

# **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: Guidance for Industry**

## **Small Entity Compliance Guide**

*Additional copies are available from:  
Office of Nutrition and Food Labeling  
Center for Food Safety and Applied Nutrition (HFS-820)  
Food and Drug Administration  
5001 Campus Drive  
College Park, MD 20740  
(Tel) 240-402-2371  
<http://www.fda.gov/FoodGuidances>*

You may submit either electronic or written comments regarding this guidance at any time. Submit electronic comments to <https://www.regulations.gov>. Submit written comments on the guidance to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number FDA-2023-D-4722 listed in the notice of availability that publishes in the *Federal Register*.

**U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Food Safety and Applied Nutrition**

**November 2023**

# Table of Contents

I.	Introduction.....	4
II.	Background .....	5
III.	Who Is Subject to the Rule?.....	6
IV.	Changes to the Standard of Identity .....	6
	IV.A What did we change for yogurt products? .....	6
V.	The Rule’s Basic Requirements for Yogurt.....	6
	V.A How does the rule describe “yogurt”? .....	6
	V.B Ingredients Used to Produce Yogurt.....	6
	V.B.1 Required Ingredients and Minimum Dairy Requirements.....	6
	V.B.1.a What are the basic dairy ingredients? .....	6
	V.B.1.b What are the minimum dairy requirements for yogurt? .....	7
	V.B.1.c How are the basic dairy ingredients in yogurt used?.....	7
	V.B.1.d What bacterial cultures must you use?.....	7
	V.B.1.e How do you determine the level of live and active cultures in the yogurt?.....	7
	V.B.1.f Can you use other bacterial cultures? .....	8
	V.B.2 Optional Ingredients.....	8
	V.B.2.a How do you use optional dairy ingredients? .....	8
	V.B.2.b What are the other optional ingredients you may use?.....	8
	V.C Other Yogurt Specifications.....	8
	V.C.1 Milkfat and milk solids not fat .....	8
	V.C.1.a What are the requirements for milkfat and milk solids not fat?.....	8
	V.C.1.b How do you measure the milkfat and milk solids not from fat of yogurt?.....	9
	V.C.2 pH.....	9
	V.C.2.a What are the pH requirements for yogurt? .....	9
	V.C.2.b How do you measure the pH of yogurt? .....	10
	V.D Clarification Regarding Certain Optional Ingredients .....	10
	V.D.1 What sweeteners may you use in yogurt?.....	10
	V.D.2 What are the required specifications for adding vitamin A or vitamin D to yogurt? .	10
VI.	Requirements for Products with Less Than 3.25% Milkfat.....	11
	VI.A Can you produce yogurt with less than 3.25% milkfat? .....	11
	VI.B Are there different requirements for producing reduced fat yogurt, lowfat yogurt, and nonfat yogurt?.....	11
	VI.C What are the nutrient content claim requirements for reduced fat yogurt, lowfat yogurt, and nonfat yogurt? .....	11
VII.	Labeling Requirements .....	12
	VII.A How do you label sweeteners used in yogurt? .....	12
	VII.B How do you label use of added Vitamins A or D?.....	13

*Contains Nonbinding Recommendations*

<b>VII.C</b>	<b>How do you name yogurt products that contain less than 3.25 percent milkfat but do not have a 25% reduction in milkfat (2.44 %)?</b> .....	<b>13</b>
<b>VII.D</b>	<b>How do you name reduced fat yogurt, lowfat yogurt, nonfat or fat free yogurt that contains fat-containing flavoring ingredients, such as chocolate or nuts?</b> .....	<b>14</b>
<b>VII.E</b>	<b>Can you include a statement on the label indicating that a yogurt product contains live and active cultures?</b> .....	<b>15</b>
<b>VII.F</b>	<b>When and how do you indicate that yogurt that has been treated to inactivate viable microorganisms after culturing?</b> .....	<b>15</b>
<b>VIII.</b>	<b>Compliance Information</b> .....	<b>16</b>
<b>VIII.A</b>	<b>When must you comply with the rule?</b> .....	<b>16</b>

# **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: Guidance for Industry<sup>1</sup>**

## **Small Entity Compliance Guide**

This guidance represents the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance at the phone number listed on the title page.

