimentarius Commission, ''Codex Standard for Fermented Milks (CODEX STAN 243–2003),'' In *Milk and Milk Products,* Second edition, (2011), available at: *http://www.fao.org/3/i2085e/i2085e00.pdf.*
6. *FDA Memorandum, ''Live and Active Culture Survey Submitted by the National Yogurt Association Consumer Studies Comment on Survey Report,'' 2009b.
7. Dave, R.I. and N.P. Shah, ''Viability of Yoghurt and Probiotic Bacteria in Yoghurts Made From Commercial Starter Cultures,'' *International Dairy Journal,* 7:31–41, 1997.
8. Ibrahim, S.A. and J.P. Carr, ''Viability of Bifidobacteria in Commercial Yogurt Products in North Carolina During Refrigerated Storage,'' *International Journal of Dairy Technology,* 59:272–277, 2006.
9. Rosburg, V., T. Boylston, and P. White, ''Viability of Bifidobacteria Strains in Yogurt With Added Oat Beta-Glucan and Corn Starch During Cold Storage,'' *Journal of Food Science,* 75:C439–C444, 2010.
10. *United States Government Accountability Office (GAO), ''GAO–01–326, Dairy Products: Imports, Domestic Production, and Regulation of Ultra-Filtered Milk,'' 2001.
11. *FDA, GRAS Notice No. GRN 000504 to American Dairy Products Institute and U.S. Dairy Export Council, November 21, 2014.
12. Boer, Ruud de. (2014). Chapter 6: Vital Membrane Processes. *From Milk By-Products to Milk Ingredients—Upgrading the Cycle.* John Wiley & Sons.
13. *FDA, ''Bacteriological Analytical Manual (BAM), Chapter 3. Aerobic Plate Count,'' 2001; available at: *https://www.fda.gov/food/laboratory-methods-food/bam-chapter-3-aerobic-plate-count.*
14. International Organization for Standardization (ISO) and International Dairy Federation (IDF), ''International Standard. ISO 7889/IDF 117:2003. Yogurt—Enumeration of Characteristic Microorganisms—Colony-Count Technique at 37 °C,'' 2003.
15. Duncan, S.E., B.R. Yaun, and S.S. Sumner, ''Microbiological Methods for Dairy Products, Method 9.080. Yogurt and Other Fermented Milk Products,'' In: *Standard Methods for the Examination of Dairy Products,* edited by H.M. Wehr and J.F. Frank, 17th Ed., Washington, DC, Chapter 9, pp. 261–263, American Public Health Association, 2004.
16. Lerebours, E., C. N'Djitoyap Ndam, A. Lavoine, et al., ''Yogurt and Fermented-Then-Pasteurized Milk: Effects of Short-Term and Long-Term Ingestion on Lactose Absorption and Mucosal Lactase Activity in Lactase-Deficient Subjects,'' *American Journal of Clinical Nutrition,* 49:823–827, 1989.
17. Marteau, P., B. Flourie, P. Pochart, C. et al., ''Effect of the Microbial Lactase (*EC* 3.2.1.23) Activity in Yoghurt on the Intestinal Absorption of Lactose: An in Vivo Study in Lactase-Deficient Humans,'' *British Journal of Nutrition,* 64:71–79, 1990.
18. Ouwehand, A.C. and S.J. Salminen, ''The Health Effects of Cultured Milk Products With Viable and Non-Viable Bacteria,'' *International Dairy Journal,* 8:749–758, 1998.
19. Shermak, M.A., J.M. Saavedra, T.L. Jackson, et al., ''Effect of Yogurt on Symptoms and Kinetics of Hydrogen Production in Lactose-Malabsorbing Children,'' *American Journal of Clinical Nutrition,* 62:1003–1006, 1995.
20. Varela-Moreiras, G., J. M. Antoine, B. Ruiz-Roso, et al., ''Effects of Yogurt and Fermented-Then-Pasteurized Milk on Lactose Absorption in an Institutionalized Elderly Group,'' *Journal of the American College of Nutrition,* 11:168–171, 1992.
21. *FDA Memorandum, Juan, WenYen, ''Documentation for the Analysis of Lowfat and Nonfat Yogurts Consumption and Contribution of Vitamin A Over Time in the U.S. Population,'' 2021.
22. White, W.J., Gledhill, E., Karns, S., et al. (2002). *Cost of Reformulating Foods and Cosmetics* (FDA Labeling Cost Model). Research Triangle Park: RTI.

