



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 130, 131, 133, 136, 137, 139, 145, 150, 155, 156, 158, 161, 163, 166, 168, and 169

[Docket No. FDA-2022-N-2226]

RIN 0910-AI72

Use of Salt Substitutes To Reduce the Sodium Content in Standardized Foods

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or we) is issuing a final rule to amend our standard of identity regulations that specify salt (sodium chloride) as a required or optional ingredient to permit the use of salt substitutes in standardized foods, to reduce the sodium content. Reducing sodium may help reduce the risk of hypertension, a major risk factor for heart disease and stroke. The rule will help support a healthier food supply by providing flexibility to facilitate industry innovation in the production of standardized foods lower in sodium while maintaining the basic nature and essential characteristics of the foods.

DATES: This rule is effective [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The incorporation by reference of certain material listed in this rule is approved by the Director of the Federal Register as of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Submit either electronic or written/paper objections or requests for a hearing on amendments to standards of identity for dairy products in parts 131 and 133 (21 CFR parts 131 and 133) under this final rule by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. See section VI for further information on the filing of objections on amendments to standards of identity for dairy products in parts 131 and 133.

ADDRESSES: You may submit objections and requests for a hearing on amendments to standards of identity for dairy products in parts 131 and 133 as follows. Please note that late, untimely filed objections will not be considered. Electronic objections must be submitted on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Objections received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic objections 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-2022-N-2226 for “Use of Salt Substitutes To Reduce the Sodium Content in Standardized Foods.” 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 objection 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 objections. 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 objection 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 comments received, go to <https://www.regulations.gov> and insert the docket number found in brackets in the heading of this final rule 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: Andrew Yeung and Rumana Yasmeen, Office of Nutrition and Food Labeling, Human Foods Program (HFS-800), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2371; or Holli Kubicki, Office of Regulations and International Programs, Human Foods Program, 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
- B. Summary of the Major Provisions of the Final Rule
- C. Legal Authority
- D. Costs and Benefits

II. Table of Abbreviations/Acronyms in This Document

III. Background

- A. Need for the Regulation/History of the Rulemaking
- B. Summary of Comments to the Proposed Rule
- C. Incorporation by Reference

IV. Legal Authority

V. Comments on the Proposed Rule and FDA Response

- A. Introduction

- B. Description of General Comments and FDA Response
- C. Salt Substitute Definition Comments and FDA Response
- D. Fish and Shellfish Comments and FDA Response
- E. Incorporation by Reference Comments and FDA Response
- F. Technical Amendments
- G. Out-of-Scope Comments

VI. Effective Date

VII. Economic Analysis of Impacts

- A. Introduction
- B. Overview of Benefits, Costs, and Transfers

VIII. Analysis of Environmental Impact

IX. Paperwork Reduction Act of 1995

X. Federalism

XI. Consultation and Coordination with Indian Tribal Governments

XII. References

I. Executive Summary

A. Purpose of the Final Rule

The final rule amends FDA’s definitions and standards of identity (SOI; the acronym is used to refer to both the singular “standard of identity” and the plural “standards of identity”) that specify salt (sodium chloride) as a required or optional ingredient in a food. Foods for which FDA has established SOI are referred to as “standardized foods.” The amendments permit the use of safe and suitable salt substitutes to replace some or all of the added salt used in the manufacture of standardized foods. (Salt substitutes may already be used in the manufacture of non-standardized foods.) The final rule does not list specific salt substitutes; instead, the final rule generally allows ingredients or combinations of ingredients to be used as salt substitutes in standardized foods by manufacturers currently or in the future.

The final rule supports efforts to reduce sodium content in standardized foods and may help to improve consumer dietary patterns by reducing sodium consumption. According to the Dietary Guidelines for Americans, the general population, ages 14 and above, should consume less than 2,300 milligrams per day of sodium (Ref. 1). Reducing sodium consumption may help reduce the risk of hypertension, a major risk factor for heart disease and stroke. The final rule provides manufacturers the flexibility to use safe and suitable salt substitutes and allows for innovation in producing healthier standardized foods. The final rule also promotes honesty and fair dealing in the interest of consumers and accommodates their preferences for lower-sodium varieties of foods.

B. Summary of the Major Provisions of the Final Rule

FDA is amending its SOI that specify salt as a required or optional ingredient to permit the use of safe and suitable salt substitutes in standardized foods, to reduce the sodium content. We are amending our regulation titled “Food Standards: General” (part 130 (21 CFR part 130)) to create a new subpart C titled “Flexibility in Standardized Foods” and add a new section titled “Ingredient Flexibility in Standardized Foods” to define salt substitute. We also amend 80 SOI to permit salt substitutes.

Within the 80 SOI we are amending, we are also updating the incorporation by reference (IBR) information to refer to the most recent versions of the IBR materials available at the time of publication and to provide updated contact information for obtaining the IBR materials. For example, the rule updates the referenced methods of analysis to those in the “Official Methods of Analysis of AOAC INTERNATIONAL,” 22nd Ed., 2023. We also make technical amendments to correct inconsistencies and typographical errors in some SOI regulations.

We conclude that these amendments are necessary to modernize SOI to provide flexibility and facilitate innovation in the production of standardized foods with less sodium, and to promote honesty and fair dealing in the interest of consumers.

C. Legal Authority

We are issuing this rule under sections 201, 401, 402, and 701 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 321, 341, 342, and 371). We discuss our legal authority in greater detail in section IV.

D. Costs and Benefits

There are no regulatory costs of the final rule as there are no regulatory requirements or regulatory penalties if manufacturers of a standardized food choose not to take advantage of the flexibility to use salt substitutes. We qualitatively discuss other costs that may come from voluntary reformulation and re-labeling costs, as well as potential consumer dissatisfaction with altered product properties. We qualitatively discuss the benefits of the final rule, which come in the form of increased flexibility for manufacturers and potential public health benefits stemming from decreased sodium consumption.

II. Table of Abbreviations/Acronyms in This Document

Abbreviation/Acronym	What It Means
CFR	Code of Federal Regulations
FD&C Act	Federal Food, Drug, and Cosmetic Act
FDA	Food and Drug Administration
FR	<i>Federal Register</i>
GRAS	Generally Recognized as Safe
IBR	Incorporation by Reference
SOI	Standard(s) of Identity
U.S.C.	United States Code

III. Background

A. Need for the Regulation/History of the Rulemaking

In the *Federal Register* of April 10, 2023 (88 FR 21148), we published a proposed rule titled “Use of Salt Substitutes To Reduce the Sodium Content in Standardized Foods.”

Salt substitutes are ingredients that can help reduce sodium in processed, packaged, and prepared foods. Manufacturers wishing to reduce salt in their products to accommodate consumer preferences or for other reasons sometimes use substitute ingredients that provide

similar taste and other technical functions of salt in foods. Most of our SOI that include salt as a required or optional ingredient do not permit the use of salt substitutes. Therefore, manufacturers are currently precluded from using salt substitutes in the production of these standardized foods. However, manufacturers may use salt substitutes in the production of non-standardized foods.

SOI have been established to ensure that the characteristics, ingredients, and production processes of specific foods are consistent with what consumers expect. Various parties have expressed concern that many SOI are out of date and may impede innovation, including the ability to produce healthier foods (Ref. 2). FDA's work to update SOI generally falls into three categories:

- Establishing principles to more transparently communicate what we will consider when determining whether to revise, eliminate, or establish a food standard;
- Updating individual SOI to allow for continued innovation in the marketplace, including updating SOI to reflect modern technologies and processing methods; and
- Updating SOI to ensure they are supporting the production and innovation of healthier food.

See <https://www.fda.gov/food/nutrition-food-labeling-and-critical-foods/standards-identity-food>.

Manufacturers seeking to reduce sodium in standardized foods are limited because they are unable to produce foods using salt substitutes and still conform to the SOI. While manufacturers may modify the sodium content of certain standardized foods using salt substitutes in accordance with the general definition and standard under § 130.10, they must decrease the sodium in the foods consistent with the amount specified in a nutrient content claim under § 101.61 (21 CFR 101.61). It may be impracticable for manufacturers to reduce sodium content of standardized foods to these amounts.

We heard support from interested parties for the use of salt substitutes through our related work to help reduce sodium consumption. Through our work on the “Voluntary Sodium

Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods; Guidance for Industry” (2021 Voluntary Sodium Reduction guidance) (Ref. 3) and “The Use of an Alternate Name for Potassium Chloride in Food Labeling; Guidance for Industry” (Potassium Chloride guidance) (Ref. 4), we learned that various parties, including industry, consumers, consumer advocacy groups, scientific organizations, and professional health organizations, generally support allowing the use of salt substitutes. In another public engagement, some parties discussed modernizing SOI to allow the use of salt substitutes using a “horizontal approach” (Ref. 2). A horizontal approach to amending standards is a change that could be made across all or broad categories of SOI to provide flexibility and facilitate innovation in the production of more nutritious foods.

As discussed in the proposed rule, we considered several options for permitting salt substitutes in standardized foods and evaluated how to apply this change across multiple SOI (88 FR 21148 at 21151). The final rule uses a horizontal approach to amending the SOI in that a single provision defining salt substitutes (see § 130.30 (21 CFR 130.30(c)(1))) applies across the various SOI that permit salt as an ingredient. Because the use of salt substitutes in these SOI is currently limited, any use of salt substitutes by manufacturers under the rule would contribute to reduced sodium intake to some degree.

Permitting the use of salt substitutes in standardized foods may also contribute to our goal to help reduce sodium across the food supply. It may facilitate voluntary industry efforts toward sodium reduction by providing flexibility and supporting innovation in the production of healthier standardized foods. This in turn may provide more choices to consumers and help some consumers to gradually reduce the sodium in their diet and contribute to better health outcomes. Reducing sodium may help reduce the risk of hypertension, a major risk factor for heart disease and stroke (Refs. 5 through 7). The final rule supports the Make America Healthy Again initiative by providing manufacturers of standardized foods flexibility to innovate and

make more healthful, lower-sodium foods, which may help lower chronic disease rates. See <https://www.whitehouse.gov/priorities/maha/>.

Ingredients added to standardized foods, like ingredients added to non-standardized foods, must comply with other requirements of the FD&C Act, including the pre-market review and approval requirements for food additives under section 409 of the FD&C Act (21 U.S.C. 348). This rulemaking does not provide either an authorization or an exemption from regulation as a food additive under section 409 of the FD&C Act. Ingredients that are food additives are deemed unsafe except to the extent that FDA has approved their use (section 409(a) of the FD&C Act). The FD&C Act defines “food additive,” in relevant part, as any substance, the intended use of which results or may reasonably be expected to result, directly or indirectly, in it becoming a component of food, if such substance is not generally recognized among qualified experts as safe (GRAS) under the conditions of its intended use (section 201(s) of the FD&C Act). Food is adulterated when it contains an unapproved food additive (section 402(a)(2)(C) of the FD&C Act).

B. Summary of Comments to the Proposed Rule

We received more than 120 comments on the proposed rule from consumers, consumer groups, trade organizations, manufacturers, public health organizations, public advocacy groups, local government agencies, and other organizations. We describe and respond to the comments in section V (“Comments on the Proposed Rule and FDA Response”) of this document. The topics addressed most frequently in the comments include:

- General supportive comments regarding the rule and sodium reduction efforts.
- General supportive comments regarding ingredient flexibility to use salt substitutes to support innovation to make healthier foods.
- Additional or alternative efforts to achieve sodium reduction.
- Concerns with specific ingredients.

- Support for and additional suggestions or questions regarding the definition of salt substitute.

C. Incorporation by Reference

Several SOI amended by the rule previously referred to older versions of the AOAC Official Methods. We are updating the IBR information to provide the most recent version of the IBR materials and up-to-date contact information for obtaining the IBR materials. Therefore, FDA is incorporating by reference the methods listed below from the “Official Methods of Analysis of AOAC INTERNATIONAL,” 22nd Ed., 2023, which have been approved by the Office of the Federal Register.

- Definition of Terms and Explanatory Notes. This front matter to Official Methods of Analysis includes Table 1, Nominal Dimensions of Standard Test Sieves (USA Standard Series). The table lists the test sieve designations and their nominal dimensions.
- AOAC Appendix C, Reference Tables, 909.04, Correction Factors for Gasometric Determination of Carbon Dioxide (Reference Table 909.04). The reference lists the correction factors of carbon dioxide measurements for different atmospheric conditions.
- AOAC Official Method 923.02, Carbon Dioxide (Total) in Baking Powders: Gasometric Determination. The reference describes the reagent and the apparatus used in measuring the amount of carbon dioxide released from a sample.
- AOAC Official Method 926.07, Solids (Total) and Loss on Drying (Moisture) in Macaroni Products. The reference provides method references for the preparation of a sample and the total solid determination of a sample.
- AOAC Official Method 932.12, Solids (Soluble) in Fruits and Fruit Products: Refractometer Method. The reference provides a method reference for measuring soluble solids and the formula for calculating the percentage of soluble solids in a sample.
- AOAC Official Method 932.14, Solids in Syrups. The reference provides the method for measuring the percentage of soluble solids in a sample.

- AOAC Official Method 935.36, Solids (Total) in Bread. The reference provides the method for measuring the percentage of solids in a sample.
- AOAC Official Method 938.06, Fat in Butter. The reference provides the method for measuring the percentage of fat in a sample.
- AOAC Official Method 938.10, Solids (Alcohol-Insoluble) in Canned Peas: Gravimetric Method. The reference provides the method for measuring the percentage of alcohol-insoluble solids in a sample.
- AOAC Official Method 945.48, Evaporated Milk (Unsweetened). The reference provides the method for sample preparation and a method reference for measuring the percentage of milk fat in a sample.
- AOAC Official Method 947.05, Acidity of Milk: Titrimetric Method. The reference provides the method for measuring the percentage of lactic acid in a sample.
- AOAC Official Method 989.05, Fat in Milk: Modified Mojonnier Ether Extraction Method. The reference provides the method for measuring the percentage of milk fat in a sample.
- AOAC Official Method 990.21, Solids-Not-Fat in Milk: By Difference between Total Solids and Fat Contents. The reference provides method references for measuring total solids and fat contents of a sample and the formula for calculating the percentage of nonfat solid in a sample.

You may purchase a copy of the material from AOAC International (AOAC), 2275 Research Blvd., Suite 300, Rockville, MD 20850-3250, 1-800-379-2622

(<https://academic.oup.com/officialmethodsofanalysis-aoac>). You may inspect a copy at Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500, IBR_Material_Inquiries@fda.hhs.gov, between 9 a.m. and 4 p.m., Monday through Friday.

IV. Legal Authority

We are issuing this final rule under sections 201, 401, 402, and 701 of FD&C Act. Section 401 of the FD&C Act directs the Secretary of Health and Human Services (Secretary) to issue regulations fixing and establishing for any food a reasonable definition and standard of identity, standard of quality, or standard of fill of container, whenever in the judgment of the Secretary, such action will promote honesty and fair dealing in the interest of consumers. We conclude that permitting the use of salt substitutes to replace some or all of the added salt used in the production of standardized foods will promote honesty and fair dealing in the interest of consumers. Many consumers desire more nutritious and healthy food options, such as lower-sodium versions of foods. The final rule allows for industry development and sale of such foods while ensuring that standardized foods meet consumer expectations and preferences with respect to lower-sodium varieties.

We also are issuing this final rule under section 701(a) of the FD&C Act, which authorizes FDA to issue regulations for the efficient enforcement of the FD&C Act. Regulations issued under section 701(a) of the FD&C Act “must effectuate a congressional objective expressed elsewhere in the Act” (*Association of American Physicians and Surgeons, Inc. v. FDA*, 226 F. Supp. 2d 204 (D.D.C. 2002) (citing *Pharm. Mfrs. Ass’n. v. FDA*, 484 F. Supp. 1179, 1183 (D. Del. 1980))). Amending SOI to permit the use of salt substitutes effectuates the congressional objective “to promote honesty and fair dealing in the interest of consumers” expressed in section 401 of the FD&C Act. Permitting salt substitutes in standardized foods under this final rule may help provide more options to consumers while ensuring that the foods maintain their basic nature and essential characteristics. The amendments to the SOI for dairy products under parts 131 and 133 are issued under section 701(e) of the FD&C Act.

V. Comments on the Proposed Rule and FDA Response

A. Introduction

FDA proposed amending its SOI that specify salt as a required or optional ingredient to permit the use of safe and suitable salt substitutes in standardized foods, to reduce the sodium

content. Additionally, we proposed amending our regulation entitled “Food Standards: General” (21 CFR part 130) to create a new subpart C entitled “Flexibility in Standardized Foods” and add a new section entitled “Ingredient Flexibility in Standardized Foods” to define salt substitute. We also proposed amending 80 SOI to permit salt substitutes (see Table 1).

Table 1. Amendments to Standards of Identity to Permit Salt Substitutes.

CFR Section and Title	Revision
§ 131.111 Acidified milk.	Revises other optional ingredients to add salt substitute to paragraph (e)(8)
§ 131.112 Cultured milk.	Revises other optional ingredients to add salt substitute to paragraph (d)(8)
§ 131.160 Sour cream.	Revises optional ingredients to add salt substitute to paragraph (b)(5)
§ 131.162 Acidified sour cream.	Revises optional ingredients to add salt substitute to paragraph (b)(4)
§ 131.170 Eggnog.	Revises other optional ingredients to add salt substitute to paragraph (e)(2)
§ 133.102 Asiago fresh and asiago soft cheese.	Adds paragraph (c)(3) to permit salt substitute
§ 133.106 Blue cheese.	Revises other optional ingredients to add paragraph (b)(3)(vii) to list salt substitute
§ 133.108 Brick cheese.	Revises other optional ingredients to add paragraph (b)(3)(v) to list salt substitute
§ 133.111 Caciocavallo siciliano cheese.	Adds paragraph (c)(3) to permit salt substitute
§ 133.113 Cheddar cheese.	Revises other optional ingredients to add paragraph (b)(3)(vi) to list salt substitute
§ 133.118 Colby cheese.	Adds paragraph (c)(4) to permit salt substitute
§ 133.123 Cold-pack and club cheese.	Revises optional ingredients to add salt substitute to paragraph (c)(3)
§ 133.124 Cold-pack cheese food.	Revises other optional ingredients to add salt substitute to paragraph (e)(3)
§ 133.127 Cook cheese, koch kaese.	Revises other optional ingredients to add salt substitute to paragraph (b)(3)(v)
§ 133.129 Dry curd cottage cheese.	Revises paragraphs (b)(1)(i), (ii), and (iii) that describe the food to permit salt substitute
§ 133.133 Cream cheese.	Revises other optional ingredients to add salt substitute to paragraph (b)(3)(i)
§ 133.136 Washed curd and soaked curd cheese.	Revises other optional ingredients to add paragraph (b)(3)(vi) to list salt substitute
§ 133.138 Edam cheese.	Revises other optional ingredients to add paragraph (b)(3)(v) to list salt substitute
§ 133.141 Gorgonzola cheese.	Revises other optional ingredients to add paragraph (b)(3)(vii) to list salt substitute
§ 133.144 Granular and stirred curd cheese.	Revises other optional ingredients to add paragraph (b)(3)(vi) to list salt substitute
§ 133.147 Grated American cheese food.	Revises other optional ingredients to add salt substitute to paragraph (c)(5)
§ 133.148 Hard grating cheeses.	Adds paragraph (c)(2) to permit salt substitute
§ 133.149 Gruyere cheese.	Revises other optional ingredients to add paragraph (b)(3)(iv) to list salt substitute
§ 133.150 Hard cheeses.	Adds paragraph (c)(3) to permit salt substitute
§ 133.152 Limburger cheese.	Revises other optional ingredients to add paragraph (b)(3)(iv) to list salt substitute
§ 133.153 Monterey cheese and monterey jack cheese.	Revises other optional ingredients to add salt substitute to paragraph (b)(3)(iii)