### **I. Introduction**

The U.S. Food and Drug Administration (“FDA” or “we”) is issuing this Small Entity Compliance guide to help explain the actions that a small entity must take to comply with 21 CFR parts 130 and 131, “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” after recent changes made in 2021 and 2022.

We have prepared this Small Entity Compliance Guide in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Public Law 104-121, as amended by Public Law 110-28). This guidance document is intended to help small entities comply with 21 CFR parts 130 and 131 concerning the standard of identity for yogurt and revoking the standards of identity for lowfat yogurt and nonfat yogurt.

FDA’s guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe our current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA guidances means that something is suggested or recommended, but not required.

---

<sup>1</sup> This guidance has been prepared by the Office of Nutrition and Food Labeling, Product Evaluation & Labeling Branch in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

## *Contains Nonbinding Recommendations*

In the remainder of this guidance, “you” refers to yogurt manufacturers whose products are subject to 21 CFR parts 130 and 131. Many answers in this guidance are followed by citations to show where a specific requirement can be found in either the Federal Food, Drug, and Cosmetic Act (FD&C Act) and/or Title 21 of the *Code of Federal Regulations*.

## **II. Background**

In the *Federal Register* of June 11, 2021 (86 FR 31117), we published a final rule titled “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” (“2021 final rule”). The 2021 final rule amended Title 21 of the *Code of Federal Regulations* at parts 130 and 131 by revoking the standards of identity for lowfat yogurt and nonfat yogurt and amending the standard of identity for yogurt in numerous respects.

The International Dairy Foods Association (IDFA) and Chobani, Inc. (Chobani) timely filed objections and requested a hearing with respect to several provisions in the 2021 final rule. In the *Federal Register* of March 23, 2022 (87 FR 16394), we issued a notice providing clarification on which provisions of the 2021 final rule were not in effect (“stay of action”), and which requirements of the previous final rule that we issued in 1981 to establish the standard of identity for yogurt (46 FR 9924) were in effect pending final action.

We responded to IDFA and Chobani’s objections in a final rule issued on December 15, 2022, “International Dairy Foods Association and Chobani, Inc.: Response to the Objections and Requests for a Public Hearing on the Final Rule To Revoke the Standards for Lowfat Yogurt and Nonfat Yogurt and To Amend the Standard for Yogurt” (87 FR 76559) (“2022 final rule”). In response to these objections, the 2022 final rule denied requests for a hearing for all but one of the objections, revised certain provisions in the 2021 final rule, and announced that the stay of action of provisions for which hearings were denied was lifted. The 2022 final rule did not address IDFA’s objection and request for a hearing on the acidity requirement of yogurt, and we instead addressed this in a proposed order sent to IDFA and posted to a public docket for public comment.<sup>2</sup>

We did not receive any responses to the proposed order, and on April 14, 2023, we published a final order, “International Dairy Foods Association: Response to the Objections and Requests for a Public Hearing on the Final Rule to Revoke the Standards for Lowfat Yogurt and Nonfat Yogurt and Amend the Standard for Yogurt” (88 FR 22907) (“2023 final order”).<sup>3</sup> The 2023 final order modified the acidity requirement in 21 CFR 131.200(a) of the 2021 final rule. The modification eliminated the minimum titratable acidity option and requires that yogurt have a pH of 4.6 or lower measured on the finished product within 24 hours after filling. The modification aligns the rule with the 2007 Grade “A” Pasteurized Milk Ordinance, a model regulation intended to help States and municipalities initiate and maintain effective programs for the prevention of milkborne disease.

---

<sup>2</sup> See Docket No. FDA-2000-P-0126, available at <https://www.regulations.gov/document/FDA-2000-P-0126-0129>.

<sup>3</sup> Subsequently, we issued a correction in the *Federal Register* of May 18, 2023, to clarify that the compliance date of the 2023 final order is January 1, 2024.

### **III. Who Is Subject to the Rule?**

The rule applies to food manufacturers producing yogurt products for the U.S. market.