List of Subjects

21 CFR Part 130

Food additives, Food grades and standards.

21 CFR Part 131

Cream, Food grades and standards, Incorporation by reference, Milk, Yogurt.

Therefore, 21 CFR parts 130 and 131 are amended as follows:

PART 130—FOOD STANDARDS: GENERAL

■ 1. The authority citation for part 130 continues to read as follows:

Authority: 21 U.S.C. 321, 336, 341, 343, 371.

■ 2. In § 130.10, revise paragraph (b) to read as follows:

§ 130.10 Requirements for foods named by use of a nutrient content claim and a standardized term.

* * * * *

(b) *Nutrient addition.* (1) Nutrients shall be added to the food to restore nutrient levels so that the product is not nutritionally inferior, as defined in § 101.3(e)(4) of this chapter, to the standardized food as defined in parts 131 through 169 of this chapter. The addition of nutrients shall be reflected in the ingredient statement.

(2) Yogurt containing less than 3.25 percent milkfat is exempt from compliance with paragraph (b)(1) of this section with respect to vitamin A fortification provided the product complies with all other requirements.

* * * * *

PART 131—MILK AND CREAM

■ 3. The authority citation for part 131 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 343, 348, 371, 379e.

■ 4. Revise § 131.200 to read as follows:

§ 131.200 Yogurt.

(a) *Description.* Yogurt is the food produced by culturing one or more of the basic dairy ingredients specified in paragraph (b) of this section and any of the optional dairy ingredients specified in paragraph (c) of this section with a characterizing bacterial culture that contains the lactic acid-producing bacteria, *Lactobacillus delbrueckii*

subsp. *bulgaricus* and *Streptococcus thermophilus.* The ingredients specified in paragraphs (b) and (c) of this section may be homogenized and must be pasteurized or ultra-pasteurized before the addition of the characterizing bacterial culture. One or more of the other optional ingredients specified in paragraph (d) of this section may also be added. Yogurt, before the addition of bulky flavoring ingredients, contains not less than 3.25 percent milkfat and not less than 8.25 percent milk solids not fat and has either a titratable acidity of not less than 0.7 percent, expressed as lactic acid, or a pH of 4.6 or lower. To extend the shelf life of the food, yogurt may be treated after culturing to inactivate viable microorganisms.

(b) *Basic dairy ingredients.* Cream, milk, partially skimmed milk, skim milk, or the reconstituted versions of these ingredients may be used alone or in combination.

(c) *Optional dairy ingredients.* Other safe and suitable milk-derived ingredients may be used to increase the milk solids not fat content of the food above the minimum of 8.25 percent required in paragraph (a) of this section, provided that the ratio of protein to total nonfat solids of the food, and the protein efficiency ratio of all protein present must not be decreased as a result of adding such ingredients.

(d) *Other optional ingredients.* The following safe and suitable ingredients may be used:

(1) Cultures, in addition to the characterizing bacterial culture specified in paragraph (a) of this section.

(2) Nutritive carbohydrate sweeteners.

(3) Flavoring ingredients.

(4) Color additives.

(5) Stabilizers.

(6) Emulsifiers.

(7) Preservatives.

(8) Vitamin addition (optional).

(i) If added, vitamin A must be present in such quantity that the food contains not less than 10 percent Daily Value per Reference Amount Commonly Consumed (RACC) thereof, within limits of current good manufacturing practice.

(ii) If added, vitamin D must be present in such quantity that the food contains not less than 25 percent Daily Value per Reference Amount Commonly Consumed (RACC) thereof, within limits of current good manufacturing practices.