CFR Section and Title	Revision
§ 133.155 Mozzarella cheese and scamorza cheese.	Revises other optional ingredients to add salt substitute to paragraph (b)(3)(iii)
§ 133.156 Low-moisture mozzarella and scamorza cheese.	Revises other optional ingredients to add salt substitute to paragraph (b)(3)(iii)
§ 133.160 Muenster and munster cheese.	Revises other optional ingredients to add paragraph (b)(3)(vi) to list salt substitute
§ 133.162 Neufchatel cheese.	Revises other optional ingredients to add salt substitute to paragraph (b)(3)(i)
§ 133.164 Nuworld cheese.	Revises other optional ingredients to add paragraph (b)(3)(iv) to list salt substitute
§ 133.165 Parmesan and reggiano cheese.	Adds paragraph (c)(3) to permit salt substitute
§ 133.169 Pasteurized process cheese.	Revises other optional ingredients to add salt substitute to paragraph (d)(3)
§ 133.173 Pasteurized process cheese food.	Revises other optional ingredients to add salt substitute to paragraph (e)(4)
§ 133.179 Pasteurized process cheese spread.	Revises other optional ingredients to add salt substitute to paragraph (f)(5)
§ 133.181 Provolone cheese.	Revises other optional ingredients to add paragraph (b)(3)(vi) to list salt substitute
§ 133.182 Soft ripened cheeses.	Revises paragraph (b) that describes the food to permit salt substitute
§ 133.183 Romano cheese.	Adds paragraph (c)(3) to permit salt substitute
§ 133.184 Roquefort cheese, sheep's milk blue-mold, and blue-mold cheese from sheep's milk.	Revises other optional ingredients to add paragraph (b)(3)(ii) to list salt substitute
§ 133.185 Samsoe cheese.	Revises other optional ingredients to add paragraph (v)(3)(v) to list salt substitute
§ 133.186 Sap sago cheese.	Revises paragraph (a)(2) to permit salt substitute
§ 133.187 Semisoft cheeses.	Revises paragraph (b) that describes the food to permit salt substitute
§ 133.188 Semisoft part-skim cheeses.	Revises paragraph (b) that describes the food to permit salt substitute
§ 133.189 Skim milk cheese for manufacturing.	Add paragraph (d)(2) to permit salt substitute
§ 133.190 Spiced cheeses.	Revises other optional ingredients to add salt substitute in paragraph (b)(3)(iii)
§ 133.195 Swiss and emmentaler cheese.	Revises other optional ingredients to add paragraph (b)(3)(vii) to list salt substitute
§ 136.110 Bread, rolls, and buns.	Revises optional ingredients to add salt substitute to paragraph (c)(4)
§ 137.180 Self-rising flour.	Revises paragraph (a) that describes the food to add salt substitute
§ 137.270 Self-rising white corn meal.	Revises paragraph (a) that describes the food to add salt substitute
§ 139.110 Macaroni products.	Revises optional ingredients to add salt substitute to paragraph (a)(4)
§ 139.150 Noodle products.	Revises optional ingredients to add salt substitute to paragraph (a)(2)
§ 145.110 Canned applesauce.	Revises optional ingredients to add salt substitute to paragraph (a)(2)(iii)
§ 145.130 Canned figs.	Revises optional ingredients to add salt substitute to paragraph (a)(5)
§ 150.110 Fruit butter.	Revises optional ingredients to add salt substitute to paragraph (c)(4)
§ 155.120 Canned green beans and canned wax beans.	Revises optional ingredients to add salt substitute to paragraph (a)(3)(i)
§ 155.130 Canned corn.	Revises optional ingredients to add salt substitute to paragraph (a)(3)(i)
§ 155.170 Canned peas.	Revises optional ingredients to add salt substitute to paragraph (a)(2)(i)

CFR Section and Title	Revision
§ 155.190 Canned tomatoes.	Revises optional ingredients to add salt substitute to paragraph (a)(2)(iv)
§ 155.191 Tomato concentrates.	Revises optional ingredients to add salt substitute to paragraph (a)(2)(i)
§ 155.194 Catsup.	Revises paragraph (a)(1)(iv) that describes the food to add salt substitute
§ 155.200 Certain other canned vegetables.	Revises optional ingredients to add salt substitute to paragraph (c)(4)(i)
§ 155.201 Canned mushrooms.	Revises optional ingredients to add salt substitute to paragraph (a)(3)(i)
§ 156.145 Tomato juice.	Revises paragraph (a)(1) that describes the food to add salt substitute
§ 158.170 Frozen peas.	Revises optional ingredients to add salt substitute in paragraph (a)(1)(iv)
§ 161.145 Canned oysters.	Revises paragraph (a)(1) that describes the food to add salt substitute
§ 161.170 Canned Pacific salmon.	Revises optional ingredients to add salt substitute to paragraph (a)(4)(i)
§ 161.173 Canned wet pack shrimp in transparent or nontransparent containers.	Revises optional ingredients to add salt substitute to paragraph (a)(4)(i)
§ 161.190 Canned tuna.	Revises seasoning and flavoring ingredients to add salt substitute to paragraph (a)(6)(1)
§ 163.111 Chocolate liquor.	Revises optional ingredients to add salt substitute to paragraph (b)(6)
§ 163.112 Breakfast cocoa.	Revises optional ingredients to add salt substitute to paragraph (b)(4)
§ 163.123 Sweet chocolate.	Revises optional ingredients to add salt substitute to paragraph (b)(3)
§ 163.124 White chocolate.	Revises optional ingredients to add salt substitute to paragraph (b)(4)
§ 163.130 Milk chocolate.	Revises optional ingredients to add salt substitute to paragraph (b)(3)
§ 166.110 Margarine.	Revises optional ingredients to add salt substitute to paragraph (b)(2)
§ 168.130 Cane sirup.	Revises optional ingredients to add salt substitute to paragraph (b)(1)
§ 168.140 Maple sirup.	Revises optional ingredients to add salt substitute to paragraph (b)(1)
§ 168.160 Sorghum sirup.	Revises optional ingredients to add salt substitute to paragraph (b)(1)
§ 168.180 Table sirup.	Revises optional ingredients to add salt substitute to paragraph (b)(7)
§ 169.140 Mayonnaise.	Revises other optional ingredients to add salt substitute to paragraph (d)(1)
§ 169.150 Salad dressing.	Revises other optional ingredients to add salt substitute to paragraph (e)(1)

We proposed updating the IBR information of several SOI to refer to the most recent versions of the IBR materials and to provide up-to-date contact information for obtaining the IBR materials. We also proposed technical amendments to correct inconsistencies and typographical errors in some SOI regulations.

We tentatively concluded that the proposed amendments were necessary to modernize SOI to provide flexibility and facilitate innovation in the production of standardized foods with less sodium, and to promote honesty and fair dealing in the interest of consumers.

We describe and respond to the comments on the proposed rule in sections B through F of this section. We have numbered each comment to help distinguish between different comments. We have grouped similar comments together under the same number, and, in some cases, we have separated different issues discussed in the same comment and designated them as distinct comments for purposes of our responses. The number assigned to each comment or comment topic is purely for organizational purposes and does not signify the comment's value or importance or the order in which comments were received.

B. Description of General Comments and FDA Response

Many comments we received on the proposed rule make general remarks supporting or opposing the proposed rule without focusing on a particular proposed provision. In the following paragraphs, we discuss and respond to such general comments. We respond to more specific comments in sections V.C, V.D, V.E, and V.F.

(Comment 1) Many comments support the proposed rule and other FDA efforts to reduce sodium in the food supply as an important step to reducing diet-related chronic disease risk. Some comments that support the proposed rule also state that ingredient flexibility to use salt substitutes would help support ongoing sodium reduction efforts by industry to make healthier foods.

(Response 1) In the proposed rule, we stated that reducing sodium in the food supply may help reduce sodium intake, which in turn may help to reduce the risk of diet-related chronic disease, including hypertension, heart disease, and stroke (see 88 FR 21148 at 21150). We appreciate the comments supporting the rule and acknowledging the potential for ingredient flexibility to reduce sodium content in the food supply.

(Comment 2) We proposed using, and the final rule adopts, a “horizontal approach” to amending the SOI to allow salt substitutes in certain standardized foods. As described in the proposed rule, a horizontal approach to amending standards involves making changes that apply to all or to broad categories of SOI (see 88 FR 21148 at 21151 and Ref. 2). Several comments support the horizontal approach for this rulemaking and say that concurrently updating the SOI to allow salt substitutes is efficient, practical, and results in uniform application of principles. A few comments question whether the horizontal approach to amending the SOI could be more efficiently achieved by a single amendment to part 130 without the corresponding amendments to each SOI.

One comment asks us to clarify that the use of salt substitutes as defined in the rule applies to the SOI that cross-reference the SOI amended by the final rule.

(Response 2) We appreciate the support for the horizontal approach to amending the SOI to allow salt substitutes in standardized foods. In developing the proposed rule, we carefully reviewed the structure of part 130 in relationship to the individual standards in parts 131 through 169 (21 CFR parts 131 through 169) and determined that the clearest and most efficient way to permit the use of salt substitutes in the individual standards was to create a definition in part 130 along with individual amendments to certain standards based on the context in which salt is permitted and how the standards are written. Additionally, not every SOI that permits salt corresponded to a food for which use of salt substitutes should be allowed (see request for comments regarding the SOI for oysters (§ 161.130) (88 FR 21148 at 21152)). For these reasons, we disagree that a single amendment to part 130 without amendments to the individual standards would be the right approach for the types of revisions included in this rulemaking; however, we may consider that approach in future rulemakings, as appropriate.

The final rule amends 80 SOI to permit the use of salt substitutes as defined in § 130.30. A SOI that cross-references one of the 80 SOI amended by the final rule would also be permitted to use salt substitutes as defined in § 130.30. Therefore, the final rule permits the use of salt

substitutes in 139 SOI: 80 SOI by amendment to the SOI in the final rule and the remaining 59 SOI by an existing cross-reference in SOI amended by the final rule.

(Comment 3) A few comments suggest that sodium reduction be achieved by lowering the sodium content of standardized foods without the addition of salt substitutes. Some comments state that consumer tastes will adapt over time to a gradual reduction of sodium content in foods and argue that we do not need to allow the use of salt substitutes in standardized foods. Some comments say that we should focus our efforts on working with manufacturers to develop and promote lower-sodium options, such as using only herbs and spices, to replace salt or requiring manufacturers to reduce sodium in food products.

(Response 3) By providing greater flexibility to manufacturers who wish to use salt substitutes in standardized foods, this rulemaking also aligns with our efforts to help reduce sodium consumption. As more than 70 percent of Americans' sodium intake comes from foods where sodium is added during food manufacturing and commercial food preparation, lowering population intake of sodium to more moderate levels involves lowering the amount of sodium added to commercially processed, packaged, and prepared foods in the U.S. marketplace (Refs. 8 and 9). For this reason, in addition to continued education initiatives, a multi-faceted approach is needed to help lower the burden of diet-related chronic disease, including providing consumers with information about sodium via nutrition labeling, encouraging sodium reduction in the food supply with our voluntary sodium reduction goals, and offering manufacturers the flexibility to use safe and suitable salt substitutes in standardized foods to allow for the development of lower-sodium foods.

We agree with the comments that consumer taste preferences may adapt and adjust over time to the gradual reduction of sodium content in foods. We have noted that people usually do not notice small reductions in sodium, and, over time, people's taste buds adjust to these changes, especially if they are made gradually (see <https://www.fda.gov/food/food-labeling-nutrition/sodium-reduction-food-supply>). However, the amount of sodium that can be removed

without substitution may be limited, particularly in standardized foods for which salt is a required ingredient.

Depending on the food, salt may be important for taste, microbial safety, or other functions. The extent to which salt can be replaced depends on the ability of the salt substitute to replicate the functions of salt in the food without compromising the food's safety and nutritional quality. For this reason, relying on sodium reduction alone, without the use of salt substitutes or limiting to specific ingredients such as herbs and spices only to replace salt, may not sufficiently help with an overall reduction in sodium in the food supply.

Regarding the comments suggesting that we require manufacturers to reduce sodium, we discuss our approach to set voluntary sodium reduction goals in response 4.

(Comment 4) Several comments discuss our efforts to reduce sodium in the food supply through the sodium reduction goals announced via our October 2021 Voluntary Sodium Reduction guidance (Ref. 3).

Some comments state that, without the ability to use salt substitutes in standardized foods, there is a significant limitation on a manufacturer's ability to reduce sodium content as recommended by the goals in the guidance.

Several comments suggest that we monitor progress toward meeting the sodium reduction targets in addition to allowing the use of salt substitutes in standardized foods. The comments state that we should issue new sodium reduction targets adjusted based on progress made on sodium reduction as well as the flexibility to use salt substitutes in standardized foods under this rulemaking.

(Response 4) In the proposed rule, we recognized that manufacturers of standardized foods have few options for reducing the sodium content of their products (88 FR 21148 at 21151). Thus, the final rule provides manufacturers the flexibility to use salt substitutes to reduce sodium content of standardized foods. In the proposed rule, we also discussed our other efforts aimed at encouraging gradual, efficient reduction in overall sodium content in processed,

packaged, and prepared food products (see 88 FR 21148 at 21150), including the Voluntary Sodium Reduction guidance (Ref. 3). The 2021 Voluntary Sodium Reduction guidance is intended to provide measurable, voluntary short-term (2.5-year) goals for sodium content in commercially processed, packaged, and prepared foods to reduce excess population sodium intake, while recognizing and supporting the important technical and safety roles of sodium in food. The goals are intended to complement existing efforts by manufacturers, restaurants, and food service operations to achieve sodium reduction.

We continue to monitor the sodium content of the food supply, evaluate progress towards achieving the targets in the October 2021 Voluntary Sodium Reduction guidance, and engage with interested parties on sodium reduction efforts and the targets. In the *Federal Register* of August 16, 2024 (89 FR 66727), we announced the availability of the “Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods; Draft Guidance for Industry (Edition 2).” The draft guidance, when finalized, will describe our views on the next voluntary goals (Phase II (3-year)) for sodium reduction in a variety of identified categories of foods that are commercially processed, packaged, or prepared. Anyone may submit comments to the public docket for the draft guidance.

(Comment 5) Some comments state that taste is an important attribute of food and that the use of salt substitutes can help reduce sodium intake without compromising consumers’ taste preferences or expectations when choosing healthier foods. Other comments say that the use of potassium chloride may give a bitter or metallic taste to food but suggest that research supports replacement of sodium with potassium chloride below certain levels to help avoid the bitter or metallic taste.

(Response 5) We agree with comments that the use of salt substitutes can help meet consumer taste preferences in foods with lower sodium and that the bitter or metallic taste of potassium chloride may be avoided at certain lower usage levels. We recognize that salt serves

various functions in standardized foods and that salt may be important for taste. Further, the definition of salt substitute states, in relevant part, that a salt substitute is an ingredient (or combination of ingredients) used to perform the functions of salt in the food (see § 130.30(c)(1) and 88 FR 21148 at 21153). Therefore, manufacturers have the flexibility to choose the salt substitute and amount used to accommodate consumer taste preferences when replacing salt in the food.

(Comment 6) Many comments discuss the role of salt in food aside from taste and the technical challenges in reformulating foods to contain less sodium. The comments say salt may play important microbiological safety and stability roles, including, for example, controlling moisture and fermentation, and, as a result, reformulating products can take time. Some comments ask that we ensure that using other ingredients to replace salt does not impact safety due to the role of salt in food. Many comments also state that any further guidance or requirements for specific ingredients beyond what is existing and in the proposed rule would inhibit reformulation.

A few comments request clarification that the final rule does not require a minimum amount of sodium reduction to use salt substitutes in standardized foods.

(Response 6) The general provisions of § 130.30 prohibit ingredients used as substitutes from changing the basic nature and essential characteristics of standardized foods (see § 130.30(b)). When an ingredient that serves as a substitute is used to replace salt, i.e., a salt substitute, this requirement ensures that characteristics such as stability and moisture content are maintained. The definition of salt substitute in the final rule requires that the ingredient or combination of ingredients used as the salt substitute serve the functions of salt in the food (see § 130.30(c)(1)). Thus, the extent to which salt can be replaced depends on the ability of the salt substitute to replicate the functions of salt in the food, including functions related to safety and quality. Food manufacturers are responsible for ensuring the safety of their food, regardless of whether they choose to use salt substitutes.

As for the comments asking us to clarify that the final rule does not require a minimum amount of sodium reduction to use salt substitutes in standardized foods, we note that the definition of salt substitute (§ 130.30(c)(1)) does not require a minimum replacement level of salt or prescribe the sodium content of standardized foods containing salt substitutes. The final rule only requires that some of the salt be replaced when a salt substitute is used in a standardized food (*id.*).

(Comment 7) Several comments are concerned that allowing the use of salt substitutes in standardized foods will result in the addition of what comments characterize as “harmful” or “man-made” chemicals. According to some comments, these chemicals are not needed or wanted in food and may cause adverse health consequences to consumers or pose risks to individuals suffering from various medical conditions or co-morbidities. Some comments disagree with the proposed rule because they believe it would introduce the use of salt substitutes in general (in both standardized and non-standardized foods) or would introduce or otherwise “approve” specific salt substitutes in the food supply.

Some comments say the rulemaking would provide manufacturers with the opportunity to use salt substitutes without sufficient, long-term, or transparent safety data. Other comments ask whether safe levels have been established for salt substitutes and whether guidelines are needed to prevent excessive use.

(Response 7) We disagree that the final rule will allow harmful chemicals to be used as salt substitutes in standardized foods or that salt substitutes will be used without sufficient safety data or at unsafe levels. As discussed in section III.A of this document, salt substitutes used as ingredients in food (whether standardized or not) must comply with the pre-market review and approval requirements for food additives under section 409 of the FD&C Act or be exempt from the definition of a food additive. Ingredients that are food additives are deemed unsafe except to the extent that FDA has approved their use (section 409(a) of the FD&C Act). FDA’s authorization of a food additive is based on the conditions of use and includes specific use

limitations where appropriate. In addition, the use of substances under the GRAS provision in the definition of a food additive must meet the criteria for GRAS. The definition of salt substitute in § 130.30(c)(1) specifies that a salt substitute is “a safe and suitable ingredient.” An unapproved food additive is deemed unsafe under section 409(a) of the FD&C Act and is not “safe and suitable,” as defined in § 130.3(d)(3). The definition of “safe and suitable” in § 130.3(d)(2) further limits the amount of salt substitutes used to levels no higher than necessary to achieve their intended purpose in food. This final rule does not permit the use of any ingredients or substances that are not already permitted in non-standardized foods. Therefore, the final rule does not permit unsafe ingredients or substances in the food supply.

The term “man-made” is not defined in the FD&C Act, and we are unclear what substances or ingredients are referred to by this term. However, as discussed in response 11, salt substitutes must be included in the ingredient declaration on the label of standardized foods, which will enable consumers to select foods in accordance with their dietary preferences or other needs, such as medical conditions (see § 130.3(e)).

Regarding the comments that suggest the rulemaking “approved” salt substitutes for use in the food supply, the comments may have misinterpreted the rule. As discussed earlier in this response, the final rule provides manufacturers the flexibility to replace salt in certain standardized foods with ingredients available to manufacturers of non-standardized food. The final rule does not alter the statutory or regulatory processes pertaining to food additives.

(Comment 8) Many comments discuss the use of potassium-based ingredients as salt substitutes, primarily potassium chloride. (In this document, we use the term “potassium-based ingredients” to refer to “potassium,” “potassium chloride,” or other types of potassium-containing ingredients.) Some comments note that allowing potassium-based ingredients as a salt substitute could increase the potassium content of a standardized food, thereby increasing the amount of potassium in the U.S. food supply. Some comments believe that the final rule would

result in salt being replaced only with potassium chloride or that potassium chloride is the only salt substitute.

Some comments discuss the positive effects of potassium on lowering the risk of high blood pressure and other health benefits and that the information on potassium content of a food is already provided in the updated Nutrition Facts label for individuals who may need to limit potassium intake.

(Response 8) While we included potassium chloride as one example of an ingredient that might be used as a salt substitute in the preamble of the proposed rule, we note that the final rule does not limit salt substitutes to only potassium-based ingredients. Furthermore, we do not know how many foods will be voluntarily reformulated because of the final rule or which ingredients will be used to reformulate standardized foods. As a result, we cannot determine the extent to which the final rule may affect the amount of potassium in the food supply. Salt substitutes, including potassium chloride, are already permitted in non-standardized foods. Product labeling, such as the Nutrition Facts label and ingredient list, informs consumers of the potassium content of the food. The same information will be available for standardized foods. Furthermore, this rule restricts the use of salt substitutes to levels no higher than necessary to achieve their intended purpose and we expect the use of potassium chloride to replace salt will be self-limiting because of its inherent bitter and metallic taste characteristics (Refs. 10 and 11).

(Comment 9) Some comments state that potassium-based ingredients used as salt substitutes could impact those that need to monitor their potassium intake due to health conditions, such as chronic kidney disease and heart failure, and medication uses because of an increased risk of hyperkalemia. (Hyperkalemia, in general terms, is a condition where there is too much potassium in the blood.) Some comments suggest that a large portion of the population is affected with chronic kidney disease (CKD), including end stage kidney disease and kidney failure, and that some individuals may not know that they are affected by the disease or may not check the labels or be able to see or understand the labels of these potentially reformulated

standardized foods. Further, some comments mention that many individuals need to limit both sodium and potassium, so low-sodium foods may be appealing to them without realizing that some of these foods may contain potassium-based ingredients. Thus, the comments claim that potassium-based ingredients added to standardized foods would effectively be sources of “hidden” potassium for individuals with CKD or who otherwise need to monitor potassium in their diet.