### **IV. Changes to the Standard of Identity**

#### **IV.A What did we change for yogurt products?**

We revoked the standards of identity for lowfat yogurt (previously at 21 CFR 131.203) and nonfat yogurt (previously at 21 CFR 131.206). As a result, lowfat yogurt and nonfat yogurt are now covered under the general definition and standard of identity in 21 CFR 130.10 for foods that deviate from other standardized foods due to compliance with a nutrient content claim. We also updated the requirements for yogurt under 21 CFR 131.200.

Section VI contains additional information for products with less than 3.25% milkfat, including lowfat yogurt and nonfat yogurt.

### **V. The Rule's Basic Requirements for Yogurt**

#### **V.A How does the rule describe "yogurt"?**

The rule describes "yogurt" as the food produced by culturing one or more of the basic dairy ingredients and any of the optional dairy ingredients with a characterizing bacterial culture. Before the addition of the characterizing bacterial cultures, the basic dairy ingredients and any optional dairy ingredients may be homogenized and must be pasteurized or ultra-pasteurized. Yogurt may also contain one or more of the other optional ingredients. (21 CFR 131.200(a).)

Yogurt must also contain at least 3.25% milkfat, with certain exceptions, and at least 8.25% milk solids not fat and have a pH of 4.6 or lower measured on the finished product within 24 hours after filling. (21 CFR 131.200(a).)

Section V.B contains additional information about the ingredients used to produce yogurt. Section V.C contains additional information about the specifications for yogurt.

#### **V.B Ingredients Used to Produce Yogurt**

##### **V.B.1 Required Ingredients and Minimum Dairy Requirements**

###### **V.B.1.a What are the basic dairy ingredients?**

Yogurt must include one or more of the following basic dairy ingredients:

- Cream;
- Milk;
- Partially skimmed milk;
- Skim milk; or

## ***Contains Nonbinding Recommendations***

- The reconstituted version of any of the above ingredients.

(21 CFR 131.200(b).)

### **V.B.1.b What are the minimum dairy requirements for yogurt?**

Yogurt must contain not less than 3.25 percent milkfat and not less than 8.25 percent milk solids not fat. (21 CFR 131.200(a).) These are referred to as the “minimum dairy requirements.”

### **V.B.1.c How are the basic dairy ingredients in yogurt used?**

The basic dairy ingredients must be used to meet the minimum dairy requirements set forth in 21 CFR 131.200(a). To meet these minimum requirements, you may use the basic dairy ingredients alone or in combination. (21 CFR 131.200(b).) The basic dairy ingredients may be homogenized and *must* be pasteurized or ultra-pasteurized before adding the required bacterial cultures. (21 CFR 131.200(a).)

Optional dairy ingredients can be used to increase the milk solids not fat content above the minimum 8.25%, as long as they do not decrease the protein to total nonfat solids ratio or protein efficiency ratio of the food. (21 CFR 131.200(c).) However, because they are optional ingredients, they cannot be used to meet the minimum dairy requirements. (21 CFR 131.200(c).)

### **V.B.1.d What bacterial cultures must you use?**

You must use bacterial cultures that contain the lactic acid-producing bacteria, *Lactobacillus delbrueckii* subsp. *bulgaricus* and *Streptococcus thermophilus*, to produce yogurt. (21 CFR 131.200(a).)

### **V.B.1.e How do you determine the level of live and active cultures in the yogurt?**

You must use the method described in ISO 7889:2003(E)/IDF 117:2003(E), Yogurt - Enumeration of Characteristic Microorganisms – Colony-Count Technique at 37 °C to measure for live and active cultures. (21 CFR 131.200(e)(3).)

If you do not have access to the standard referenced above, it is available through the FDA’s Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500. The standard is also available through the National Archives and Records Administration (NARA) by email [fedreg.legal@nara.gov](mailto:fedreg.legal@nara.gov) or by going to [www.archives.gov/federal-register/cfr/ibr-locations.html](http://www.archives.gov/federal-register/cfr/ibr-locations.html). (See 21 CFR 131.200(i).)

You may also purchase a copy of the standard from the International Organization for Standardization, ISO Central Secretariat, Chemin de Blandonnet 8, CP 401, 1214 Vernier, Geneva, Switzerland. (See 21 CFR 131.200(i)(2).)

## *Contains Nonbinding Recommendations*

### **V.B.1.f Can you use other bacterial cultures?**

Yes, in addition to the required bacterial cultures, you may use other bacterial cultures, when producing yogurt. These other bacterial cultures are considered “optional ingredients.” (21 CFR 131.200(d)(1).)