(e) *Methods of analysis*—(1) *Milk*—(i) *Milkfat content.* As determined by the method prescribed in section 33.2.26, AOAC Official Method 989.05, Fat in Milk Modified Mojonnier Ether Extraction Method.

(ii) *Milk solids not fat.* Calculated by subtracting the milkfat content from the total solids content using the method prescribed in section 33.2.45, AOAC Official Method 990.21, Solids-Not-Fat in Milk by Difference between Total Solids and Fat Contents.

(iii) *Titratable acidity.* As determined by the method prescribed in section 33.2.06, AOAC Official Method 947.05, Acidity of Milk Titrimetric Method.

(2) *pH.* As determined by the potentiometric method described in § 114.90(a) of this chapter.

(3) *Live and active cultures.* As determined by the method described in ISO 7889:2003(E)/IDF 117:2003(E), Yogurt—Enumeration of Characteristic Microorganisms—Colony-Count Technique at 37 °C.

(f) *Nomenclature.* The name of the food is ''yogurt.'' The name of the food must be accompanied by a declaration indicating the presence of any characterizing flavoring as specified in § 101.22 of this chapter.

(1) The following term(s) must accompany the name of the food wherever it appears on the principal display panel or panels of the label in letters not less than one-half of the height of the letters used in such name:

(i) The word ''sweetened'' if a nutritive carbohydrate sweetener is added without the addition of characterizing flavor.

(ii) The phrase ''does not contain live and active cultures'' if the dairy ingredients have been treated after culturing to inactivate viable microorganisms.

(iii) The phrase ''vitamin A'' or ''vitamin A added'', or ''vitamin D'' or ''vitamin D added'', or ''vitamins A and D added'', as appropriate. The word ''vitamin'' may be abbreviated ''vit''.

(2) The name of the food may be accompanied by the phrase ''contains live and active cultures'' or another appropriate descriptor if the food contains a minimum level of live and active cultures of 10^7 colony forming units per gram (CFU/g) at the time of manufacture with a reasonable expectation of 10^6 CFU/g through the manufacturer's assigned shelf life of the product.

(3) The term ''homogenized'' may appear on the label if the dairy ingredients used are homogenized.

(g) *Label declaration.* Each of the ingredients used in the food must be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.

(h) *Incorporation by reference.* The standards required in this section are incorporated by reference into this section with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, FDA must publish a document in the **Federal Register**, and the material must be available to the public. All approved material is available for inspection at the Food and Drug Administration's Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500, and is available from the sources indicated in this paragraph (h). It is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fedreg.legal@nara.gov* or go to *www.archives.gov/federal-register/cfr/ibr-locations.html.*

(1) AOAC INTERNATIONAL, 2275 Research Blvd., Suite 300, Rockville, MD 20850–3250:

(i) AOAC Official Method 947.05, Acidity of Milk Titrimetric Method, Section 33.2.06, Official Methods of Analysis, 21st edition, 2019, Vol. 1.

(ii) AOAC Official Method 989.05, Fat in Milk Modified Mojonnier Ether Extraction Method, Section 33.2.26, Official Methods of Analysis, 21st edition, 2019, Vol. 1.

(iii) AOAC Official Method 990.21, Solids-Not-Fat in Milk by Difference between Total Solids and Fat Contents, Section 33.2.45, Official Methods of Analysis, 21st edition, 2019, Vol. 1.

(2) ISO, ISO Central Secretariat, Chemin de Blandonnet 8, CP 401, 1214 Vernier, Geneva, Switzerland.

(i) ISO 7889:2003(E), Yogurt—Enumeration of Characteristic Microorganisms—Colony-Count Technique at 37 °C, First edition, 2003–02–01.

(ii) [RESERVED]

Note 1 to paragraph (h)(2)(i): ISO 7889:2003(E) is co-published as IDF 117:2003(E).

§ 131.203 [Removed]

■ 5. Remove § 131.203.

§ 131.206 [Removed]

■ 6. Remove § 131.206.

Dated: June 2, 2021.

Janet Woodcock,

Acting Commissioner of Food and Drugs.

Dated: June 7, 2021.

Xavier Becerra,

Secretary, Department of Health and Human Services.

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