Other comments express concerns that allowing potassium-based ingredients in standardized foods would further reduce food choices of those with kidney disease who may already struggle with limited food options. Some comments suggest that evidence may not support the notion that the use of potassium-based ingredients as salt substitutes leads to hyperkalemia. Other comments say more research is needed to understand the relationship between potassium intake and hyperkalemia. The comments urge us to consider the risk posed by using, or the lack of research or guidelines on the use of, potassium-based ingredients in standardized foods to individuals requiring careful monitoring of potassium intake.

(Response 9) We recognize the need for certain individuals to monitor potassium intake and emphasize the importance of using information on the food label to help with food selections. The nutrient declaration and percent Daily Values on the Nutrition Facts label provide quantitative information for consumers so that they may follow advice they have received from a health care professional concerning their conditions (81 FR 33742 at 33750). A manufacturer of a standardized food choosing to use potassium-based ingredients must declare the required potassium information on the Nutrition Facts label of a food containing two or more percent of the recommended daily intake for potassium per serving (21 CFR 101.9(c)(8)(ii) and (iii)). As a result, the potassium information about standardized foods that may be reformulated in response to this rule will be readily available to consumers--just as it is currently available on the label of non-standardized foods that have been permitted to contain potassium chloride for decades. The ingredient statement of standardized foods made with potassium chloride as an

ingredient must declare “potassium chloride” or “potassium salt” to inform consumers of its presence (see section 403(i)(2) of the FD&C Act (21 U.S.C. 343(i)(2)); see also § 101.4(a)(1) (21 CFR 101.4(a)(1)) and Ref. 4).

(Comment 10) Some comments express concerns that glutamate-containing ingredients, mainly monosodium glutamate (MSG), will be used as a salt substitute in standardized foods, thereby making it harder to find foods that do not contain MSG.

(Response 10) The final rule does not require any specific ingredient to be used in standardized foods as a salt substitute. Rather, as discussed in response 7, the final rule permits the use of safe and suitable ingredients to replace salt in standardized foods. We did not receive information about the number of foods that will be reformulated based on the final rule, or which ingredients will be used to reformulate standardized foods. Therefore, we have no data or information supporting the opinion expressed in comments that it will become harder to find foods that do not contain MSG as a result of this rule. If MSG is used as a salt substitute in standardized foods as a result of this rule, manufacturers must declare MSG in the ingredient statement in accordance with our labeling requirements (see § 101.4(a)) and 21 U.S.C. 343(i)(2)) as discussed in response 11. Additionally, 21 CFR 101.22(h)(5) requires that MSG used as an ingredient in food be declared by the common or usual name of “monosodium glutamate.” Therefore, consumers can use the information in the ingredient statement of the label to decide whether to purchase a food containing MSG as an ingredient and can avoid these foods if desired.

(Comment 11) Some comments express concerns that ingredients used to replace salt would not appear on the label or that the final rule would allow these ingredients to be labeled with the general term “salt substitute” in standardized foods. Some comments state that certain consumers will be more likely to purchase lower-sodium foods if the foods are labeled with the specific salt substitute used or are otherwise labeled as lower-sodium foods.

Other comments ask that the final rule require clear, consistent, and easy to understand labeling of the ingredients used to replace salt for transparency and to help consumers to make informed food choices, such as avoiding an ingredient that can cause sensitivity or allergenic reaction. Several comments request that the final rule require a clear labeling mechanism for consumers to easily identify the ingredients which were not previously used in standardized foods, such as new ingredients or allergens. In contrast, some comments indicate that existing labeling regulations already require the declaration of the ingredients used to replace salt.

(Response 11) The final rule does not prescribe any new labeling requirements for ingredients used to replace salt in standardized foods. However, existing labeling requirements apply to salt substitutes used in standardized foods. Ingredients, including salt substitutes, are required to be declared in the ingredient statement of standardized foods by their common or usual names (§ 101.4(a)(1); see also 21 U.S.C. 343(i)(2) and § 130.3(e)). Our regulations, at § 101.4(b), require that food ingredients be declared by a specific name and not a collective (generic) name unless a specific exception is provided. While the final rule defines “salt substitute” in the new part 130, subpart C, it does not establish “salt substitute” as a collective name of ingredients used to replace salt in standardized foods. Further, if the ingredient used as a salt substitute is or contains a major food allergen, the label must also declare the allergen as prescribed in section 403(w) of the FD&C Act.

Regarding the suggestion of additional labeling mechanisms for new ingredients used in reformulated standardized foods, we do not require any additional labeling of new ingredients used in reformulated standardized or non-standardized foods. The comments did not provide a reason why the labeling for standardized foods should be different from non-standardized foods. However, manufacturers of both standardized and non-standardized foods can choose to disclose information on the package voluntarily. For example, manufacturers could include reformulation information if statements made on the package are truthful and not misleading (see section 403(a)(1) of the FD&C Act (a food is deemed to be misbranded if its labeling is false or

misleading in any particular). Thus, we decline to establish additional labeling mechanisms as suggested by the comments.

(Comment 12) Some comments discuss the use of additional labeling for standardized foods reformulated with potassium ingredients as a safeguard for individuals who need to monitor or limit their potassium intake. Several comments recommend clear labeling of any potassium added from salt substitutes for these individuals if the final rule will allow the use of potassium-based ingredients as salt substitutes. The comments suggest labeling of potassium added from salt substitutes, and other comments recommend use of a temporary disclosure of increased potassium content in front-of-package labeling. Comments also support the need for potassium disclosure when potassium is added to standardized foods labeled as “low sodium” since many individuals to whom this labeling may appeal (i.e., individuals who need to monitor sodium intake) must monitor potassium intake. Some comments suggest that the additional food labeling would help individuals recognize the potassium from salt substitutes in the reformulated standardized foods and lead them to check the Nutrition Facts label and make appropriate food choices. Some comments say that foods containing potassium-based ingredients should bear a warning statement for individuals at risk for hyperkalemia.

Other comments suggest that any added statement on the front of the package regarding potassium should not dissuade consumers who do not need to limit potassium intake. Some comments oppose additional labeling of reformulated standardized foods and suggest that such a requirement could negate the intent of the final rule to help support a healthier food supply. These comments say that labeling that focuses on risk could hinder consumers’ understanding of potassium’s health benefits and noted that potassium is an under-consumed nutrient in the general U.S. population.

(Response 12) As discussed in response 11, the final rule does not create new labeling requirements or change existing labeling requirements for a standardized food reformulated with salt substitutes. If manufacturers of a standardized food replace sodium chloride with potassium-

based ingredients, they must declare these ingredients on the label in accordance with § 101.4(a) (see also section 403(i)(2) of the FD&C Act). As discussed in response 9, manufacturers must also declare quantitative information on potassium in the food on the Nutrition Facts label (21 CFR 101.9(c)(8)(ii)), and consumers can decide whether to consume the food based on this information.

We disagree that foods containing potassium-based ingredients should bear a warning statement for individuals at risk for hyperkalemia. Warning statements can be required under sections 403(a)(1) and 201(n) of the FD&C Act on grounds that the labeling is misleading if it fails to reveal facts material with respect to consequences which may result from the use of the article to which the labeling relates under the conditions of use as are customary or usual (see section 201(n) of the FD&C Act). However, given that facts about potassium content are already required on other parts of the label, we do not believe that a warning statement about hyperkalemia should be required. Individuals who limit their potassium intake for health reasons are already on notice to monitor the potassium content of foods they consume and can use the Nutrition Facts label and ingredient statement to decide whether a food may contain too much potassium for their diet. We also note that many foods, standardized and non-standardized, contain potassium and such a requirement could result in a large quantity of products in the food supply bearing a warning statement, which would undermine the utility of such a statement. Widespread use of such warning statements could also deter people who need to consume more potassium from consuming potassium-containing foods. Further, manufacturers can already choose to voluntarily disclose potassium-related information on the package. For example, we discussed in response 11 that manufacturers can include reformulation information provided that statements made on the package are truthful and not misleading. Manufacturers can also choose to declare the level of potassium in accordance with 21 CFR 101.13 and 101.54. For food labeled as “low sodium,” the sodium content of the food must meet the requirements of the nutrient content claim (§ 101.61(b)(4)).

(Comment 13) Several comments suggest monitoring or modeling certain ingredients before or in addition to implementing the final rule. Some comments ask that we monitor sodium and potassium in the food supply. Other comments ask that we conduct modeling or other studies to ensure that ingredients used as salt substitutes continue to be safe.

Other comments suggest that, following the publication of the final rule, we encourage the use of the Nutrition Facts label, conduct outreach to educate stakeholders, consumers, and clinicians on the potential presence of potassium-based ingredients in standardized foods, and update education materials as appropriate with certain information about standardized foods likely to be reformulated with potassium-based ingredients.

(Response 13) We discuss our effort to monitor sodium in the food supply in response 4. Regarding the suggestion to monitor or model the amount of potassium in the food supply, the rule does not limit salt substitutes to potassium-based ingredients in standardized foods. For example, yeast extracts, MSG, amino acids, and dairy extracts are other ingredients discussed in the scientific literature that could potentially serve as a salt substitute (Ref. 8). We did not receive information regarding the number of standardized foods likely to be reformulated with potassium-based ingredients. We plan to monitor relevant data and scientific publications for changes in U.S. consumption patterns in potassium intake.

Currently, we have made available extensive nutrition education resources on the Nutrition Facts label for consumers, dietitians, and educators as well as continuing medical education videos for physicians and health care professionals on how to counsel patients to make healthy food choices using the Nutrition Facts label (<https://www.fda.gov/food/nutrition-education-resources-materials/nutrition-facts-label>). These resources include information on sodium in packaged foods (<https://www.fda.gov/food/nutrition-education-resources-materials/sodium-nutrition-facts-label>) as well as the changes to the Nutrition Facts label that require declaration of the amount of potassium and its percent daily value (<https://www.fda.gov/food/nutrition-facts-label/whats-nutrition-facts-label>). We also have

information available to help educate consumers about how to use the Nutrition Facts label as a tool to make informed decisions about dietary sodium (<https://www.fda.gov/food/nutrition-education-resources-materials/sodium-your-diet>). Additionally, on January 16, 2025, FDA issued a proposed rule titled, “Food Labeling: Front-of-Package Nutrition Labeling” (90 FR 5426), which, among other things, would require most foods to bear a front-of-package Nutrition Info box on the principal display panel that details and interprets the relative amount of certain nutrients to limit, including sodium, in a serving of food. If finalized this rule will provide accessible, at-a-glance information to help consumers quickly and easily identify how foods can be part of a healthy diet.

We decline to develop consumer and patient education materials with information on reformulated standardized foods likely to have potassium-based ingredients. In the proposed rule, we requested public comment on the possible producer response, including how many manufacturers may choose to take voluntary action in response to the final rule, what share of standardized foods may be reformulated, and the types of salt substitutes manufacturers may use (see 88 FR 21148 at 21158). While some comments express general support for the flexibility to use salt substitutes to innovate to develop lower sodium standardized foods, the comments do not provide information about definitive plans to reformulate products based on the proposed rule. Some comments make general remarks about the potential to use potassium in various categories of products but do not provide information on the specific standardized foods to be reformulated or levels of substitution associated with reformulations. Therefore, any list that we could develop of standardized foods likely to be reformulated with potassium-based ingredients would be too speculative to be useful.

(Comment 14) Some comments state that the proposed rule would help to address health disparities. A few comments say that the proposed rule would particularly benefit older individuals who are both more at risk for hypertension and less likely to have taste buds adjust to gradual reductions in sodium. Other comments say that the proposed rule would not help reduce

racial health disparities because the use of salt substitutes to reduce sodium content of food is not an intervention specific to the diets or disease risks of African Americans but of all Americans.

Some comments express concern that several minority populations and lower-income and food-insecure communities are more likely to be affected by kidney disease and that risks associated with the adoption of potassium-based salt substitutes would contribute to structural injustices and health disparities.

(Response 14) We discussed in the proposed rule that permitting the use of salt substitutes in standardized foods would contribute to the reduction of sodium across the food supply (88 FR 21148 at 21151). Reducing the sodium content in the food supply is not intended as an intervention for any particular group of consumers, but for all consumers.

SOI regulations are intended to promote honesty and fair dealing in the interest of consumers (section 401 of the FD&C Act). SOI regulations do not address dietary restrictions related to individuals' specific disease conditions or their use of certain medications. The product's ingredient list and Nutrition Facts label, including nutrient declaration and percent Daily Value, while not targeting individuals' specific diseases or conditions, may be able to provide quantitative information for consumers to use to follow advice they have received from a health care professional concerning their conditions.

C. Salt Substitute Definition Comments and FDA Response

Several comments address various aspects of the definition of salt substitute under new subpart C--Flexibility in Standardized Foods in part 130. This definition applies to all standardized foods in parts 131 through 169 for which salt substitutes are a permitted ingredient under this rulemaking (see § 130.30(a); see Table 1 for the list of SOI amended). New subpart C limits ingredients used as salt substitutes to those that do not change the basic nature and essential characteristics of the food (§ 130.30(b)). The definition in the proposed rule under § 130.30(c) provided that a "salt substitute" is "a safe and suitable ingredient (or combination of ingredients) that is used to replace some or all of the added salt (sodium chloride), to reduce

sodium in the food, and that serves the functions of salt in the food.” We explained in the proposal that salt substitute was defined broadly to provide flexibility and facilitate innovation without the need for future rulemaking. By not listing specific salt substitutes, the definition could cover ingredients or combinations of ingredients that may be used as salt substitutes in the future, because of advances in food science and technological changes (see 88 FR 21148 at 21153).

(Comment 15) Many comments generally support the proposed definition’s approach to not list specific salt substitutes and agree it would allow flexibility to innovate to develop more healthful offerings while maintaining the basic nature and essential characteristics of the food. A few comments disagree with the approach and request that the definition list specific salt substitutes so that only the listed ingredients could be used as salt substitutes. The comments state that such change to the rule would increase the development of new salt substitutes and that we should have a process for approving new salt substitutes to be added to the list. A few comments request that FDA amend the definition of salt substitute to specifically exclude salt substitutes that are “self-certified” as GRAS. The comments argue that allowing salt substitutes that are “self-certified” as GRAS would not promote honesty and fair dealing in the interest of consumers because “self-certified” salt substitutes would effectively allow introduction of salt substitutes into standardized foods without notifying FDA or the public.

(Response 15) We decline to change the definition in the final rule to list specific salt substitutes that are allowed in standardized foods or to include a process for adding certain salt substitutes to such a list. As we explained in the proposed rule, by defining salt substitute broadly and by not listing specific salt substitutes, we are providing for flexibility and facilitating innovation without the need for additional rulemaking (see 88 FR 21148 at 21153). We agree that the final rule may result in development of new salt substitutes and noted the potential for innovation throughout the proposed rule; however, we disagree that there is a need to create a separate process for approving salt substitutes for use in standardized foods. As we explained in

the proposed rule, the requirements for food additives and GRAS uses of substances apply to salt substitutes used in standardized foods, just as they apply to non-standardized foods (see 88 FR 21148 at 21153). Furthermore, the general requirements for substitutes in § 130.30(b) and the definition of salt substitute in § 130.30(c)(1) ensure that the substitute will not change the basic nature and essential characteristics of the food and that only safe and suitable ingredients are used as salt substitutes.

We interpret the comments' references to "self-certified" as referring to salt substitutes for which a firm has not obtained FDA review of a GRAS conclusion. Requirements related to GRAS conclusions are outside the scope of this rulemaking. For more information about GRAS and available resources, see <https://www.fda.gov/food/food-ingredients-packaging/generally-recognized-safe-gras>.

Additionally, as discussed in response 11, the ingredients used in a food must be labeled according to applicable requirements.

(Comment 16) Some comments suggest minor revisions to the definition of salt substitute. The comments acknowledge that the proposed definition would cover "ingredients or combinations of ingredients that may be used as salt substitutes in the future" (88 FR 21148 at 21153) but propose revisions to the codified to incorporate this language. Specifically, the comments would revise proposed § 130.30(c) to read as follows: "Salt substitute means a safe and suitable ingredient (or combination of ingredients) that is used *at present or in the future* to replace some or all of the added salt (sodium chloride), to reduce sodium in the food, and that serves *one or more* functions of salt in the food" (suggested revisions are italicized). The comments say these revisions would provide more clarity and ensure flexibility for necessary salt substitute functionality, including the combinations of ingredients that may be needed.

(Response 16) We decline to revise § 130.30(c)(1) to explicitly include the text "at present or in the future" as requested by some comments. We agree that the definition of salt substitute in § 130.30(c)(1) includes safe and suitable ingredients that are presently in use or that

will be in future use, that replace some or all of the added salt, and that serve the functions of salt in the food. However, we believe that the definition of § 130.30(c)(1) is written broadly enough to include both ingredients in present use and ingredients in future use, so that the proposed revision to the text is not needed. This interpretation was explained in the preamble of the proposed rule, which stated that the proposed definition “would cover ingredients or combinations of ingredients currently used as salt substitutes and ingredients and combinations of ingredients that may be used as salt substitutes in the future, as a result of advances in food science and technological changes” (88 FR 21148 at 21153).

Further, we decline to revise § 130.30(c)(1) to state that a salt substitute replaces “one or more” functions of the salt in the food. The text of § 130.30(c)(1) states that a salt substitute “serves the functions of salt in the food.” For an ingredient or combination of ingredients to be a salt substitute, it must replace the functions of salt when added salt is reduced. The text proposed by the comments indicates that an ingredient or combination of ingredients need only serve one of the functions of salt in a food. If the amount of salt removed impacts multiple functions, then the ingredient(s) used as salt substitutes should serve those functions. If the salt only served one function in the food, then the salt substitute must serve the same function. We note that if we were to revise the text of § 130.30(c)(1) as proposed, manufacturers could arbitrarily choose which functions of salt are replaced by the salt substitute.

(Comment 17) Some comments request additional guidance or clarification regarding the definition of salt substitute. A few comments request additional guidance on what constitutes “safe and suitable” in § 130.30(c). Other comments ask us to clarify in the preamble to the final rule that types of ingredients, e.g., flavors, flavor enhancers, and mineral salts, are included in the definition of salt substitute because, according to the comments, these types of ingredients are often crucial components of reformulations to reduce sodium while maintaining consumer taste preferences.

(Response 17) Regarding comments requesting additional guidance on the meaning of “safe and suitable” in the definition of salt substitute, “safe and suitable” is defined in the definitions and interpretations for standardized foods (see § 130.3(d)). According to this definition, an ingredient is safe and suitable if it performs an appropriate function in the food, is used at a level no higher than necessary to achieve its intended purpose, and is not an unapproved food additive or color additive as used in the food. We note that we have revised the parenthetical in the definition of salt substitute so that “safe and suitable” also modifies the combination of ingredients to read as follows: “(or combination of safe and suitable ingredients).” This additional language further clarifies that all ingredients used as a salt substitute, whether used alone or in combination, must be safe and suitable.

We note that certain types of ingredients, such as flavors, flavor enhancers, and mineral salts, may comprise salt substitutes if they meet the criteria in § 130.30(b) and (c). As we stated in the proposed rule, we drafted the definition of salt substitute to provide manufacturers flexibility and facilitate sodium reduction across the food supply, while not changing the basic nature and essential characteristics or adversely affecting the nutritional quality and safety of standardized foods (88 FR 21148 at 21153). The types of ingredients, such as flavors, flavor enhancers, and mineral salts, that may be used as salt substitutes will depend on the ingredient or ingredients that can replace the functions of salt in the food, while still meeting the other criteria in the definition of salt substitute. It is important that manufacturers consider the particular functions of salt that would be lost at a given level of substitution in the standardized food and the types of ingredients to substitute for the lost function. For example, the SOI for self-rising flour (21 CFR 137.180) and canned corn (21 CFR 155.130) include salt as an ingredient. If the replacement of salt causes a loss of flavor in these foods, the rule will permit a flavor ingredient or flavor ingredients that otherwise meet the definition of salt substitute to be used. However, since self-rising flour has a low level of moisture and does not need preservation with ingredients to prevent microbial spoilage and canned corn is thermally processed to achieve commercial

sterility, using an ingredient that only prevents microbial spoilage will not align with the definition of salt substitute because salt does not serve the function of preventing spoilage in these products.