### **V.B.2 Optional Ingredients**

#### **V.B.2.a How do you use optional dairy ingredients?**

You may use other safe and suitable, milk-derived ingredients to increase the milk solids not fat content of the food above the required minimum of 8.25 percent. (21 CFR 131.200(c).) Section V.C contains additional information about yogurt specifications.

If you use such optional dairy ingredients, 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. (Id.)

Optional dairy ingredients may be homogenized and *must* be pasteurized or ultra-pasteurized before adding the required bacterial cultures. (21 CFR 131.200(a).)

#### **V.B.2.b What are the other optional ingredients you may use?**

You may use the following additional safe and suitable ingredients. These ingredients are not required to be milk-derived.

- Cultures, in addition to the required bacterial cultures (discussed in V.B.1.c)
- Sweeteners
- Flavoring ingredients
- Color additives
- Stabilizers
- Emulsifiers
- Preservatives
- Vitamin A
- Vitamin D

(21 CFR 131.200(d).)

Section V.D. contains additional information about the use of sweeteners and vitamins A and D.

### **V.C Other Yogurt Specifications**

#### **V.C.1 Milkfat and milk solids not fat**

##### **V.C.1.a What are the requirements for milkfat and milk solids not fat?**



## ***Contains Nonbinding Recommendations***

As stated in V.B.1.b. above, yogurt has minimum dairy requirements. Specifically, yogurt must contain not less than 3.25 percent milkfat and not less than 8.25 percent milk solids not fat. (21 CFR 131.200(a).)

Flavoring ingredients, which include bulky flavoring ingredients,<sup>4</sup> are considered “optional ingredients” under 21 CFR 131.200(d), and cannot be used to meet the minimum dairy requirements. (See 21 CFR 131.200(a); see also 88 FR 22907, 22909.) As such, yogurt must meet the minimum dairy requirements *before* the addition of bulky flavoring ingredients.

More information about producing yogurt with fat content below 3.25 percent milkfat (21 CFR 131.200(g)) can be found in Section VI.

### **V.C.1.b      How do you measure the milkfat and milk solids not from fat of yogurt?**

Milkfat content is measured using the method found in section 33.2.26 of the AOAC Official Method 989.05, Fat in Milk Modified Mojonnier Ether Extraction Method. (21 CFR 131.200(e)(1)(i).)

Milk solids not fat can be calculated by subtracting the milkfat content from the total solids content using the method found in section 33.2.45 of the AOAC Official Method 990.21, Solids-Not-Fat in Milk by Difference between Total Solids and Fat Contents. (21 CFR 131.200(e)(1)(ii).)

If you do not have access to the methods referenced above, they are available through FDA’s Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500. The methods also available through the National Archives and Records Administration (NARA) by email [fedreg.legal@nara.gov](mailto:fedreg.legal@nara.gov) or by going to [www.archives.gov/federal-register/cfr/ibr-locations.html](http://www.archives.gov/federal-register/cfr/ibr-locations.html). (See 21 CFR 131.200(i).)

You may also purchase these methods from the AOAC INTERNATIONAL, 2275 Research Boulevard, Suite 300, Rockville, MD 20850. (See 21 CFR 131.200(i)(1).)

### **V.C.2 pH**

#### **V.C.2.a      What are the pH requirements for yogurt?**

Yogurt is required to have a pH of 4.6 or lower measured on the finished product within 24 hours after filling. (21 CFR 131.200(a).) The “finished product” means a product that contains the

---

<sup>4</sup> Previously, the 2021 final rule required yogurt to meet the milkfat, milk solids not fat, and acidity requirements before the addition of bulky flavoring ingredients. (See 86 FR 31117, 31138.) In our 2023 final order, we eliminated the reference to bulky flavoring ingredients in order to instead specifically require that acidity be measured on the finished product within 24 hours after filling. (See 88 FR 22907, 22909-22910.) However, FDA continues to interpret the requirement for measuring milk fat and milk solids not fat requirements to mean that such measurements must be taken before the addition of bulky flavoring ingredients.