D. Fish and Shellfish Comments and FDA Response

Salt is a required or optional ingredient in several SOI in part 161 (21 CFR part 161) Fish and shellfish. We proposed amending the following SOI in part 161 which permit salt as a required or optional ingredient: Canned oysters (§ 161.145), Canned Pacific salmon (§ 161.170), Canned wet pack shrimp in transparent or nontransparent containers (§ 161.173), and Canned tuna (§ 161.190). We did not propose to amend the SOI for Oysters (§ 161.130), Frozen raw breaded shrimp (§ 161.175), and Frozen raw lightly breaded shrimp (§ 161.176).

The SOI for oysters (§ 161.130) does not include salt as a required or optional ingredient. Instead, the SOI provides for the optional use of saltwater containing less than 0.75 percent salt in the shucking of oysters (§ 161.130(b)). In the proposed rule, we described our understanding that current industry practice is to use accessible seawater rather than to constitute a solution for the shucking process. Therefore, because salt was not an added ingredient, we did not propose to amend the SOI to allow salt substitutes. We requested comment on this approach and our understanding of current industry practice (see 88 FR 21148 at 21152).

(Comment 18) One comment asks us to amend the SOI for oysters (§ 161.130) to allow for the use of salt substitutes. The comment acknowledges that current industry practice is not to use a prepared salt and water solution for the processing of oysters but suggests that we permit the use of salt substitutes in the SOI for oysters to accommodate any future use of salt substitutes in such solution.

(Response 18) The SOI for oysters prescribes the amount of salt present in the saltwater solution (less than 0.75 percent salt) and the length of time the oysters are in contact with the water or saltwater solution (not more than 30 minutes) (see § 161.130(b)). These parameters were set to help ensure that no appreciable loss of solids or absorption of water occurs during

washing, which could impact flavor and nutritive content of the oysters (see 11 FR 9331 at 9332-9333, August 27, 1946). Allowing the use of salt substitutes to lower the salt content of this solution without also changing the other parameters, such as length of time the oysters are in contact with water, could affect the amount of shrinkage or water absorption of the oysters. Further, the SOI requires that the oysters are packed without any added substance (see § 161.130(b)). The effect of using salt substitutes for processing oysters is unlikely to be the same as using salt, which could result in oysters being packed with an added substance. Therefore, we decline to amend the SOI for oysters in the final rule.

(Comment 19) One comment requests that the SOI for frozen raw breaded shrimp at § 161.175 and, by reference, the SOI for frozen raw lightly breaded shrimp at § 161.176, also be amended to permit the use of salt substitutes. The comment explains that these SOI allow for safe and suitable batter and breading ingredients but prohibit the use of artificial flavorings, artificial sweeteners, artificial colors, and chemical preservatives. The comment would amend the SOI to explicitly allow salt substitutes and also provide that use of a salt substitute is not limited by the existing ingredient prohibitions in the SOI.

(Response 19) As previously discussed, we intended to amend SOI that include salt as a required or optional ingredient to provide manufacturers with ingredient flexibility to reduce salt in these foods. The SOI for frozen raw breaded shrimp at § 161.175 does not explicitly provide for the use of salt as an ingredient. The SOI provides for the use of safe and suitable batter and breading ingredients (§ 161.175(a)), but excludes artificial flavorings, artificial sweeteners, artificial colors, and chemical preservatives (§ 161.175(d)). Thus, manufacturers can use salt and salt substitutes that are not artificial flavorings, artificial sweeteners, artificial colors, or chemical preservatives in frozen raw breaded shrimp. Therefore, we decline to amend the SOI for frozen raw breaded shrimp (§ 161.175) to explicitly permit salt substitutes. Because the SOI for frozen raw lightly breaded shrimp at § 161.176 cross references § 161.175, we are not amending the SOI for frozen raw lightly breaded shrimp for the same reasons.

E. Incorporation by Reference Comments and FDA Response

(Comment 20) Some comments ask that we update the incorporation by reference information. One comment notes that the rule should incorporate by reference the 22nd Ed. (2023) of the “Official Methods of Analysis of AOAC INTERNATIONAL” and not the 21st Ed. (2019) as proposed. One comment agrees with the change to update the number for the method in 21 CFR 155.170 for canned peas.

Other comments request that we update the incorporation by reference information in other sections which we did not propose to update, e.g., the SOI for frozen raw breaded shrimp and frozen raw lightly breaded shrimp (§§ 161.175 and 161.176).

(Response 20) We have reviewed the specific methods referenced by the proposed rule and note that there were no substantive changes between the 21st Ed. of the “Official Methods of Analysis of AOAC INTERNATIONAL” that we proposed to incorporate by reference and the newer 22nd Ed. Therefore, we agree to incorporate by reference the 22nd Ed. (2023) of the “Official Methods of Analysis of AOAC INTERNATIONAL” in the final rule.

As for the comments requesting updates to the incorporation by reference information in the SOI for frozen raw breaded shrimp and frozen raw lightly breaded shrimp (§§ 161.175 and 161.176), we decline this request. We are reviewing materials incorporated by reference in other regulations and will consider updating the material incorporated by reference in these SOI within the scope of that effort. We note that we have included technical amendments to make formatting changes to certain SOI that have not been updated to allow the use of salt substitutes to accommodate the use of a centralized IBR section in 21 CFR parts 131, 137, 139, 150, 155, and 161. There are no substantive changes to these SOI, and we have not updated the material that they incorporate by reference; these SOI have only been updated to point to a new centralized IBR section, if applicable. This change will help consolidate and streamline future IBR updates.

F. Technical Amendments

We proposed technical amendments to correct inconsistencies and typographical errors in several of the SOI that specify salt as a required or optional ingredient. We received no adverse comments regarding these proposed changes.

Therefore, the final rule amends:

- 21 CFR 133.118(c)(2) to replace “143” with “145”.
- 21 CFR 133.150(c)(2) to replace “143” with “145”.
- 21 CFR 133.150(e)(1) to replace “unusual” with “usual”.
- 21 CFR 133.182(c)(2) to replace “143” with “145”.
- 21 CFR 133.184(b) to replace “Operational” with “Optional”.
- 21 CFR 133.186(c) to replace “Nonmenclature” with “Nomenclature”.
- 21 CFR 133.187(c)(2) to replace “143” with “145”.
- 21 CFR 133.188(c)(2) to replace “143” with “145”.
- 21 CFR 155.170(b)(1)(iii) to replace “shrivelled” with “shriveled”.
- 21 CFR 158.170(b)(1)(iii) to replace “shrivelled” with “shriveled”.
- 21 CFR 168.140(a) to replace “mapel” with “maple”.

G. Out-of-Scope Comments

FDA also received several comments outside of the scope of this rulemaking. These comments raise issues related to:

- The Environmental Protection Agency’s (EPA’s) “Safer Choice and Design for the Environment” program and insect repellants.
- Work with the United States Department of Agriculture (USDA), Food Safety and Inspection Service to harmonize broader SOI principles.
- Appropriate use of the horizontal approach for other SOI changes (e.g., processing changes).
- Enforcement discretion to use salt substitutes in standardized foods pending issuance of the final rule.

- Intake of certain ingredients (e.g., sugar), nutrients (e.g., phosphorus), or types of foods (e.g., processed foods) or use of chemicals generally in the food supply.
- FDA’s sodium reduction efforts or sodium reduction strategies we could consider (e.g., labeling, taxation).
- The safety of specific, individual ingredients that may be used as salt substitutes.
- Impacts of the rule on specific, individual ingredients (e.g., kosher salt).
- Proposed amendments to § 101.4(b) (21 CFR 101.4(b) to allow the use of “and/or” labeling for salt substitutes.
- Consumer education for target populations, including those with specific conditions and/or nutrition needs.
- Work to address factors affecting health equity and cardiovascular disease.

We do not respond to these out-of-scope comments. Regarding comments about the safety of specific salt substitutes, we note that we re-review substances when we receive new safety information or data and have instituted a post-market review process to review substances more systematically for continued safety.

VI. Effective Date

This rule is effective [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] except as to any provisions in the SOI for dairy products that may be stayed by the filing of proper objections. If you will be adversely affected by one or more provisions in the SOI for dairy products of this regulation, you may file with the Dockets Management Staff (see ADDRESSES) either electronic or written/paper 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*.

VII. Economic Analysis of Impacts

A. Introduction

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, Executive Order 14192, the Regulatory Flexibility Act (5 U.S.C. 601-612), the Congressional Review Act/ Small Business Regulatory Enforcement Fairness Act (5 U.S.C. 801, Pub. L. 104-121), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4).

Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits. Rules are significant under section 3(f)(1) of Executive Order 12866 if they may have an annual effect on the economy of \$100 million or more; or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities. The Office of Information and Regulatory Affairs (OIRA) has determined that this final rule is a significant regulatory action as defined by section 3(f)(1) of Executive Order 12866.

Executive Order 14192 requires that any new incremental costs associated with certain significant regulatory actions “shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least 10 prior regulations.” The final rule allows manufacturers of affected products to gain flexibility in using salt substitutes. This flexibility

potentially would allow them to reformulate their products to increase their product offerings and therefore potentially increase their profits. Producing new products can reduce average operational costs by enabling economies of scale and scope. Increasing the number of products increases consumer surplus by providing more options tailored to individual preferences, allowing consumers to choose products that better align with their willingness to pay. However, due to the voluntary nature of the rule, no changes in costs of production or increase in consumer satisfaction can be quantified. This final rule is considered an Executive Order 14192 deregulatory action.

Because this rule is likely to result in an annual effect on the economy of \$100 million or more or to meet other criteria specified in the Congressional Review Act/Small Business Regulatory Enforcement Fairness Act, OIRA has determined that this rule does fall within the scope of 5 U.S.C. 804(2).

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the final rule would not impose regulatory costs on small entities, we certify that the final rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes estimates of anticipated impacts, before issuing “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 \$187 million, using the most current (2024) Implicit Price Deflator for the Gross Domestic Product. This final rule will not result in a mandated expenditure in any year that meets or exceeds this amount.

B. Overview of Benefits, Costs, and Transfers

There are no regulatory costs of the final rule as there are no regulatory requirements or

regulatory penalties if manufacturers of a standardized food choose not to take advantage of the flexibility to use salt substitutes. Other costs considered may come from voluntary reformulation and re-labeling costs, as well as potential consumer dissatisfaction with altered product properties. The benefits of the final rule come in the form of increased flexibility for manufacturers and potential public health benefits stemming from decreased sodium consumption.

We believe that some manufacturers may reformulate (and as a result, re-label) standardized foods with salt substitutes to lower sodium in their products if the voluntary reformulation of their products would be profitable (producer surplus). The resulting new products may lead to increased consumer satisfaction (consumer surplus). Table 1 summarizes the estimated benefits and costs of the final rule.

Table 1.--Summary of Benefits, Costs, and Distributional Effects of the Final Rule (millions of 2024 dollars)

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
Benefits	Annualized Monetized \$millions/year	\$0	\$0	\$0	2024	7%	10 years	
		\$0	\$0	\$0	2024	3%	10 years	
	Annualized Quantified							
	Qualitative	Potential increased consumer surplus and producer surplus. Potential health benefits of reduced sodium consumption.						
Costs	Annualized Monetized \$millions/year	\$0	\$0	\$0	2024	7%	10 years	
		\$0	\$0	\$0	2024	3%	10 years	
	Annualized Quantified							
	Qualitative	Potential costs from voluntary reformulation and re-labeling, as well as possible consumer dissatisfaction.						Compliance with the final rule is voluntary. There are no regulatory costs.
Transfers	Federal Annualized	\$0	\$0	\$0	2024	7%		
		\$0	\$0	\$0	2024	3%		

Category		Primary Estimate	Low Estimate	High Estimate	Units			Notes
					Year Dollars	Discount Rate	Period Covered	
	Monetized \$millions/year							
	From/To	From:			To:			
	Other Annualized Monetized \$millions/year	\$0	\$0	\$0	2024	7%		
		\$0	\$0	\$0	2024	3%		
	From/To	From:			To:			
Effects	State, Local or Tribal Government: Small Business: Wages: Growth:							

In line with Executive Order 14192, in table 2 we estimate present and annualized values of costs, cost savings, and net costs over a perpetual time horizon. We estimate that this rule will generate \$0 in annualized net costs at a 7 percent discount rate, discounted relative to year 2024, over a perpetual time horizon.

Table 2.--Executive Order 14192 Summary Table (millions of 2024 dollars, discounted over a perpetual time horizon relative to year 2024 at a 7 percent discount rate)

	Primary (7%)	Lower Bound (7%)	Upper Bound (7%)
Present Value of Costs	\$0	\$0	\$0
Present Value of Cost Savings	\$0	\$0	\$0
Present Value of Net Costs	\$0	\$0	\$0
Annualized Costs	\$0	\$0	\$0
Annualized Cost Savings	\$0	\$0	\$0
Annualized Net Costs	\$0	\$0	\$0

We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the final rule. The full analysis of economic impacts is available in the docket for this final rule (Ref. 12) and at <https://www.fda.gov/about-fda/economics-staff/regulatory-impact-analyses-ria>.

VIII. Analysis of Environmental Impact

We previously considered the environmental effects of this rule, as stated in the proposed rule (88 FR 21148 at 21160). We stated that we had 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” such that neither an environmental assessment nor an environmental impact statement is required. We have not received any new information or comments that would affect our previous determination (Ref. 13).

IX. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required. This final rule refers to the previously approved collection of information for food labeling regulations (OMB Control No. 0910-0381).

X. Federalism

We have analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

XI. 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.

XII. 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 are also 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. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

*1. U.S. Department of Agriculture and U.S. Department of Health and Human Services, “Dietary Guidelines for Americans, 2025-2030,” 10th Ed., January 2026. Available at <https://www.dietaryguidelines.gov> (accessed May 28, 2026).

*2. FDA, “Horizontal Approaches to Food Standards of Identity Modernization; Public Meeting; Request for Comments,” September 27, 2019. Transcript available at <https://www.fda.gov/food/workshops-meetings-webinars-food-and-dietary-supplements/public-meeting-horizontal-approaches-food-standards-identity-modernization-09272019-09272019> (accessed May 28, 2026).

*3. FDA, “Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods: Guidance for Industry,” October 2021, Docket number FDA-2014-D-0055. Available at <https://www.fda.gov/media/98264/download> (accessed May 28, 2026).

*4. FDA, “The Use of an Alternate Name for Potassium Chloride in Food Labeling: Guidance for Industry,” December 2020, Docket number FDA-2019-D-0892. Available at <https://www.fda.gov/media/125081/download> (accessed May 28, 2026).

5. Coxson, P.G., N.R. Cook, M. Joffres, et al., “Mortality Benefits From US Population-Wide Reduction in Sodium Consumption: Projections From 3 Modeling Approaches,” *Hypertension*, 61(3):564-570, 2013. Available at <https://www.ahajournals.org/doi/10.1161/hypertensionaha.111.201293> (accessed May 28, 2026).

6. National Academies of Sciences, Engineering, and Medicine, “Dietary Reference Intakes for Sodium and Potassium,” Washington, DC: The National Academies Press, 2019. Available at <https://doi.org/10.17226/25353> (accessed June 24, 2026).

7. Graudal, N.A., T. Hubeck-Graudal and G. Jurgens, “Effects of Low Sodium Diet Versus High Sodium Diet on Blood Pressure, Renin, Aldosterone, Catecholamines, Cholesterol, and Triglyceride,” *Cochrane Database of Systematic Reviews*, 12:CD004022, 2020. Available at <https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD004022.pub5/full> (accessed June 24, 2026).

*8. Institute of Medicine, “Strategies To Reduce Sodium Intake in the United States,” Washington, DC: The National Academies Press, 2010. Available at <https://www.ncbi.nlm.nih.gov/books/n/nap12818/pdf/> (accessed May 28, 2026).

*9. Harnack L.J., M.E. Cogswell, J.M. Shikany, et al. “Sources of Sodium in US Adults From 3 Geographic Regions,” *Circulation*, 135:1775-1783, 2017. Available at <https://www.ahajournals.org/doi/10.1161/CIRCULATIONAHA.116.024446> (accessed May 28, 2026).

*10. van Buren L., M. Dötsch-Klerk, G. Seewi, et al. “Dietary Impact of Adding Potassium Chloride to Foods as a Sodium Reduction Technique,” *Nutrients*, 8:235, 2016. Available at <https://doi.org/10.3390/nu8040235> (accessed May 28, 2026).

11. Sinopoli D.A. and H.T. Lawless, “Taste Properties of Potassium Chloride Alone and in Mixtures with Sodium Chloride Using a Check-All-That-Apply Method,” *Journal of Food Science*, 77:S319-S322, 2012. Available at

<https://ift.onlinelibrary.wiley.com/doi/10.1111/j.1750-3841.2012.02862.x> (accessed May 28, 2026).

*12. FDA, “Use of Salt Substitutes To Reduce the Sodium Content in Standardized Foods: Final Regulatory Impact Analysis, Regulatory Flexibility Analysis, Unfunded Mandates Reform Act Analysis,” 2026. Available at <https://www.fda.gov/economics-staff/regulatory-impact-analyses-ria>.

*13. FDA, Human Foods Program. Memorandum from Mariellen Pfeil, Supervisory Biologist, Office of Food Chemical Safety, Dietary Supplements and Innovation, Office of Pre-Market and Additive Safety, Environmental Review Team, to Andrew Yeung, Senior Advisor, Nutrition Center of Excellence (NCE), Office of Nutrition and Food Labeling (ONFL), Division of Food Labeling and Standards (DFLS), and Rumana Yasmeen, Food Technologist, NCE, ONFL, DFLS, Product Evaluation & Labeling Branch 2. “Categorical Exclusion--Use of Salt Substitutes To Reduce the Sodium Content in Standardized Foods,” June 1, 2026.

List of Subjects

21 CFR Part 130

Food additives, Food grades and standards.

21 CFR Part 131

Dairy products, Food grades and standards, Incorporation by reference, Milk.

21 CFR Part 133

Dairy products, Food grades and standards, Food labeling.

21 CFR Part 136

Bakery products, Food grades and standards, Incorporation by reference.

21 CFR Part 137

Foods, Food grades and standards, Incorporation by reference.

21 CFR Part 139

Food grades and standards, Incorporation by reference.

21 CFR Parts 145 and 150

Food grades and standards, Fruits, Incorporation by reference.

21 CFR Part 155

Food grades and standards, Incorporation by reference, Vegetables.

21 CFR Part 156

Food grades and standards, Vegetable juices.

21 CFR Part 158

Food grades and standards, Frozen foods, Vegetables.

21 CFR Part 161

Food grades and standards, Frozen foods, Incorporation by reference, Seafood.

21 CFR Part 163

Cacao products, Food grades and standards.

21 CFR Part 166

Food grades and standards, Food labeling, Incorporation by reference, Margarine.

21 CFR Part 168

Food grades and standards, Sugar.

21 CFR Part 169

Food grades and standards, Oils and fats, Spices and flavorings.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 130, 131, 133, 136, 137, 139, 145, 150, 155, 156, 158, 161, 163, 166, 168, and 169 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. Add subpart C, consisting of §§ 130.30 through 130.39, to read as follows:

Subpart C--Flexibility in Standardized Foods

Sec.

130.30 Ingredient flexibility in standardized foods.

130.31 through 130.39 [Reserved]

Subpart C--Flexibility in Standardized Foods

§ 130.30 Ingredient flexibility in standardized foods.

(a) The definitions listed in paragraph (c) of this section apply to parts 131 through 169 of this subchapter.

(b) The ingredients used as substitutes must not change the basic nature and essential characteristics of the food.

(c)(1) *Salt substitute* means a safe and suitable ingredient (or combination of safe and suitable ingredients) that is used to replace some or all of the added salt (sodium chloride), to reduce sodium in the food, and that serves the functions of salt in the food.

(2) [Reserved]

§§ 130.31 through 130.39 [Reserved]

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. Add § 131.1 to subpart A to read as follows:

§ 131.1 Incorporation by reference.

Certain material is incorporated by reference into this part with the approval of the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. All approved incorporation by reference (IBR) material is available for inspection at the Food and Drug Administration (FDA) and at the National Archives and Records Administration (NARA). Contact FDA's Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852; 240-402-7500; IBR_Material_Inquiries@fda.hhs.gov. For information on the availability

of this material at NARA, visit www.archives.gov/federal-register/cfr/ibr-locations or email fr.inspection@nara.gov. The material may be obtained from the following sources:

(a) AOAC INTERNATIONAL (AOAC), 2275 Research Blvd., Suite 300, Rockville, MD 20850-3250; 1-800-379-2622; www.aoac.org.

(1) *Official Methods of Analysis of the Association of Official Analytical Chemists*, 13th Ed., 1980; IBR approved for §§ 131.110(d); 131.115(d); 131.120(c); 131.125(c); 131.127(d); 131.130(d); 131.147(d); 131.149(c); 131.150(c); 131.155(c); 131.157(c); 131.180(c).

(2) *Official Methods of Analysis of AOAC INTERNATIONAL*, 21st Ed., 2019, vol. 1—

(i) AOAC Official Method 989.05, Fat in Milk: Modified Mojonnier Ether Extraction Method, Section 33.2.26; IBR approved for § 131.200(e).

(ii) AOAC Official Method 990.21, Solids-Not-Fat in Milk: By Difference between Total Solids and Fat Contents, Section 33.2.45; IBR approved for § 131.200(e).

(3) *Official Methods of Analysis of AOAC INTERNATIONAL*, 22nd Ed., published 4 January 2023 (available at <https://academic.oup.com/aoac-publications/book/45491>)—

(i) AOAC Official Method 945.48, Evaporated Milk (Unsweetened); IBR approved for §§ 131.160(c); 131.162(c).

(ii) AOAC Official Method 947.05, Acidity of Milk: Titrimetric Method; IBR approved for §§ 131.111(f); 131.112(e); 131.160(c); 131.162(c).

(iii) AOAC Official Method 989.05, Fat in Milk: Modified Mojonnier Ether Extraction Method; IBR approved for §§ 131.111(f); 131.112(e); 131.170(f).

(iv) AOAC Official Method 990.21, Solids-Not-Fat in Milk: By Difference between Total Solids and Fat Contents; IBR approved for §§ 131.111(f); 131.112(e); 131.170(f).

(b) International Organization for Standardization (ISO), Chemin de Blandonnet 8, CP 401, 1214 Vernier, Geneva, Switzerland; +41 22 749 01 11; www.iso.org.

(1) ISO 7889:2003(E), Yogurt--Enumeration of Characteristic Microorganisms--Colony-Count Technique at 37 °C, 1st Ed., 2003-02-01.

(2) [Reserved]

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

5. In § 131.110, revise the introductory text of paragraph (d) to read as follows:

§ 131.110 Milk.

* * * * *

(d) *Methods of analysis.* The methods referenced in this paragraph (d) are from the *Official Methods of Analysis of the Association of Official Analytical Chemists*, 13th Ed.

(incorporated by reference, see § 131.1).

* * * * *

6. In § 131.111, revise paragraphs (e)(8) and (f) to read as follows:

§ 131.111 Acidified milk.

* * * * *

(e) * * *

(8) Salt or salt substitute.

* * * * *

(f) *Methods of analysis.* The AOAC methods referenced in this paragraph (f) are incorporated by reference (see § 131.1):

(1) Milkfat content--As determined by the method prescribed in AOAC Official Method 989.05.

(2) Milk solids not fat content--Calculated by subtracting the milkfat content from the total solids content using the method prescribed in AOAC Official Method 990.21.

(3) Titratable acidity--As determined by the methods prescribed in AOAC Official Method 947.05 or by an equivalent potentiometric method.

* * * * *

7. In § 131.112, revise paragraphs (d)(8) and (e) to read as follows:

§ 131.112 Cultured milk.

* * * * *

(d) * * *

(8) Salt or salt substitute.

* * * * *

(e) *Methods of analysis.* The AOAC methods referenced in this paragraph (e) are incorporated by reference (see § 131.1):

(1) Milkfat content--As determined by the method prescribed in AOAC Official Method 989.05.

(2) Milk solids not fat content--Calculated by subtracting the milkfat content from the total solids content using the method prescribed in AOAC Official Method 990.21.

(3) Titratable acidity--As determined by the methods prescribed in AOAC Official Method 947.05 or by an equivalent potentiometric method.

* * * * *

8. In § 131.115, revise the introductory text of paragraph (d) to read as follows:

§ 131.115 Concentrated milk.

* * * * *

(d) *Methods of analysis.* The methods referenced in this paragraph (d) are from the *Official Methods of Analysis of the Association of Official Analytical Chemists*, 13th Ed. (incorporated by reference, see § 131.1).

* * * * *

9. In § 131.120, revise paragraph (c) to read as follows:

§ 131.120 Sweetened condensed milk.

* * * * *

(c) *Methods of analysis.* The milkfat content is determined by the method prescribed in “Fat--Official Final Action,” Section 16.185 from the *Official Methods of Analysis of the Association of Official Analytical Chemists*, 13th Ed. (incorporated by reference, see § 131.1).

* * * * *

10. In § 131.125, revise the introductory text of paragraph (c) to read as follows:

§ 131.125 Nonfat dry milk.

* * * * *

(c) *Methods of analysis.* The methods referenced in this paragraph (c) are from the *Official Methods of Analysis of the Association of Official Analytical Chemists*, 13th Ed. (incorporated by reference, see § 131.1).

* * * * *

11. In § 131.127, revise the introductory text of paragraph (d) to read as follows:

§ 131.127 Nonfat dry milk fortified with vitamins A and D.

* * * * *

(d) *Methods of analysis.* The methods referenced in this paragraph (d) are from the *Official Methods of Analysis of the Association of Official Analytical Chemists*, 13th Ed. (incorporated by reference, see § 131.1).

* * * * *

12. In § 131.130, revise the introductory text of paragraph (d) to read as follows:

§ 131.130 Evaporated milk.

* * * * *

(d) *Methods of analysis.* The methods referenced in this paragraph (d) are from the *Official Methods of Analysis of the Association of Official Analytical Chemists*, 13th Ed. (incorporated by reference, see § 131.1).

* * * * *

13. In § 131.147, revise the introductory text of paragraph (d) to read as follows:

§ 131.147 Dry whole milk.

* * * * *

(d) *Methods of analysis.* The methods referenced in this paragraph (d) are from the *Official Methods of Analysis of the Association of Official Analytical Chemists*, 13th Ed. (incorporated by reference, see § 131.1).

* * * * *

14. In § 131.149, revise the introductory text of paragraph (c) to read as follows:

§ 131.149 Dry cream.

* * * * *

(c) *Methods of analysis.* The methods referenced in this paragraph (c) are from the *Official Methods of Analysis of the Association of Official Analytical Chemists*, 13th Ed. (incorporated by reference, see § 131.1).

* * * * *

15. In § 131.150, revise paragraph (c) to read as follows:

§ 131.150 Heavy cream.

* * * * *

(c) *Methods of analysis.* The milkfat content is determined by the method prescribed in sections 16.156 and 16.059, under “Fat, Roesse-Gottlieb Method—Official Final Action” from the *Official Methods of Analysis of the Association of Official Analytical Chemists*, 13th Ed. (incorporated by reference, see § 131.1).

* * * * *

16. In § 131.155, revise paragraph (c) to read as follows:

§ 131.155 Light cream.

* * * * *

(c) *Methods of analysis.* The milkfat content is determined by the method prescribed in sections 16.156 and 16.059, under “Fat, Roesse-Gottlieb Method--Official Final Action” from the *Official Methods of Analysis of the Association of Official Analytical Chemists*, 13th Ed. (incorporated by reference, see § 131.1).

* * * * *

17. In § 131.157, revise paragraph (c) to read as follows:

§ 131.157 Light whipping cream.

* * * * *

(c) *Methods of analysis.* The milkfat content is determined by the method prescribed in sections 16.156 and 16.059, under “Fat, Roesse-Gottlieb Method--Official Final Action” from the *Official Methods of Analysis of the Association of Official Analytical Chemists*, 13th Ed.

(incorporated by reference, see § 131.1).

* * * * *

18. In § 131.160, revise paragraphs (b)(5) and (c) to read as follows:

§ 131.160 Sour cream.

* * * * *

(b) * * *

(5) Salt or salt substitute.

* * * * *

(c) *Methods of analysis.* The AOAC methods referenced in this paragraph (c) are incorporated by reference (see § 131.1):

(1) Milkfat content--AOAC Official Method 945.48G.

(2) Titratable acidity--AOAC Official Method 947.05.

* * * * *

19. In § 131.162, revise paragraphs (b)(4) and (c) to read as follows:

§ 131.162 Acidified sour cream.

* * * * *

(b) * * *

(4) Salt or salt substitute.

* * * * *

(c) *Methods of analysis.* The AOAC methods referenced in this paragraph (c) are incorporated by reference (see § 131.1):

(1) Milkfat content--AOAC Official Method 945.48G.

(2) Titratable acidity--AOAC Official Method 947.05.

* * * * *

20. In § 131.170, revise paragraphs (e)(2) and (f) to read as follows:

§ 131.170 Eggnog.

* * * * *

(e) * * *

(2) Salt or salt substitute.

* * * * *

(f) *Methods of analysis.* The AOAC methods referenced in this paragraph (f) are incorporated by reference (see § 131.1).

(1) Milkfat content--As determined by the method prescribed in AOAC Official Method 989.05.

(2) Milk solids not fat content--Calculated by subtracting the milkfat content from the total solids content using the method prescribed in AOAC Official Method 990.21.

* * * * *

21. In § 131.180, revise paragraph (c) to read as follows:

§ 131.180 Half-and-half.

* * * * *

(c) *Methods of analysis.* The milkfat content is determined by the method prescribed in sections 16.156 and 16.059, under “Fat, Roese-Gottlieb Method--Official Final Action” from the *Official Methods of Analysis of the Association of Official Analytical Chemists*, 13th Ed. (incorporated by reference, see § 131.1).

* * * * *

§ 131.200 [Amended]

22. In § 131.200:

a. Amend paragraphs (e)(1)(i) and (ii) and (e)(3) by adding the text “(incorporated by reference, see § 131.1)” immediately before the closing period of each paragraph.

b. Remove paragraph (i).

PART 133--CHEESES AND RELATED CHEESE PRODUCTS

23. The authority citation for part 133 continues to read as follows:

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

24. In § 133.102, add paragraph (c)(3) to read as follows:

§ 133.102 Asiago fresh and asiago soft cheese.

* * * * *

(c) * * *

(3) During the cheesemaking process, where the curd is salted, salt substitute may be used.

* * * * *

25. In § 133.106, add paragraph (b)(3)(vii) to read as follows:

§ 133.106 Blue cheese.

* * * * *

(b) * * *

(3) * * *

(vii) Salt substitute.

* * * * *

26. In § 133.108, add paragraph (b)(3)(v) to read as follows:

§ 133.108 Brick cheese.

* * * * *

(b) * * *

(3) * * *

(v) Salt substitute.

* * * * *

27. In § 133.111, add paragraph (c)(3) to read as follows:

§ 133.111 Caciocavallo siciliano cheese.

* * * * *

(c) * * *

(3) During the cheesemaking process, where the curd is salted, salt substitute may be used.

* * * * *

28. In § 133.113, add paragraph (b)(3)(vi) to read as follows:

§ 133.113 Cheddar cheese.

* * * * *

(b) * * *

(3) * * *

(vi) Salt substitute.

* * * * *

29. In § 133.118, revise the first sentence of paragraph (c)(2) and add paragraph (c)(4) to read as follows:

§ 133.118 Colby cheese.

* * * * *

(c) * * *

(2) Milk shall be deemed to have been pasteurized if it has been held at a temperature of not less than 145 °F for a period of not less than 30 minutes, or for a time and at a temperature equivalent thereto in phosphatase destruction. * * *

* * * * *

(4) During the cheesemaking process, where the curd is salted, salt substitute may be used.

* * * * *

30. In § 133.123, revise paragraph (c)(3) to read as follows:

§ 133.123 Cold-pack and club cheese.

* * * * *

(c) * * *

(3) Salt or salt substitute.

* * * * *

31. In § 133.124, revise paragraph (e)(3) to read as follows:

§ 133.124 Cold-pack cheese food.

* * * * *

(e) * * *

(3) Salt or salt substitute.

* * * * *

32. In § 133.127, revise paragraph (b)(3)(v) to read as follows:

§ 133.127 Cook cheese, koch kaese.

* * * * *

(b) * * *

(3) * * *

(v) Salt or salt substitute.

* * * * *

33. In § 133.129, revise paragraphs (b)(1)(i) through (iii) to read as follows:

§ 133.129 Dry curd cottage cheese.

* * * * *

(b)(1) * * *

(i) Harmless lactic-acid-producing bacteria, with or without rennet and/or other safe and suitable milk-clotting enzyme that produces equivalent curd formation, are added and it is held until it becomes coagulated. The coagulated mass may be cut, it may be warmed, it may be stirred, and it is then drained. The curd may be washed with water and further drained. It may be pressed, chilled, worked, seasoned with salt or salt substitute; or

(ii) Food grade phosphoric acid, lactic acid, citric acid, or hydrochloric acid, with or without rennet and/or other safe and suitable milk-clotting enzyme that produces equivalent curd formation, is added in such amount as to reach a pH of between 4.5 and 4.7; coagulation to a firm curd is achieved while heating to a maximum of 120 °F without agitation during a continuous process. The coagulated mass may be cut; it may be warmed; it may be stirred; it is then drained. The curd is washed with water, stirred, and further drained. It may be pressed, chilled, worked, seasoned with salt or salt substitute.

(iii) Food grade acids as provided in paragraph (b)(1)(ii) of this section, D-Glucono-delta-lactone with or without rennet, and/or other safe and suitable milk clotting enzyme that produces equivalent curd formation, are added in such amounts as to reach a final pH value in the range of 4.5-4.8, and it is held until it becomes coagulated. The coagulated mass may be cut; it may be warmed; it may be stirred; it is then drained. The curd is then washed with water and further drained. It may be pressed, chilled, worked, and seasoned with salt or salt substitute.

* * * * *

34. In § 133.133, revise paragraph (b)(3)(i) to read as follows:

§ 133.133 Cream cheese.

* * * * *

(b) * * *

(3) * * *

(i) Salt or salt substitute.

* * * * *

35. In § 133.136, add paragraph (b)(3)(vi) to read as follows:

§ 133.136 Washed curd and soaked curd cheese.

* * * * *

(b) * * *

(3) * * *

(vi) Salt substitute.

* * * * *

36. In § 133.138, add paragraph (b)(3)(v) to read as follows:

§ 133.138 Edam cheese.

* * * * *

(b) * * *

(3) * * *

(v) Salt substitute.

* * * * *

37. In § 133.141, add paragraph (b)(3)(vii) to read as follows:

§ 133.141 Gorgonzola cheese.

* * * * *

(b) * * *

(3) * * *

(vii) Salt substitute.

* * * * *

38. In § 133.144, add paragraph (b)(3)(vi) to read as follows:

§ 133.144 Granular and stirred curd cheese.

* * * * *

(b) * * *

(3) * * *

(vi) Salt substitute.

* * * * *

39. In § 133.147, revise paragraph (c)(5) to read as follows:

§ 133.147 Grated American cheese food.

* * * * *

(c) * * *

(5) Salt or salt substitute.

* * * * *

40. In § 133.148, revise paragraph (c) to read as follows:

§ 133.148 Hard grating cheeses.

* * * * *

(c)(1) For the purposes of this section, the word “milk” means cow’s milk or goat’s milk or sheep’s milk or mixtures of two or all of these. Such milk may be adjusted by separating part of the fat therefrom or (in the case of cow’s milk) by adding one or more of the following: Cream, skim milk, concentrated skim milk, nonfat dry milk; (in the case of goat’s milk) the corresponding products from goat’s milk; (in the case of sheep’s milk) the corresponding products from sheep’s milk; water in a quantity sufficient to reconstitute any such concentrated or dried products used.

(2) During the cheesemaking process, where the curd is salted, salt substitute may be used.

* * * * *

41. In § 133.149, add paragraph (b)(3)(iv) to read as follows:

§ 133.149 Gruyere cheese.

* * * * *

(b) * * *

(3) * * *

(iv) Salt substitute.

* * * * *

42. In § 133.150, revise the first sentence of paragraph (c)(2), add paragraph (c)(3), and revise paragraph (e)(1) to read as follows:

§ 133.150 Hard cheeses.

* * * * *

(c) * * *

(2) Milk shall be deemed to have been pasteurized if it has been held at a temperature of not less than 145 °F for a period of not less than 30 minutes, or for a time and at a temperature equivalent thereto in phosphatase destruction. * * *

(3) During the cheesemaking process, where the curd is salted, salt substitute may be used.

* * * * *

(e) * * *

(1) The specific common or usual name of such hard cheese, if any such name has become generally recognized therefor; or

* * * * *

43. In § 133.152, add paragraph (b)(3)(iv) to read as follows:

§ 133.152 Limburger cheese.

* * * * *

(b) * * *

(3) * * *

(iv) Salt substitute.

* * * * *

44. In § 133.153, revise paragraph (b)(3)(iii) to read as follows:

§ 133.153 Monterey cheese and monterey jack cheese.

* * * * *

(b) * * *

(3) * * *

(iii) Salt or salt substitute.

* * * * *

45. In § 133.155, revise paragraph (b)(3)(iii) to read as follows:

§ 133.155 Mozzarella cheese and scamorza cheese.

* * * * *

(b) * * *

(3) * * *

(iii) Salt or salt substitute.

* * * * *

46. In § 133.156, revise paragraph (b)(3)(iii) to read as follows:

§ 133.156 Low-moisture mozzarella and scamorza cheese.

* * * * *

(b) * * *

(3) * * *

(iii) Salt or salt substitute.

* * * * *

47. In § 133.160, add paragraph (b)(3)(vi) to read as follows:

§ 133.160 Muenster and munster cheese.

* * * * *

(b) * * *

(3) * * *

(vi) Salt substitute.

* * * * *

48. In § 133.162, revise paragraph (b)(3)(i) to read as follows:

§ 133.162 Neufchatel cheese.

* * * * *

(b) * * *

(3) * * *

(i) Salt or salt substitute.

* * * * *

49. In § 133.164, add paragraph (b)(3)(iv) to read as follows:

§ 133.164 Nuworld cheese.

* * * * *

(b) * * *

(3) * * *

(iv) Salt substitute.

* * * * *

50. In § 133.165, add paragraph (c)(3) to read as follows:

§ 133.165 Parmesan and reggiano cheese.

* * * * *

(c) * * *

(3) During the cheesemaking process, where the curd is salted, salt substitute may be used.

* * * * *

51. In § 133.169, revise paragraph (d)(4) to read as follows:

§ 133.169 Pasteurized process cheese.

* * * * *

(d) * * *

(4) Salt or salt substitute.

* * * * *

52. In § 133.173, revise paragraph (e)(4) to read as follows:

§ 133.173 Pasteurized process cheese food.

* * * * *

(e) * * *

(4) Salt or salt substitute.

* * * * *

53. In § 133.179, revise paragraph (f)(5) to read as follows:

§ 133.179 Pasteurized process cheese spread.

* * * * *

(f) * * *

(5) Salt or salt substitute.

* * * * *

54. In § 133.181, add paragraph (b)(3)(vi) to read as follows:

§ 133.181 Provolone cheese.

* * * * *

(b) * * *

(3) * * *

(vi) Salt substitute.

* * * * *

55. In § 133.182, revise and republish paragraph (b) and revise paragraph (c)(2) to read as follows:

§ 133.182 Soft ripened cheeses.

* * * * *

(b) Milk, which may be pasteurized or clarified or both, and which may be warmed, is subjected to the action of harmless lactic-acid-producing bacteria or other harmless flavor-

producing bacteria, present in such milk or added thereto. Sufficient rennet, rennet paste, extract of rennet paste, or other safe and suitable milk-clotting enzyme that produces equivalent curd formation, singly or in any combination (with or without purified calcium chloride in a quantity not more than 0.02 percent, calculated as anhydrous calcium chloride, of the weight of the milk) is added to set the milk to a semisolid mass. Harmless artificial coloring may be added. After coagulation, the mass is so treated as to promote and regulate the separation of whey and curd. Such treatment may include one or more of the following: cutting, stirring, heating, dilution with water or brine. The whey, or part of it, is drained off, and the curd is collected and shaped. It may be placed in forms and may be pressed. Harmless flavor-producing microorganisms may be added. It is cured under conditions suitable for development of biological curing agents on the surface of the cheese, and the curing is conducted so that the cheese cures from the surface toward the center. Salt or salt substitute may be added during the procedure. A harmless preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of soft ripened cheeses may be added, in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used.

(c) * * *

(2) Milk shall be deemed to have been pasteurized if it has been held at a temperature of not less than 145 °F for a period of not less than 30 minutes, or for a time and at a temperature equivalent thereto in phosphatase destruction.