## *Contains Nonbinding Recommendations*

basic dairy ingredients required by 21 CFR 131.200(a), as well as any optional ingredients under 21 CFR 131.200(c) and (d).

### **V.C.2.b How do you measure the pH of yogurt?**

You must measure pH using the potentiometric method described in 21 CFR 114.90(a). (21 CFR 131.200(e)(2).) Our regulations at 21 CFR 114.90(a) describe the methodology, including providing additional detail about the principles of this method, the instruments used, and the general procedure for measuring pH using this method.

### **V.D Clarification Regarding Certain Optional Ingredients**

#### **V.D.1 What sweeteners may you use in yogurt?**

All safe and suitable sweeteners are optional ingredients that may be added to yogurt. (See 21 CFR 131.200(a), (d)(2).) FDA interprets the term “sweeteners” to encompass all safe and suitable nutritive carbohydrate sweeteners and non-nutritive sweeteners. (See 87 FR 76559, 76565.)

#### **V.D.2 What are the required specifications for adding vitamin A or vitamin D to yogurt?**

Vitamins added to yogurt are considered optional ingredients. (21 CFR 131.200(a), (d)(8).)

If you add vitamin A or D to your yogurt, it must be present in such quantity that the yogurt contains not less than 10 percent Daily Value (DV)<sup>5</sup> per the applicable Reference Amount Customarily Consumed (RACC), within limits of current good manufacturing practice. (21 CFR 131.200(d)(8)(i), (ii).) The RACC for yogurt is 170 grams. (See 21 CFR 101.12(b), Table 2, Product Category: Dairy Products and Substitutes.)

The following examples demonstrate the quantity of vitamins A and D that yogurt must contain, if added, based on the DV for adults and children aged four years and older.

- Vitamin A
  - For adults and children aged four years and older, the DV of vitamin A is 900 micrograms (mcg) retinol activity equivalents (RAE). (See 21 101.9(c)(8)(iv).)
  - For such age group, if you add vitamin A to your yogurt, it should be not less than 90 mcg RAE per 170g of yogurt.
- Vitamin D
  - For adults and children aged four years and older, the DV of vitamin D is 20 mcg. (Id.)
  - For such age group, if you add vitamin D to your yogurt, it should be not less than 2 mcg per 170g of yogurt.

---

<sup>5</sup> The DV for vitamins A and D is found in our regulations at 21 CFR 101.9(c)(8)(iv) and provides different DVs for different age groups, as well as for women that are pregnant or lactating.

## **VI. Requirements for Products with Less Than 3.25% Milkfat**

There are specific requirements for yogurt with less than 3.25% milkfat and for reduced fat yogurt, lowfat yogurt, and nonfat yogurt. As discussed in section IV, we revoked the standards of identity for lowfat yogurt (previously at 21 CFR 131.203) and nonfat yogurt (previously at 21 CFR 131.206). As a result, lowfat yogurt and nonfat yogurt are now covered under the general definition and standard of identity in 21 CFR 130.10, which sets out requirements for foods that deviate from other standardized foods due to compliance with a nutrient content claim. Foods subject to 21 CFR 130.10 are labeled with the name of a standardized food, such as “yogurt,” and a nutrient content claim, such as “reduced fat,” to indicate the difference from the standardized food.

### **VI.A Can you produce yogurt with less than 3.25% milkfat?**

Yes. Our regulations, at 21 CFR 131.200(g), indicate that you may produce yogurt with less than 3.25% milkfat and at least 2.44% milkfat. Such yogurt is subject to specific labeling requirements, discussed in more detail in section VII.C.

In addition, you may produce a product with less than 2.44% milkfat. (21 CFR 131.200(g)(1).) Such product is considered a modified food and must comply with 21 CFR 130.10. Such products include reduced fat yogurt, lowfat yogurt, and nonfat yogurt.

### **VI.B Are there different requirements for producing reduced fat yogurt, lowfat yogurt, and nonfat yogurt?**

If your yogurt product is named using a nutrient content claim, such as “reduced fat,” “lowfat,” or “nonfat,” you must comply with 21 CFR 130.10 and the applicable regulation under 21 CFR 101.62(b). (See 21 CFR 130.10(a).)