* * * * *

56. In § 133.183, add paragraph (c)(3) to read as follows:

§ 133.183 Romano cheese.

* * * * *

(c) * * *

(3) During the cheesemaking process, where the curd is salted, salt substitute may be used.

* * * * *

57. In § 133.184, revise paragraphs (b) introductory text and (b)(3) to read as follows:

§ 133.184 Roquefort cheese, sheep's milk blue-mold, and blue-mold cheese from sheep's milk.

* * * * *

(b) *Optional Ingredients.* The following safe and suitable ingredients may be used:

* * * * *

(3) *Other optional ingredients.* (i) Enzymes of animal, plant, or microbial origin, used in curing or flavor development.

(ii) Salt substitute.

* * * * *

58. In § 133.185, add paragraph (b)(3)(v) to read as follows:

§ 133.185 Samsoe cheese.

* * * * *

(b) * * *

(3) * * *

(v) Salt substitute.

* * * * *

59. In § 133.186, revise paragraphs (a)(2) and (c) to read as follows:

§ 133.186 Sap sago cheese.

(a) * * *

(2) One or more of the dairy ingredients specified in paragraph (b)(1) of this section is allowed to become sour, and is heated to boiling temperature, with stirring. Sufficient sour whey is added to precipitate the casein. The curd is removed, spread out in boxes, and pressed, and while under pressure is allowed to drain and ferment. It is ripened for not less than 5 weeks. The ripened curd is dried and ground; salt or salt substitute and dried clover of the species

Melilotus coerulea are added. The mixture is shaped into truncated cones and ripened. The optional ingredient in paragraph (b)(2) of this section may be added during this procedure.

* * * * *

(c) *Nomenclature.* The name of the food is “sap sago cheese.”

* * * * *

60. In § 133.187, revise and republish paragraph (b) and the first sentence of paragraph (c)(2) to read as follows:

§ 133.187 Semisoft cheeses.

* * * * *

(b) Milk, which may be pasteurized or clarified or both, and which may be warmed, is subjected to the action of harmless lactic-acid-producing bacteria or other harmless flavor-producing bacteria, present in such milk or added thereto. Sufficient rennet, rennet paste, extract of rennet paste, or other safe and suitable milk-clotting enzyme that produces equivalent curd formation, singly or in any combination (with or without purified calcium chloride in a quantity not more than 0.02 percent, calculated as anhydrous calcium chloride, of the weight of the milk) is added to set the milk to a semisolid mass. Harmless artificial coloring may be added. After coagulation, the mass is so treated as to promote and regulate the separation of whey and curd. Such treatment may include one or more of the following: cutting, stirring, heating, dilution with water or brine. The whey, or part of it, is drained off, and the curd is collected and shaped. It may be placed in forms and may be pressed. Harmless flavor-producing microorganisms may be added. It may be cured in a manner to promote the growth of biological curing agents. Salt or salt substitute may be added during the procedure. A harmless preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of semisoft cheese may be added, in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used.

(c) * * *

(2) Milk shall be deemed to have been pasteurized if it has been held at a temperature of not less than 145 °F for a period of not less than 30 minutes, or for a time and at a temperature equivalent thereto in phosphatase destruction. * * *

* * * * *

61. In § 133.188, revise and republish paragraph (b) and the first sentence in paragraph (c)(2) to read as follows:

§ 133.188 Semisoft part-skim cheeses.

* * * * *

(b) Milk, which may be pasteurized or clarified or both, and which may be warmed, is subjected to the action of harmless lactic-acid-producing bacteria or other harmless flavor-producing bacteria, present in such milk or added thereto. Sufficient rennet, rennet paste, extract of rennet paste, or other safe and suitable milk-clotting enzyme that produces equivalent curd formation singly or in any combination (with or without purified calcium chloride in a quantity not more than 0.02 percent, calculated as anhydrous calcium chloride, of the weight of the milk) is added to set the milk to a semisolid mass. Harmless artificial coloring may be added. After coagulation, the mass is so treated as to promote and regulate the separation of whey and curd. Such treatment may include one or more of the following: cutting, stirring, heating, dilution with water or brine. The whey, or part of it, is drained off, and the curd is collected and shaped. It may be placed in forms and may be pressed. Harmless flavor-producing microorganisms may be added. It may be cured in a manner to promote the growth of biological curing agents. Salt or salt substitute may be added during the procedure. A harmless preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of semisoft part-skim cheese may be added in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used.

(c) * * *

(2) Milk shall be deemed to have been pasteurized if it has been held at a temperature of not less than 145 °F for a period of not less than 30 minutes, or for a time and at a temperature equivalent thereto in phosphatase destruction. * * *

* * * * *

62. In § 133.189, revise paragraph (d) to read as follows:

§ 133.189 Skim milk cheese for manufacturing.

* * * * *

(d)(1) For the purposes of this section, “skim milk” means cow’s milk from which the milk fat has been separated.

(2) During the cheesemaking process, where the curd is salted, salt substitute may be used.

* * * * *

63. In § 133.190, revise paragraph (b)(3)(iii) to read as follows:

§ 133.190 Spiced cheeses.

* * * * *

(b) * * *

(3) * * *

(iii) Salt or salt substitute.

* * * * *

64. In § 133.195, add paragraph (b)(3)(vii) to read as follows:

§ 133.195 Swiss and emmentaler cheese.

* * * * *

(b) * * *

(3) * * *

(vii) Salt substitute.

* * * * *

PART 136--BAKERY PRODUCTS

65. The authority citation for part 136 continues to read as follows:

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

66. In § 136.110, revise paragraphs (c)(4) and (d) to read as follows:

§ 136.110 Bread, rolls, and buns.

* * * * *

(c) * * *

(4) Salt or salt substitute.

* * * * *

(d) Total solids are determined by the method prescribed in AOAC Official Method 935.36(a), Solids (Total) in Bread, except that if the baked unit weighs 454 grams (1 pound) or more, one entire unit is used for the determination; if the baked unit weighs less than 454 grams, enough units to weigh 454 grams or more are used. AOAC Official Method 935.36(a), Solids (Total) in Bread, *Official Methods of Analysis*, 22nd Ed., published 4 January 2023 (available at <https://academic.oup.com/aoac-publications/book/45491>), is 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. This incorporation by reference (IBR) material is available for inspection at the Food and Drug Administration (FDA) and at the National Archives and Records Administration (NARA). Contact FDA's Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852; 240-402-7500; IBR_Material_Inquiries@fda.hhs.gov. For information on the availability of this material at NARA, visit www.archives.gov/federal-register/cfr/ibr-locations or email fr.inspection@nara.gov. This material is also available from AOAC INTERNATIONAL, 2275 Research Blvd., Suite 300, Rockville, MD 20850-3250; 1-800-379-2622; www.aoac.org.

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PART 137--CEREAL FLOURS AND RELATED PRODUCTS

67. The authority citation for part 137 continues to read as follows:

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

68. Add subpart A, consisting of §§ 137.1 through 137.100, to read as follows:

Subpart A--General Provisions

Sec.

137.1 Incorporation by reference.

137.2 through 137.100 [Reserved]

Subpart A--General Provisions

§ 137.1 Incorporation by reference.

Certain material is incorporated by reference into this part with the approval of the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. All approved incorporation by reference (IBR) material is available for inspection at the Food and Drug Administration (FDA) and at the National Archives and Records Administration (NARA). Contact FDA's Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852; 240-402-7500; IBR_Material_Inquiries@fda.hhs.gov. For information on the availability of this material at NARA, visit www.archives.gov/federal-register/cfr/ibr-locations or email fr.inspection@nara.gov. The material may be obtained from AOAC INTERNATIONAL (AOAC), 2275 Research Blvd., Suite 300, Rockville, MD 20850-3250; 1-800-379-2622; www.aoac.org/:

(a) *Official Methods of Analysis of the Association of Official Analytical Chemists*, 13th Ed., 1980; IBR approved for §§ 137.105(a) and (c); 137.190; 137.195; 137.200(c); 137.211(b); 137.250(b); 137.300(b); 137.350(e).

(b) *Official Methods of Analysis of AOAC INTERNATIONAL*, 22nd Ed., published 4 January 2023 (available at <https://academic.oup.com/aoac-publications/book/45491>) —

(1) AOAC Official Method 923.02, Carbon Dioxide (Total) in Baking Powders: Gasometric Determination; IBR approved for §§ 137.180(c); 137.270(b).

(2) AOAC Appendix C, Reference Tables, 909.04, Correction Factors for Gasometric Determination of Carbon Dioxide (Reference Table 909.04); IBR approved for §§ 137.180(c); 137.270(b).

§§ 137.2 through 137.100 [Reserved]

69. In § 137.105:

- a. Revise and republish the introductory text of paragraph (a); and
- b. Amend paragraphs (c)(1) through (3) by revising the first sentence and removing the second sentence in each paragraph.

The revisions read as follows:

§ 137.105 Flour.

(a) Flour, white flour, wheat flour, plain flour, is the food prepared by grinding and bolting cleaned wheat, other than durum wheat and red durum wheat. To compensate for any natural deficiency of enzymes, malted wheat, malted wheat flour, malted barley flour, or any combination of two or more of these, may be used; but the quantity of malted barley flour so used is not more than 0.75 percent. Harmless preparations of α -amylase obtained from *Aspergillus oryzae*, alone or in a safe and suitable carrier, may be used. When tested for granulation as prescribed in paragraph (c)(4) of this section, not less than 98 percent of the flour passes through a cloth having openings not larger than those of woven wire cloth designated “212 μ m (No. 70)” complying with the specifications for such cloth set forth in Table 1 “Nominal Dimensions of Standard Test Sieves (U.S.A. Standard Series)”, under the heading “Definitions of Terms and Explanatory Notes” from the *Official Methods of Analysis of the Association of Official Analytical Chemists*, 13th Ed. (incorporated by reference, see § 137.1). The flour is freed from bran coat, or bran coat and germ, to such extent that the percent of ash therein, calculated to a moisture-free basis, is not more than the sum of 1/20 of the percent of protein therein, calculated to a moisture-free basis, plus 0.35. Its moisture content is not more than 15 percent. It may contain ascorbic acid in a quantity not to exceed 200 parts per million as

a dough conditioner. Unless such addition conceals damage or inferiority or makes the flour appear to be better or of greater value than it is, one or any combination of two or more of the following optional bleaching ingredients may be added in a quantity not more than sufficient for bleaching or, in case such ingredient has an artificial aging effect, in a quantity not more than sufficient for bleaching and such artificial aging effect:

* * * * *

(c)* * *

(1) Ash is determined by the method prescribed in section 14.006, “Direct Method—Official Final Action”, under the heading “Ash (5)”, from the *Official Methods of Analysis of the Association of Official Analytical Chemists*, 13th Ed. (incorporated by reference, see § 137.1). *

* *

(2) Protein is 5.7 times the nitrogen as determined by the method prescribed in section 2.057, “Improved Kjeldahl Methods for Nitrate-Free Samples (20--Official Final Action”, from the *Official Methods of Analysis of the Association of Official Analytical Chemists*, 13th Ed. (incorporated by reference, see § 137.1). * * *

(3) Moisture is determined by the method prescribed in sections 14.002 and 14.003, “Vacuum Oven Method (2)--Official Final Action”, under the heading “Total Solids Moisture, Indirect Method”, from the *Official Methods of Analysis of the Association of Official Analytical Chemists*, 13th Ed. (incorporated by reference, see § 137.1).

* * * * *

70. In § 137.180, revise paragraphs (a), (c) introductory text, and (c)(1) to read as follows:

§ 137.180 Self-rising flour.

(a) *Description.* Self-rising flour, self-rising white flour, self-rising wheat flour, is an intimate mixture of flour, sodium bicarbonate, and one or more of the acid-reacting substances monocalcium phosphate, sodium acid pyrophosphate, and sodium aluminum phosphate. It is

seasoned with salt or salt substitute. When it is tested by the method prescribed in paragraph (c) of this section, not less than 0.5 percent of carbon dioxide is evolved. The acid-reacting substance is added in sufficient quantity to neutralize the sodium bicarbonate. The combined weight of such acid-reacting substance and sodium bicarbonate is not more than 4.5 parts to each 100 parts of flour used. Subject to the conditions and restrictions prescribed by § 137.105(a), the bleaching ingredients specified in such section may be added as optional ingredients. If the flour used in making the self-rising flour is bleached, the optional bleaching ingredient used therein (see § 137.105(a)) is also an optional ingredient of the self-rising flour.

* * * * *

(c) *Method of analysis.* Follow the method prescribed in AOAC Official Method 923.02A, and 923.02B (incorporated by reference, see § 137.1): Instead of using AOAC Official Method 923.02C use the following procedure:

(1) Weigh 17 grams of the official sample into flask A, add 15-20 glass beads (4-6 mm. diameter), and connect this flask with the apparatus (fig. 923.02). Open stopcock C and by means of the leveling bulb E bring the displacement solution to the 25 cc. graduation above the zero mark. (This 25 cc. is a partial allowance for the volume of acid to be used in the decomposition.) Allow the apparatus to stand 1-2 minutes to ensure that the temperature and pressure within the apparatus are the same as those of the room. Close the stopcock, lower the leveling bulb somewhat to reduce the pressure within the apparatus, and slowly run into the decomposition flask from burette F 45 cc. of sulfuric acid (1 + 5). To prevent the liberated carbon dioxide from escaping through the acid burette into the air, keep the displacement solution in the leveling bulb at all times during the decomposition at a lower level than that in the gas-measuring tube. Rotate and then vigorously agitate the decomposition flask for 3 minutes to mix the contents intimately. Allow to stand for 10 minutes to bring to equilibrium. Equalize the pressure in the measuring tube by means of the leveling bulb and read the volume of gas from the zero point on the tube. Deduct 20 cc. from this reading (this 20 cc. together with previous

allowance of 25 cc. compensates for the 45 cc. acid used in the decomposition). Observe the temperature of the air surrounding the apparatus and also the barometric pressure and multiply the number of milliliters of gas evolved by the factor given in Reference Table 909.04 (incorporated by reference, see § 137.1) for the temperature and pressure observed. Divide the corrected reading by 100 to obtain the apparent percent by weight of carbon dioxide in the official sample.

* * * * *

71. In § 137.190:

- a. Remove the last two sentences; and
- b. Revise the 3rd sentence.

The revision reads as follows:

§ 137.190 Cracked wheat.

* * *Cracked wheat contains not more than 15 percent of the moisture as determined by the method prescribed in section 7.002 under “Preparation of Sample--Official Final Action”, and section 7.003 under “Moisture--Official Final Action. I. Drying in Vacuo at 95-100° (2)”, from the *Official Methods of Analysis of the Association of Official Analytical Chemists*, 13th Ed. (incorporated by reference, see § 137.1).

72. In § 137.195:

- a. Remove the last two sentences; and
- b. Revise the 3rd sentence.

The revision reads as follows:

§ 137.195 Crushed wheat.

* * *Crushed wheat contains not more than 15 percent of moisture as determined by the method prescribed in section 7.002 under “Preparation of Sample--Official Final Action” and section 7.003 under “Moisture--Official Final Action. I. Drying in Vacuo at 95-100° (2)” from

the *Official Methods of Analysis of the Association of Official Analytical Chemists*, 13th Ed.

(incorporated by reference, see § 137.1).

73. In § 137.200, revise paragraph (c)(1) and the first sentence of paragraph (c)(2) and remove the second sentence of paragraph (c)(2) to read as follows:

§ 137.200 Whole wheat flour.

* * * * *

(c)* * *

(1) Moisture is determined by the method prescribed in section 14.002 “Vacuum Oven Method--Official Final Action” and section 14.003 “Determination” from the *Official Methods of Analysis of the Association of Official Analytical Chemists*, 13th Ed. (incorporated by reference, see § 137.1).

(2) The method referred to in paragraph (a) of this section is as follows: Use No. 8 and No. 20 sieves, having standard 8-inch full-height frames, complying with the specifications set forth in Table 1, “Nominal Dimensions of Standard Test Sieves (U.S.A. Standard Series)”, under the heading “Definitions of Terms and Explanatory Notes” from the *Official Methods of Analysis of the Association of Official Analytical Chemists*, 13th Ed. (incorporated by reference, see § 137.1). * * *

74. In § 137.211, amend paragraph (b)(2) by revising the first sentence and removing the second and third sentences to read as follows:

§ 137.211 White corn flour.

* * * * *

(b)* * *

(2) The method referred to in paragraph (a) of this section is as follows: Weigh 5 grams of sample into a tared truncated metal cone (top diameter 5 centimeters, bottom diameter 2 centimeters, height 4 centimeters), fitted at bottom with 70-mesh wire cloth complying with the specifications for No. 70 wire cloth in Table 1, “Nominal Dimensions of Standard Test Sieves

(U.S.A. Standard Series)”, under the heading “Definitions of Terms and Explanatory Notes” from the *Official Methods of Analysis of the Association of Official Analytical Chemists*, 13th Ed. (incorporated by reference, see § 137.1). * * *

75. In § 137.250:

- a. Revise the introductory text of paragraph (b)(1); and
- b. Amend paragraph (b)(2) by revising the first sentence and removing the second and third sentences.

The revisions read as follows:

§ 137.250 White corn meal.

* * * * *

(b)(1) For the purposes of this section, moisture, fat, and crude fiber content will be determined by the following methods referenced in this paragraph (b)(1) from the *Official Methods of Analysis of the Association of Official Analytical Chemists*, 13th Ed. (incorporated by reference, see § 137.1):

* * * * *

(2) The method referred to in paragraph (a) of this section is as follows: Use No. 12 and No. 25 sieves, having standard 20.3 centimeter (8-inch) diameter full-height frames, complying with the specifications for wire cloth and sieve frames in “Nominal Dimensions of Standard Test Sieves (U.S.A. Standard Series)” from the *Official Methods of Analysis of the Association of Official Analytical Chemists*, 13th Ed. (incorporated by reference, see § 137.1), prescribed in § 137.105(a). * * *

76. In § 137.270, revise paragraphs (a), (b) introductory text, and (b)(1) to read as follows:

§ 137.270 Self-rising white corn meal.

(a) *Description.* Self-rising white corn meal is an intimate mixture of white corn meal, sodium bicarbonate, and one or both of the acid-reacting substances monocalcium phosphate and

sodium aluminum phosphate. It is seasoned with salt or salt substitute. When it is tested by the method prescribed in paragraph (b) of this section, not less than 0.5 percent of carbon dioxide is evolved. The acid-reacting substance is added in sufficient quantity to neutralize the sodium bicarbonate. The combined weight of such acid-reacting substance and sodium bicarbonate is not more than 4.5 parts to each 100 parts of white corn meal used.

(b) *Method of analysis.* Follow the method prescribed in AOAC Official Method 923.02A and 923.02B (incorporated by reference, see § 137.1): Instead of using AOAC Official Method 923.02C use the following procedure:

(1) Weigh 17 grams of the official sample into flask A, add 15-20 glass beads (4-6 mm. diameter), and connect this flask with the apparatus (fig. 923.02). Open stopcock C and by means of the leveling bulb E bring the displacement solution to the 25 cc. graduation above the zero mark. (This 25 cc. is a partial allowance for the volume of acid to be used in the decomposition.) Allow the apparatus to stand 1-2 minutes to ensure that the temperature and pressure within the apparatus are the same as those of the room. Close the stopcock, lower the leveling bulb somewhat to reduce the pressure within the apparatus, and slowly run into the decomposition flask from burette F 45 cc. of sulfuric acid (1 + 5). To prevent the liberated carbon dioxide from escaping through the acid burette into the air, keep the displacement solution in the leveling bulb at all times during the decomposition at a lower level than that in the gas-measuring tube. Rotate and then vigorously agitate the decomposition flask for 3 minutes to mix the contents intimately. Allow to stand for 10 minutes to bring to equilibrium. Equalize the pressure in the measuring tube by means of the leveling bulb and read the volume of gas from the zero point on the tube. Deduct 20 cc. from this reading (this 20 cc. together with previous allowance of 25 cc. compensates for the 45 cc. acid used in the decomposition). Observe the temperature of the air surrounding the apparatus and also the barometric pressure and multiply the number of milliliters of gas evolved by the factor given in the Reference Table 909.04 (incorporated by reference, see § 137.1) for the temperature and pressure observed. Divide the

corrected reading by 100 to obtain the apparent percent by weight of carbon dioxide in the official sample.

* * * * *

77. In §137.300, amend paragraph (b)(2) by revising the first sentence and removing the second and third sentences to read as follows:

§ 137.300 Farina.

* * * * *

(b) * * *

(2) The method referred to in paragraph (a) of this section is as follows: Use No. 20 and No. 100 sieves, having standard 20.3 centimeter (8-inch) full-height frames, complying with the specifications for such cloth set forth in Table 1, “Nominal Dimensions of Standard Test Sieves (U.S.A. Standard Series)” under the heading “Definitions of Terms and Explanatory Notes” from the *Official Methods of Analysis of the Association of Official Analytical Chemists*, 13th Ed. (incorporated by reference, see § 137.1). * * *

78. In § 137.350, revise and republish paragraph (e) to read as follows:

§137.350 Enriched rice.

* * * * *

(e) The method referred to in paragraph (c) of this section is as follows: Mix the contents of one or more containers and transfer 1/2 pound thereof to a 4-liter flask containing 2 liters of distilled water at room temperature (but not below 20 °C). Stopper the flask and swirl it moderately for 1/2 minute so that the rice is in motion and in uniform suspension. Allow the rice to settle for 1/2 minute, then pour off 1,600 milliliters of the water, together with any floating and suspended matter, and discard. To the contents of the flask, add 1,600 milliliters of distilled water and 20 milliliters of 10 N hydrochloric acid. Agitate vigorously and wash down the sides of the flask with 150 milliliters of 0.1 N hydrochloric acid. To avoid excess foaming during the extraction, heat the mixture slowly to about 100 °C, agitate if necessary, and maintain at this

temperature until air is expelled. Again wash down the sides of the flask with 150 milliliters of 0.1 *N* hydrochloric acid. Heat the mixture in an autoclave at 120 °C to 123 °C for 30 minutes, remove and cool to room temperature. Dilute the mixture with distilled water so that the total volume is 2,500 milliliters. Swirl the flask, and while the solids are in uniform suspension pour off about 250 milliliters of the mixture for later determination of iron (and calcium, if this is to be determined). With filter paper that has been shown not to adsorb thiamine, riboflavin, or niacin, filter enough of the remaining mixture for determination of thiamine, riboflavin, and niacin. (In the case of a mixture difficult to filter, centrifuging or filtering through fritted glass, or both, using a suitable analytical filter-aid, may be substituted for, or may precede, filtering through paper.) Dilute an aliquot of filtrate with 0.1 *N* hydrochloric acid, so that each milliliter contains about 0.2 microgram of thiamine, and determine thiamine by the “Rapid Fluorometric Method--Official Final Action,” in section 43.034 of “Official Methods of Analysis of the Association of Official Analytical Chemists” (AOAC), 13th Ed. (incorporated by reference, see § 137.1). With a suitable aliquot determine riboflavin by the method prescribed in section 43.041(a) by the “Fluorometric Method--Official Final Action,” AOAC, 13th Ed., beginning with the third sentence of the second paragraph, “Adjust, with vigorous agitation * * *.” Determine niacin in a 200-milliliter aliquot of the filtrate by the “Colorimetric Method--Official Final Action,” in section 43.045, AOAC, 13th Ed., beginning with the sixth sentence of the first paragraph, “Adjust to pH 4.5 with * * *.” Evaporate to dryness a 100-milliliter aliquot of the nonfiltered material withdrawn while agitating, and determine iron using the method “Iron--Official Final Action,” in sections 14.011, 14.012, and 14.013, AOAC, 13th Ed., and, if required, determine calcium as directed in section 14.014 under the heading “Calcium--Official Final Action,” AOAC, 13th Ed.

* * * * *

PART 139--MACARONI AND NOODLE PRODUCTS

79. The authority citation for part 139 continues to read as follows:

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

80. Add subpart A, consisting of §§ 139.1 through 139.100, to read as follows:

Subpart A--General Provisions

Sec.

139.1 Incorporation by reference.

139.2 through 139.100 [Reserved]

Subpart A--General Provisions

§ 139.1 Incorporation by reference.

Certain material is incorporated by reference into this part with the approval of the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. All approved incorporation by reference (IBR) material is available for inspection at the Food and Drug Administration (FDA) and at the National Archives and Records Administration (NARA). Contact FDA's Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852; 240-402-7500; IBR_Material_Inquiries@fda.hhs.gov. For information on the availability of this material at NARA, visit www.archives.gov/federal-register/cfr/ibr-locations or email fr.inspection@nara.gov. The material may be obtained from AOAC INTERNATIONAL (AOAC), 2275 Research Blvd., Suite 300, Rockville, MD 20850-3250; 1-800-379-2622; www.aoac.org:

(a) *Official Methods of Analysis of the Association of Official Analytical Chemists*, 13th Ed., 1980; IBR approved for § 139.117(a).

(b) AOAC Official Method 926.07, Solids (Total) and Loss on Drying (Moisture) in Macaroni Products, *Official Methods of Analysis of AOAC INTERNATIONAL*, 22nd Ed., published 4 January 2023; IBR approved for §§ 139.110(a); 139.150(a). (Available at <https://academic.oup.com/aoac-publications/book/45491>.)

§§ 139.2 through 139.100 [Reserved]

81. In § 139.110, revise paragraphs (a)(4) and (5) to read as follows:

§ 139.110 Macaroni products.

(a) * * *

(4) Salt or salt substitute, in a quantity that seasons the food.

(5) Gum gluten, in such quantity that the protein content of the finished food is not more than 13 percent by weight. The finished macaroni product contains not less than 87 percent of total solids as determined by AOAC Official Method 926.07A (incorporated by reference, see § 139.1).

* * * * *

82. In § 139.117:

a. Lift the stay published at 43 FR 11695, Mar. 21, 1978;

b. Revise the introductory text of paragraph (a)(2); and

c. Stay the section indefinitely.

The revision reads as follows:

§ 139.117 Enriched macaroni products with fortified protein.

(a) * * *

(2) Each such finished food when tested by the methods described in the cited sections of *Official Methods of Analysis of the Association of Official Analytical Chemists*, 13th Ed. (incorporated by reference, see § 139.1):

* * * * *

83. In § 139.150, revise paragraphs (a)(2) and (4) to read as follows:

§ 139.150 Noodle products.

(a) * * *

(2) Salt or salt substitute, in a quantity that seasons the food.

* * * * *

(4) Concentrated glyceryl monostearate (containing not less than 90 percent monoester) in a quantity not exceeding 3 percent by weight of the finished food. The finished noodle product contains not less than 87 percent of total solids as determined by AOAC Official Method 926.07A (incorporated by reference, see § 139.1). The total solids of noodle products contains not less than 5.5 percent by weight of the solids of egg, or egg yolk.

* * * * *

PART 145--CANNED FRUITS

84. The authority citation for part 145 continues to read as follows:

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

85. In § 145.110:

- a. Revise the paragraph-level designation for the 4th paragraph level from lowercase italic letters (i.e., (a) *et seq.*) to uppercase non-italic letters (i.e., (A) *et seq.*);
- b. Revise paragraphs (a)(1) and (a)(2)(iii); and
- c. In paragraph (a)(4), remove the text “(a)(2)(viii)(b)” and add, in its place, the text “(a)(2)(viii)(B)”.

The revisions read as follows:

§ 145.110 Canned applesauce.

(a) * * *

(1) *Definition.* Canned applesauce is the food prepared from comminuted or chopped apples (*Malus domestica* Borkhausen), which may or may not be peeled and cored, and which may have added thereto one or more of the optional ingredients specified in paragraph (a)(2) of this section. The apple ingredient is heated and, in accordance with good manufacturing practices, bruised apple particles, peel, seed, core material, carpel tissue, and other coarse, hard, or extraneous materials are removed. The food is sealed in containers. It is so processed by heat, either before or after sealing, as to prevent spoilage. The soluble solids content, measured by refractometer and expressed as percent sucrose (degrees Brix) with correction for temperature

to the equivalent at 20 °C (68 °F), is not less than 9 percent (exclusive of the solids of any added optional nutritive carbohydrate sweeteners) as determined by AOAC Official Method 932.12 but without correction for invert sugar or other substances. AOAC Official Method 932.12, Solids (Soluble) in Fruits and Fruit Products: Refractometer Method, *Official Methods of Analysis of AOAC INTERNATIONAL*, 22nd Ed., published 4 January 2023 (available at <https://academic.oup.com/aoac-publications/book/45491>) is 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. All approved incorporation by reference (IBR) material is available for inspection at the Food and Drug Administration (FDA) and the National Archives and Records Administration (NARA). Contact the FDA at FDA's Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852; 240-402-7500; IBR_Material_Inquiries@fda.hhs.gov. For information on the availability of this material at NARA, visit www.archives.gov/federal-register/cfr/ibr-locations or email fr.inspection@nara.gov. This material is available from AOAC INTERNATIONAL, 2275 Research Blvd., Suite 300, Rockville, MD 20850-3250; 1-800-379-2622; www.aoac.org.

(2) * * *

(iii) Salt or salt substitute.

* * * * *

86. In § 145.130, revise and republish paragraphs (a) and (c)(1) to read as follows:

§ 145.130 Canned figs.

(a) *Ingredients.* Canned figs is the food prepared from one of the optional fig ingredients specified in paragraph (b) of this section and one of the optional packing media specified in paragraph (c) of this section, to which lemon juice, concentrated lemon juice or organic acid(s) is added, when necessary to reduce the pH of the finished product to pH 4.9 or below. Such food is sealed in a container and before or after sealing is so processed by heat as to prevent spoilage.

Such food may also contain one, or any combination of two or more of the following safe and suitable optional ingredients:

- (1) Natural and artificial flavoring.
- (2) Spice.
- (3) Vinegar.
- (4) Unpeeled segments of citrus fruits.
- (5) Salt or salt substitute.

* * * * *

(c) * * *

(1)(i) The optional packing media referred to in paragraph (a) of this section, as defined in § 145.3 are:

- (A) Water.
- (B) Fruit juice(s) and water.
- (C) Fruit juice(s).

(ii) Such packing media may be used as such or any one or any combination of two or more safe and suitable nutritive carbohydrate sweetener(s) may be added. Sweeteners defined in § 145.3 shall be as defined therein, except that a nutritive carbohydrate sweetener for which a standard of identity has been established in part 168 of this chapter shall comply with such standard in lieu of any definition that may appear in § 145.3.

* * * * *

PART 150--FRUIT BUTTERS, JELLIES, PRESERVES, AND RELATED PRODUCTS

87. The authority citation for part 150 continues to read as follows:

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

88. Add subpart A, consisting of §§ 150.1 through 150.100, to read as follows:

Subpart A--General Provisions

Sec.

150.1 Incorporation by reference.

150.2 through 150.100 [Reserved]

Subpart A--General Provisions

§ 150.1 Incorporation by reference.

Certain material is incorporated by reference into this part with the approval of the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. All approved incorporation by reference (IBR) material is available for inspection at the Food and Drug Administration (FDA) and at the National Archives and Records Administration (NARA). Contact FDA's Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852; 240-402-7500; IBR_Material_Inquiries@fda.hhs.gov. For information on the availability of this material at NARA, visit www.archives.gov/federal-register/cfr/ibr-locations or email fr.inspection@nara.gov. The material may be obtained from AOAC INTERNATIONAL (AOAC), 2275 Research Blvd., Suite 300, Rockville, MD 20850-3250; 1-800-379-2622; www.aoac.org:

(a) *Official Methods of Analysis of the Association of Official Analytical Chemists*, 13th Ed., 1980; IBR approved for §§ 150.140(d); 150.160.

(b) *Official Methods of Analysis of AOAC INTERNATIONAL*, 22nd Ed., published 4 January 2023 (available at <https://academic.oup.com/aoac-publications/book/45491>)--

(1) AOAC Official Method 932.12, Solids (Soluble) in Fruits and Fruit Products: Refractometer Method; IBR approved for § 150.110(d).

(2) AOAC Official Method 932.14, Solids in Syrups; IBR approved for § 150.110(d).

§§ 150.2 through 150.100 [Reserved]

89. In § 150.110, revise paragraphs (c)(4) and (d)(3) and (5) to read as follows:

§ 150.110 Fruit butter.

* * * * *

(c) * * *

(4) Salt or salt substitute.

* * * * *

(d) * * *

(3) The soluble solids content of the finished fruit butter is not less than 43 percent, as determined by AOAC Official Method 932.12 (incorporated by reference, see § 150.1).

* * * * *

(5) The weight of fruit juice or diluted fruit juice or concentrated fruit juice (optional ingredient, paragraph (c)(6) of this section) from a fruit specified in paragraph (b)(1) of this section is the weight of such juice, as determined by the method prescribed in paragraph (d)(2) of this section, except that the percent of soluble solids is determined by AOAC Official Method 932.14C (incorporated by reference, see § 150.1); the weight of diluted concentrated juice from any other fruits is the original weight of the juice before it was diluted or concentrated.

* * * * *

90. In § 150.140, revise paragraph (d)(3) to read as follows:

§ 150.140 Fruit jelly.

* * * * *

(d) * * *

(3) The soluble-solids content of the finished jelly is not less than 65 percent, as determined by the method prescribed in section 31.011, under “Solids by Means of Refractometer--Official Final Action” from the *Official Methods of Analysis of the Association of Official Analytical Chemists*, 13th Ed. (incorporated by reference, see § 150.1).

* * * * *

91. In § 150.160, revise paragraph (d)(5) to read as follows:

§ 150.160 Fruit preserves and jams.

* * * * *

(d) * * *

(5) The soluble-solids content of the finished jam or preserve is not less than 65 percent, as determined by the method prescribed in section 22.024, under “Soluble Solids by Refractometer in Fresh and Canned Fruits, Jellies, Marmalades, and Preserves--Official Final Action”, except that no correction is made for water-insoluble solids, from the *Official Methods of Analysis of the Association of Official Analytical Chemists*, 13th Ed. (incorporated by reference, see § 150.1).

* * * * *

PART 155--CANNED VEGETABLES

92. The authority citation for part 155 continues to read as follows:

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

93. Add § 155.1 to subpart A to read as follows:

§ 155.1 Incorporation by reference.

Certain material is incorporated by reference into this part with the approval of the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. All approved incorporation by reference (IBR) material is available for inspection at the Food and Drug Administration (FDA) and at the National Archives and Records Administration (NARA). Contact FDA’s Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852; 240-402-7500; IBR_Material_Inquiries@fda.hhs.gov. For information on the availability of this material at NARA, visit www.archives.gov/federal-register/cfr/ibr-locations or email fr.inspection@nara.gov. The material may be obtained from AOAC INTERNATIONAL (AOAC), 2275 Research Blvd., Suite 300, Rockville, MD 20850-3250; 1-800-379-2622 www.aoac.org:

(a) *Official Methods of Analysis of the Association of Official Analytical Chemists*, 13th Ed., 1980; IBR approved for § 155.3(a), (e), and (f).

(b) *Official Methods of Analysis of AOAC INTERNATIONAL*, 22nd Ed., published 4 January 2023 (available at <https://academic.oup.com/aoac-publications/book/45491>)--

(1) [AOAC] Definition of Terms and Explanatory Notes; IBR approved for §§ 155.120(b); 155.130(b).

(2) AOAC Official Method 938.10, Solids (Alcohol-Insoluble) in Canned Peas: Gravimetric Method; IBR § 155.170(b).

94. In § 155.3, revise paragraphs (a), (e), and (f) to read as follows:

§ 155.3 Definitions.

* * * * *

(a) The procedure for determining *drained weight* is set forth in sections 32.001-32.003 from the *Official Methods of Analysis of the Association of Official Analytical Chemists*, 13th Ed. (incorporated by reference, see § 155.1).

* * * * *

(e) *Tomato soluble solids* means the sucrose value as determined by the method prescribed in sections 32.014 to 32.016 and 52.012, under the headings “Soluble Solids in Tomato Products Official Final Action” and “Refractive Indices (n) of Sucrose Solutions at 20°” from the *Official Methods of Analysis of the Association of Official Analytical Chemists*, 13th Ed. (incorporated by reference, see § 155.1). If no salt has been added, the sucrose value obtained from the referenced tables shall be considered the percent of tomato soluble solids. If salt has been added either intentionally or through the application of the acidified break, determine the percent of such added sodium chloride as specified in paragraph (f) of this section. Subtract the percentage so found from the percentage of total soluble solids found (sucrose value from the refractive index tables) and multiply the difference by 1.016. The resultant value is considered the percent of “tomato soluble solids.”

(f) *Salt* means sodium chloride, determined as chloride and calculated as percent sodium chloride, by the method prescribed in sections 32.025 to 32.030, under the heading “Method III (Potentiometric Method)” from the *Official Methods of Analysis of the Association of Official Analytical Chemists*, 13th Ed. (incorporated by reference, see § 155.1).

95. In § 155.120:

- a. Revise the paragraph-level designation for the 4th paragraph level from lowercase italic letters (i.e., (a) *et seq.*) to uppercase non-italic letters (i.e., (A) *et seq.*);
- b. In paragraph (a)(2)(iii)(E), remove the text “(a)(2)(iii)(c)” and add, in its place, the text “(a)(2)(iii)(C)”;
- c. In paragraph (a)(2)(iii)(F), remove the text “(a)(2)(iii)(d)” and add, in its place, the text “(a)(2)(iii)(D)”;
- d. In paragraph (a)(2)(iii)(G), remove the text “paragraph (a)(2)(iii)(a) to (f)” and add, in its place, the text “paragraphs (a)(2)(iii)(A) through (F)”;
- e. Revise paragraph (a)(3)(i);
- f. In paragraph (b)(1)(i), remove the text “(a)(2)(iii) (c) and (d)” and “(a)(2)(iii)(g)” and add, in their places, the text “(a)(2)(iii)(C) and (D)” and “(a)(2)(iii)(G)”, respectively;
- g. Revise paragraph (b)(2)(i);
- h. In paragraph (b)(2)(iii) introductory text, remove the text “(a)(2)(iii) (c), (d) or (f)” and add, in its place, the text “(a)(2)(iii)(C), (D), or (F)”;
- i. In paragraph (b)(2)(vi), remove the text “(a)(2)(iii)(b)” and add, in its place, the text “(a)(2)(iii)(B)”.

The revisions read as follows:

§ 155.120 Canned green beans and canned wax beans.

(a) * * *

(3) * * *

(i) Salt or salt substitute.

* * * * *

(b) * * *

(2) * * *

(i) Determine the gross weight of the container. Open and distribute the contents of the container over the meshes of a U.S. No. 8 circular sieve with openings of 2.36 mm (0.0937 in), which has been previously weighed. The diameter of the sieve is 20.3 cm (8 in) if the quantity of contents of the container is less than 1.36 kg (3 lb) and 30.5 cm (12 in) if such quantity is 1.36 kg (3 lb) or more. The bottom of the sieve is woven-wire cloth that complies with the specifications of such cloth set forth in Table 1 of AOAC Definition of Terms and Explanatory Notes, titled Nominal Dimensions of Standard Test Sieves (USA Standard Series) (incorporated by reference, see § 155.1). Without shifting the material on the sieve, incline the sieve 17° to 20° to facilitate drainage. Two minutes after drainage begins, weigh the sieve and the drained material. Record in grams (ounces) the weight so found, less the weight of the sieve, as the drained weight. Dry and weigh the empty container and subtract this weight from the gross weight to obtain the net weight. Calculate the percent of drained liquid in the net weight.

* * * * *

96. In § 155.130:

- a. Revise the paragraph-level designation for the 4th paragraph level from lowercase italic letters (i.e., (a) *et seq.*) to uppercase non-italic letters (i.e., (A) *et seq.*); and
- b. Revise paragraphs (a)(3)(i), (b)(2)(i), and (b)(5).

The revisions read as follows:

§ 155.130 Canned corn.

(a) * * *

(3) * * *

(i) Salt or salt substitute.

* * * * *

(b) * * *

(2) * * *

(i) Determine the gross weight of the container. Open and distribute the contents of the container over the meshes of a U.S. No. 8 circular sieve, which has previously been weighed. The diameter of the sieve is 20.3 cm. (8 in) if the quantity of the contents of the container is less than 1.36 kg. (3 lb), and 30.5 cm. (12 in) if such quantity is 1.36 kg. (3 lb) or more. The bottom of the sieve is woven-wire cloth that complies with the specifications for such sieve set forth in Table 1 of AOAC Definition of Terms and Explanatory Notes, titled Nominal Dimensions of Standard Test Sieves (USA Standard Series) (incorporated by reference, see § 155.1). Without shifting the material on the sieve, so incline the sieve at approximately 17° to 20° angle to facilitate drainage. Two minutes from the time drainage begins, weigh the sieve and the drained material. Record, in grams (ounces), the weight so found, less the weight of the sieve, as the drained weight. Dry and weigh the empty container and subtract this weight from the gross weight to obtain the net weight. Calculate the percent of drained liquid in the net weight.