Producing lower fat yogurt may reduce the nutrient levels of the product. If essential nutrients present in a measurable amount in yogurt are reduced in reduced fat yogurt, lowfat yogurt, or nonfat yogurt, the regulation provides that you fortify your yogurt to restore the reduced nutrient levels, with the exception of vitamin A. (See 21 CFR 130.10(b).)

You do not have to fortify the yogurt with vitamin A to restore it to the nutrient level of yogurt (which contains 3.25% milkfat). (21 CFR 130.10(b)(2).) However, manufacturers may choose to fortify reduced fat yogurt, lowfat yogurt, and nonfat yogurt with vitamin A to the level in yogurt (86 FR 31117, 31132) or may add vitamin A to the optional fortification level permitted in 21 CFR 131.200(d)(8)(i) for yogurt.

### **VI.C What are the nutrient content claim requirements for reduced fat yogurt, lowfat yogurt, and nonfat yogurt?**

Nutrient content claims describe the level of a nutrient in the product, using terms such as “high,” “low,” or “free,” or they compare the level of a nutrient in a food to that of another food,

## ***Contains Nonbinding Recommendations***

using terms such as “reduced.” Reduced fat yogurt, lowfat yogurt, and nonfat yogurt milkfat content must comply with the nutrient content claim requirements in 21 CFR 101.62(b).

The milkfat requirements for reduced fat yogurt, lowfat yogurt, and nonfat yogurt or fat free yogurt are different and are based on the RACC for yogurt, which is 170 grams. (21 CFR 101.12(b).) If you make a nutrient content claim of:

- “reduced fat,” the product must contain at least 25 percent less milkfat<sup>6</sup> per RACC than “yogurt,” which is less than 2.44 percent milkfat (3< and <4.1g/170g) (21 CFR 101.62(b)(4)(i).)
- “lowfat,” the product must contain less than or equal to 3 grams of milkfat per RACC, which is less than or equal to 1.76 percent milkfat (= 3g/170g) (21 CFR 101.62(b)(2)(i)(A).)
- “nonfat” or “fat free” the product must contain less than 0.5 grams of milkfat per RACC, which is less than 0.29 percent milkfat (= 0.5g/170g) (21 CFR 101.62(b)(1)(i).)

Section V.C.1.b contains additional information about measuring milkfat content. (See also 21 CFR 130.10, 131.200(a), (g).)

## **VII. Labeling Requirements**

Below, we provide information specific to labeling yogurt. The labeling information provided below is not exhaustive, and you should consult the regulations referenced throughout this document to ensure you comply with all labeling requirements for your yogurt product.

More information about labeling requirements generally can be found in 21 CFR part 101.

### **VII.A How do you label sweeteners used in yogurt?**

Sweeteners, which FDA interprets to include nutritive carbohydrate sweeteners and nonnutritive sweeteners, must be declared in the ingredient statement. (See 21 CFR 131.200(h); see also 87 FR 76559, 76565.)

The revisions in the 2022 final rule clarified that all safe and suitable sweeteners may be used in yogurt. (21 CFR 131.200(d)(2).) We explained that nonnutritive sweeteners may be used in yogurt when the labeling does not bear a nutrient content claim. (See 87 FR 76559, 76565). However, use of nonnutritive sweeteners to achieve a reduction in sugar or calories does not mean that you may always label your yogurt with a nutrient content claim, such as “reduced sugar” or “reduced calorie.” Nutrient content claims may only be used when products comply with the applicable level of reduction specified by FDA’s regulations.

For example, a “reduced sugar” yogurt must contain at least 25% less sugar per RACC. (See 21 CFR 101.60(c)(5)(i).) If you use a nonnutritive sweetener so that your yogurt contains 28% less

---

<sup>6</sup> Application of the fat content requirements in 21 CFR 101.62(b) to reduced fat yogurt, low fat yogurt, and nonfat yogurt specifically pertains to milkfat.

## ***Contains Nonbinding Recommendations***

sugar per RACC, you *may* label your yogurt with a nutrient content claim, such as “reduced sugar.” Such yogurt achieves the reduction of at least 25% sugar per RACC specified by 21 CFR 101.60(c)(5)(i). Such product must also comply with the requirements found at 21 CFR 130.10.

In addition, if a nutritive carbohydrate sweetener is added without the addition of a characterizing flavor, the label must contain the word “sweetened.” (21 CFR 131.200(f)(1)(i).)

### **VII.B How do you label use of added Vitamins A or D?**

If you add vitamins A or D to your yogurt, the label must specify the amounts of added vitamins A and D based on percentages of Daily Value per RACC in the Nutrition Facts Label. (See 21 CFR 101.9(c)(8).) More information about the required values for vitamins A and D can be found in section V. More information about the required values for vitamin levels in reduced fat yogurt, lowfat yogurt, and nonfat yogurt can be found in section VI.

If vitamins A or D are added, the label must indicate that the food contains these added vitamins by one of the following phrases accompanying the name of the food wherever the name appears on the principal display panel or panels, as appropriate:

- vitamin A;
- vitamin A added;
- vitamin D;
- vitamin D added; or
- vitamins A and D added.

(21 CFR 131.200(f)(1)(iii).)

The word “vitamin” may be abbreviated “vit.” (Id.) This information must be provided on the label in letters not less than one-half the height of the letters used in the name of the food. (21 CFR 131.200(f)(1).)

### **VII.C How do you name yogurt products that contain less than 3.25 percent milkfat but do not have a 25% reduction in milkfat (2.44%)?**

If you make a product that contains less milkfat than 3.25%, but more milkfat than 2.44%, the statement of identity must contain the two phrases, which must appear together:

- the word “yogurt,” using type of the same size and style (21 CFR 131.200(g)(2)(i)); and
- a statement of the milkfat content (“\_\_percent milkfat”), rounded to the nearest half percent (e.g., “3.0 percent milkfat,” “2.5 percent milkfat”) in letters not less than one-half the height of your “yogurt” statement and at least one-eighth of an inch in height. (21 CFR 131.200(g)(2)(ii).)

## Contains Nonbinding Recommendations

**Figure 1:** The image below represents an example label of yogurt that is made with 2.5% milkfat.



### VII.D How do you name reduced fat yogurt, lowfat yogurt, nonfat or fat free yogurt that contains fat-containing flavoring ingredients, such as chocolate or nuts?

If you produce reduced fat yogurt, lowfat yogurt, nonfat or fat free yogurt that contains a fat-containing flavoring ingredient, the name must include the nutrient content claim corresponding to the product's milkfat content (e.g., "lowfat"). (21 CFR 130.10(e).) The label must also contain a descriptor of the fat-containing flavoring ingredient (Id.), such as cashews, chocolate chips, coconut. For example, a product with 1.5% milkfat and cashews as a flavoring ingredient would be labeled "lowfat yogurt with cashews."

**Figure 2:** The image below represents an example label of nonfat yogurt with a fat-containing flavoring ingredient.



## *Contains Nonbinding Recommendations*

### **VII.E Can you include a statement on the label indicating that a yogurt product contains live and active cultures?**

All yogurt is required to be produced using live and active cultures that contain lactic acid-producing bacteria. (21 CFR 131.200(a).) You are not required to include a statement on the label that your yogurt contains live and active cultures.

However, if you choose to label your yogurt to indicate the presence of live and active cultures, you may use the phrase “contains live and active cultures” or another appropriate descriptor, only if:

- The yogurt contains at least  $10^7$  Colony Forming Units per gram (CFU/g) of live and active cultures at the time the yogurt is manufactured; and
- There is a reasonable expectation that the yogurt will maintain  $10^6$  CFU/g through the shelf life assigned to the product by the manufacturer.

(21 CFR 131.200(f)(2).)

### **VII.F When and how do you indicate that yogurt that has been treated to inactivate viable microorganisms after culturing?**

If your yogurt product is treated after culturing to inactivate viable microorganisms, the label must contain the phrase “does not contain live and active cultures.” (21 CFR 131.200(f)(1)(ii).) The phrase 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. (21 CFR 131.200(f)(1).) This phrase is required regardless of the treatment method used to inactivate microorganisms. (See 86 FR 31117, 31123.)

**Figure 3:** The image below represents an example of the labeling required for yogurt products that are treated to inactivate viable microorganisms after culturing.



## **VIII. Compliance Information**

### **VIII.A When must you comply with the rule?**

Manufacturers must begin complying with the rule for products labeled on or after January 1, 2024.