* * * * *

(5) If the quality of canned corn falls below the standard prescribed in paragraph (b)(1) of this section, the label shall bear the general statement of substandard quality specified in § 130.14(a) of this chapter, in the manner and form therein specified; however, if the quality of the canned corn falls below standard with respect to only one of the factors of quality specified by paragraphs (b)(1)(i)(A) through (D) of this section, or by paragraphs (b)(1)(ii)(A) through (E) of this section, there may be substituted for the second line of such general statement of substandard quality, “Good food--not high grade”, a new line as specified after the corresponding subdivision designation of paragraph (b)(1) of this section, as follows:

Table 1 to Paragraph (b)(5)

If the canned corn fails to meet-	Then include-
(i)(A) or (ii)(A)	“Excessive discolored kernels”.
(i)(B) or (ii)(B)	“Excessive cob”.

(i)(C) or (ii)(C)	“Excessive husk”.
(i)(D) or (ii)(D)	“Excessive silk”.
(ii)(E)	“Excessively liquid”.

* * * * *

97. In § 155.170:

- a. Lift the stay on paragraph (a)(2) published at 46 FR 35086, July 1, 1981;
- b. Revise the paragraph-level designation for the 4th paragraph level from lowercase italic letters (i.e., (a) *et seq.*) to uppercase non-italic letters (i.e., (A) *et seq.*); and
- c. Revise paragraphs (a)(2)(i) and (b)(1)(iii) and (vi).

The revisions read as follows:

§ 155.170 Canned peas.

(a) * * *

(2) * * *

(i) Salt or salt substitute.

* * * * *

(b) * * *

(1) * * *

(iii) *Seriously blemished peas.* Not more than 1 percent of the drained weight is seriously blemished peas, i.e., peas that are hard, shriveled, spotted, discolored, or otherwise blemished to an extent that the appearance or eating quality is seriously affected.

* * * * *

(vi) *Alcohol-insoluble solids.* The alcohol-insoluble solids of smooth-skin or substantially smooth-skin peas, such as Alaska-type peas or hybrids having similar characteristics, may not be more than 23.5 percent and, of sweet green wrinkled varieties or

hybrids having similar characteristics, not more than 21 percent based on the procedure set forth in AOAC Official Method 938.10 (incorporated by reference, see § 155.1).

* * * * *

98. In § 155.190:

- a. Revise the paragraph-level designation for the 4th paragraph level from lowercase italic letters (i.e., (a) *et seq.*) to uppercase non-italic letters (i.e., (A) *et seq.*); and
- b. Revise paragraph (a)(2)(iv).

The revision reads as follows:

§ 155.190 Canned tomatoes.

(a) * * *

(2) * * *

(iv) Salt or salt substitute.

* * * * *

99. In § 155.191:

- a. Revise the paragraph-level designation for the 4th paragraph level from lowercase italic letters (i.e., (a) *et seq.*) to uppercase non-italic letters (i.e., (A) *et seq.*);
- b. Amend paragraph (a)(1)(iii) by removing the paragraph break between “tomatoes.” and “Such liquid”; and
- c. Revise paragraph (a)(2)(i).

The revision reads as follows:

§ 155.191 Tomato concentrates.

(a) * * *

(2) * * *

(i) Salt or salt substitute (sodium chloride formed during acid neutralization shall be considered added salt).

* * * * *

100. In § 155.194:

a. Revise the paragraph-level designation for the 4th paragraph level from lowercase italic letters (i.e., (a) *et seq.*) to uppercase non-italic letters (i.e., (A) *et seq.*)

b. Revise paragraph (a)(1)(iv); and

c. Amend paragraph (a)(3)(iii) by removing the text “§ 155.191(a)(3)(ii)(a) and (a)(3)(ii)(b)” and adding, in its place, the text “§ 155.191(a)(3)(ii)(A) and (B)”.

The revision reads as follows:

§ 155.194 Catsup.

(a) * * *

(1) * * *

(iv) The liquid obtained from the residue from partial extraction of juice from such tomatoes. Such liquid is strained so as to exclude skins, seeds, and other coarse or hard substances in accordance with current good manufacturing practice. Prior to straining, food-grade hydrochloric acid may be added to the tomato material in an amount to obtain a pH no lower than 2.0. Such acid is then neutralized with food-grade sodium hydroxide so that the treated tomato material is restored to a pH of 4.2 ± 0.2 . The final composition of the food may be adjusted by concentration and/or by the addition of water. The food may contain salt or salt substitute (sodium chloride formed during acid neutralization shall be considered added salt) and is seasoned with ingredients as specified in paragraph (a)(2) of this section. The food is preserved by heat sterilization (canning), refrigeration, or freezing. When sealed in a container to be held at ambient temperatures, it is so processed by heat, before or after sealing, as to prevent spoilage.

* * * * *

101. In § 155.200, revise paragraph (c)(4)(i) to read as follows:

§ 155.200 Certain other canned vegetables.

* * * * *

(c) * * *

(4) * * *

(i) Salt or salt substitute.

* * * * *

102. In § 155.201, revise paragraph (a)(3)(i) to read as follows:

§ 155.201 Canned mushrooms.

(a) * * *

(3) * * *

(i) Salt or salt substitute.

* * * * *

PART 156--VEGETABLE JUICES

103. The authority citation for part 156 continues to read as follows:

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

104. In § 156.145:

a. Revise the paragraph-level designation for the 4th paragraph level from lowercase italic letters (i.e., (a) *et seq.*) to uppercase non-italic letters (i.e., (A) *et seq.*); and

b. Revise paragraph (a)(1).

The revision reads as follows:

§ 156.145 Tomato juice.

(a) * * *

(1) *Definition.* Tomato juice is the food intended for direct consumption, obtained from the unfermented liquid extracted from mature tomatoes of the red or reddish varieties of *Lycopersicum esculentum* P. Mill, with or without scalding followed by draining. In the extraction of such liquid, heat may be applied by any method which does not add water thereto. Such juice is strained free from peel, seeds, and other coarse or hard substances, but contains finely divided insoluble solids from the flesh of the tomato in accordance with current good

manufacturing practice. Such juice may be homogenized, may be seasoned with salt or salt substitute, and may be acidified with any safe and suitable organic acid. The juice may have been concentrated and later reconstituted with water and/or tomato juice to a tomato soluble solids content of not less than 5.0 percent by weight as determined by the method prescribed in § 156.3(b). The food is preserved by heat sterilization (canning), refrigeration, or freezing. When sealed in a container to be held at ambient temperatures, it is so processed by heat, before or after sealing, as to prevent spoilage.

* * * * *

PART 158--FROZEN VEGETABLES

105. The authority citation for part 158 continues to read as follows:

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

106. In § 158.170:

- a. Revise the paragraph-level designation for the 4th paragraph level from lowercase italic letters (i.e., *(a) et seq.*) to uppercase non-italic letters (i.e., *(A) et seq.*);
- b. Revise paragraphs (a)(1)(iv) and (b)(1)(iii);
- c. Amend paragraph (b)(2) by removing the text “(b)(1)(vii)(a)” and adding, in its place, the text “(b)(1)(vii)(A)”; and
- d. Amend paragraphs (b)(3)(ii) and (v) by removing the text “(b)(3)(i) (a) or (b)” and adding, in its place, the text “(b)(3)(i)(A) or (B)”.

The revisions read as follows:

§ 158.170 Frozen peas.

(a) * * *

(1) * * *

(iv) Salt or salt substitute.

* * * * *

(b) * * *

(1) * * *

(iii) Not more than 2 percent by weight seriously blemished peas, i.e., peas that are hard, shriveled, spotted, discolored or otherwise blemished to an extent that the appearance or eating quality is seriously affected.

* * * * *

PART 161--FISH AND SHELLFISH

107. The authority citation for part 161 continues to read as follows:

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

108. Add § 161.1 to subpart A to read as follows:

§ 161.1 Incorporation by reference.

Certain material is incorporated by reference into this part with the approval of the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. All approved incorporation by reference (IBR) material is available for inspection at the Food and Drug Administration (FDA) and at the National Archives and Records Administration (NARA). Contact FDA's Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852; 240-402-7500; IBR_Material_Inquiries@fda.hhs.gov. For information on the availability of this material at NARA, visit www.archives.gov/federal-register/cfr/ibr-locations or email fr.inspection@nara.gov. The material may be obtained from the following sources:

(a) AOAC INTERNATIONAL (AOAC), 2275 Research Blvd., Suite 300, Rockville, MD 20850-3250; 1-800-379-2622; www.aoac.org:

(1) *Official Methods of Analysis of the Association of Official Analytical Chemists*, 13th Ed., 1980; IBR approved for § 161.175(g).

(2) *Official Methods of Analysis of AOAC INTERNATIONAL*, 22nd Ed., published 4 January 2023 (available at <https://academic.oup.com/aoac-publications/book/45491>)--

(i) [AOAC] Definition of Terms and Explanatory Notes; IBR approved for §§ 161.145(c); 161.173(c); 161.190(a).

(ii) [Reserved]

(b) Optica Publishing Group, 2010 Massachusetts Ave., NW, Washington, DC 20036-1012; 1-202-223-8130; custserv@optica.org; <https://opg.optica.org>:

(1) Sidney M. Newhall, Dorothy Nickerson, and Deane B. Judd, *Final Report of the O.S.A. Subcommittee on the Spacing of the Munsell Colors**, J. Opt. Soc. Am. 33, 385-418 (1943), IBR approved for § 161.190(a). (Available at <https://opg.optica.org/josa/fulltext.cfm?uri=josa-33-7-385>.)

(2) [Reserved]

109. In § 161.145, revise paragraphs (a)(1) and (c)(3) to read as follows:

§ 161.145 Canned oysters.

(a) * * *

(1) Canned oysters is the food prepared from one or any mixture of two or all of the forms of oysters specified in paragraph (a)(2) of this section, and a packing medium of water, or the watery liquid draining from oysters before or during processing, or a mixture of such liquid and water. The food may be seasoned with salt or salt substitute. It is sealed in containers and so processed by heat as to prevent spoilage.

* * * * *

(c) * * *

(3) Drained weight is determined by the following method: Keep the unopened canned oyster container at a temperature of not less than 68 °F or more than 95 °F for at least 12 hours immediately preceding the determination. After opening, tilt the container so as to distribute its contents evenly over the meshes of a circular sieve that has been previously weighed. The diameter of the sieve is 8 inches if the quantity of the contents of the container is less than 3 pounds and 12 inches if such quantity is 3 pounds or more. The bottom of the sieve is woven-wire cloth that complies with the specifications for such cloth set forth under “2.36 mm (No. 8)” in Table 1 of AOAC Definition of Terms and Explanatory Notes, titled Nominal Dimensions of

Standard Test Sieves (USA Standard Series) (incorporated by reference, see § 161.1). Without shifting the material on the sieve, so incline the sieve as to facilitate drainage. Two minutes from the time drainage begins, weigh the sieve and the drained oysters. The weight so found, less the weight of the sieve, shall be considered to be the drained weight of the oysters.

* * * * *

110. In § 161.170:

- a. Revise the paragraph-level designation for the 4th paragraph level from lowercase italic letters (i.e., (a) *et seq.*) to uppercase non-italic letters (i.e., (A) *et seq.*) ; and
- b. Revise paragraph (a)(4)(i).

The revision reads as follows:

§ 161.170 Canned Pacific salmon.

(a) * * *

(4) * * *

(i) Salt or salt substitute.

* * * * *

111. In § 161.173:

- a. Lift the stay on paragraphs (a) and (c) published at 44 FR 50328, Aug. 28, 1979;
- b. Revise the paragraph-level designation for the 4th paragraph level from lowercase italic letters (i.e., (a) *et seq.*) to uppercase non-italic letters (i.e., (A) *et seq.*);
- c. Revise paragraphs (a)(4)(i) and (c)(1); and
- d. Stay paragraphs (a) and (c) indefinitely.

The revisions read as follows:

§ 161.173 Canned wet pack shrimp in transparent or nontransparent containers.

(a) * * *

(4) * * *

(i) Salt or salt substitute.

* * * * *

(c) * * *

(1) The standard of fill of transparent or nontransparent containers for canned wet pack shrimp is a fill such that the cut-out weight of shrimp taken from each container is not less than 60 percent of the weight of the water required to fill the container. The weight of the water required to fill the container is determined by the general method provided in § 130.12(a) of this chapter. Cut-out weight is determined by the following method: Keep the unopened canned shrimp container at a temperature of not less than 68 °F nor more than 75 °F for at least 12 hours immediately preceding the determination. After opening, distribute the shrimp evenly over the meshes of a circular sieve that has been previously weighed. The diameter of the sieve is 20.3 centimeters (8 inches) if the quantity of the contents of the container is less than 1.36 kilograms (3 pounds), and 30.5 centimeters (12 inches) if such quantity is 1.36 kilograms (3 pounds) or more. The bottom of the sieve is woven-wire cloth that complies with the specifications for such cloth set forth as a 2.36 mm (No. 8) sieve in Table 1 of AOAC Definition of Terms and Explanatory Notes, titled Nominal Dimensions of Standard Test Sieves (USA Standard Series) (incorporated by reference, see § 161.1) Without shifting the material on the sieve, incline the sieve at an angle of approximately 17° to 20° to facilitate drainage. Allow the shrimp to drain for 2 minutes, measured from the moment the product is poured onto the sieve. Weigh the sieve and the drained shrimp. The weight so found, less the weight of the sieve, shall be considered to be the cut-out weight of the shrimp.

* * * * *

112. In § 161.175, revise paragraph (g)(1)(v) to read as follows:

§ 161.175 Frozen raw breaded shrimp.

* * * * *

(g) * * *

(1) * * *

(v) U.S. Standard Sieve No. 20, 30.5 centimeter (12 inch) diameter. The sieves shall comply with the specifications for such cloth set forth in Table 1, “Nominal Dimensions of Standard Test Sieves (U.S.A. Standard Series)”, under the heading “Definitions of Terms and Explanatory Notes” from the *Official Methods of Analysis of the Association of Official Analytical Chemists*, 13th Ed. (incorporated by reference, see § 161.1).

* * * * *

113. In § 161.190:

- a. Revise paragraphs (a)(6)(i), (a)(7) introductory text, and (a)(7)(iii); and
- b. Redesignate paragraph (c)(1) as paragraph (c)(1)(i); and
- c. Designate the undesignated paragraph following the table in newly redesignated paragraph (c)(1)(i) as paragraph (c)(1)(ii).

The revisions read as follows:

§ 161.190 Canned tuna.

(a) * * *

(6) * * *

(i) Salt or salt substitute.

* * * * *

(7) For determination of the color designations specified in paragraph (a)(4) of this section, the following method shall be used: Recombine the separations of pressed cake resulting from the method prescribed in paragraph (c)(2) of this section. Pass the combined portions through a sieve fitted with woven-wire cloth of 1/4-inch mesh complying with the specifications for such cloth set forth in Table 1 of AOAC Definition of Terms and Explanatory Notes, titled Nominal Dimensions of Standard Test Sieves (USA Standard Series) (incorporated by reference, see § 161.1). Mix the sieved material and place a sufficient quantity into a 307 × 113 size container (bearing a top seam and having a false bottom approximately 1/2-inch deep and painted flat black inside and outside) so that after tamping and smoothing the surface of the

sample the material will be 1/8-inch to 1/4-inch below the top of the container. Within 10 minutes after sieving through the 1/4-inch mesh woven-wire cloth, determine the Munsell value of sample surface.

* * * * *

(iii) The standards with which comparisons are made are essentially neutral matte-finish standards, equivalent in luminous reflectance of light of 555μ wavelength to 33.7 percent of the luminous reflectance of magnesium oxide (for Munsell value 6.3) and 22.6 percent of the luminous reflectance of magnesium oxide (for Munsell value 5.3), as given by the relationship between Munsell value and luminous reflectance, derived in *Final Report of the O.S.A. Subcommittee on the Spacing of the Munsell Colors**, page 406 (incorporated by reference, see § 161.1).

* * * * *

PART 163--CACAO PRODUCTS

114. The authority citation for part 163 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 341, 343, 348, 371, 379e.

115. In § 163.111, revise paragraph (b)(6) to read as follows:

§ 163.111 Chocolate liquor.

* * * * *

(b) * * *

(6) Salt or salt substitute.

* * * * *

116. In § 163.112, revise paragraph (b)(4) to read as follows:

§ 163.112 Breakfast cocoa.

* * * * *

(b) * * *

(4) Salt or salt substitute.

* * * * *

117. In § 163.123, revise paragraph (b)(3) to read as follows:

§ 163.123 Sweet chocolate.

* * * * *

(b) * * *

(3) Spices, natural and artificial flavorings, ground whole nut meats, ground coffee, dried malted cereal extract, salt or salt substitute, and other seasonings that do not either singly or in combination impart a flavor that imitates the flavor of chocolate, milk, or butter;

* * * * *

118. In § 163.124, revise paragraph (b)(4) to read as follows:

§ 163.124 White chocolate.

* * * * *

(b) * * *

(4) Spices, natural and artificial flavorings, ground whole nut meats, ground coffee, dried malted cereal extract, salt or salt substitute, and other seasonings that do not either singly or in combination impart a flavor that imitates the flavor of chocolate, milk, or butter;

* * * * *

119. In § 163.130, revise paragraph (b)(3) to read as follows:

§ 163.130 Milk chocolate.

* * * * *

(b) * * *

(3) Spices, natural and artificial flavorings, ground whole nut meats, ground coffee, dried malted cereal extract, salt or salt substitute, and other seasonings that do not either singly or in combination impart a flavor that imitates the flavor of chocolate, milk, or butter;

* * * * *

PART 166--MARGARINE

120. The authority citation for part 166 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 343, 347, 348, 371, 379e.

121. In § 166.110, revise the introductory text of paragraph (a) and paragraph (b)(2) to read as follows:

§ 166.110 Margarine.

(a) *Description.* Margarine (or oleomargarine) is the food in plastic form or liquid emulsion, containing not less than 80 percent fat determined by the method prescribed in AOAC Official Method 938.06A. AOAC Official Method 938.06, Fat in Butter, *Official Methods of Analysis of AOAC INTERNATIONAL*, 22nd Ed., published 4 January 2023 (available at <https://academic.oup.com/aoac-publications/book/45491>), is 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. All approved incorporation by reference (IBR) material is available for inspection at the Food and Drug Administration (FDA) and the National Archives and Records Administration (NARA). Contact the FDA at FDA's Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852; 240-402-7500; IBR_Material_Inquiries@fda.hhs.gov. For information on the availability of this material at NARA, visit www.archives.gov/federal-register/cfr/ibr-locations or email fr.inspection@nara.gov. This material is available from AOAC INTERNATIONAL, 2275 Research Blvd., Suite 300, Rockville, MD 20850-3250; 1-800-379-2622; www.aoac.org. Margarine contains only safe and suitable ingredients, as defined in § 130.3(d) of this chapter. It is produced from one or more of the optional ingredients in paragraph (a)(1) of this section, and one or more of the optional ingredients in paragraph (a)(2) of this section, to which may be added one or more of the optional ingredients in paragraph (b) of this section. Margarine contains vitamin A as provided for in paragraph (a)(3) of this section.

* * * * *

(b) * * *

(2) Salt (sodium chloride) or salt substitute; potassium chloride for dietary margarine or oleomargarine.

* * * * *

PART 168--SWEETENERS AND TABLE SIRUPS

122. The authority citation for part 168 continues to read as follows:

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

123. In § 168.130, revise paragraph (b)(1) to read as follows:

§ 168.130 Cane sirup.

* * * * *

(b) * * *

(1) Salt or salt substitute.

* * * * *

124. In § 168.140, revise the first sentence of paragraph (a) and paragraph (b)(1) to read as follows:

§ 168.140 Maple sirup.

(a) Maple sirup is the liquid food derived by concentration and heat treatment of the sap of the maple tree (*Acer*) or by solution in water of maple sugar (maple concrete) made from such sap. * * *

(b) * * *

(1) Salt or salt substitute.

* * * * *

125. In § 168.160, revise paragraph (b)(1) to read as follows:

§ 168.160 Sorghum sirup.

* * * * *

(b) * * *

(1) Salt or salt substitute.

* * * * *

126. In § 168.180, revise paragraph (b)(7) to read as follows:

§ 168.180 Table sirup.

* * * * *

(b) * * *

(7) Salt or salt substitute.

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PART 169--FOOD DRESSINGS AND FLAVORINGS

127. The authority citation for part 169 continues to read as follows:

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

128. In § 169.140, revise paragraph (d)(1) to read as follows:

§ 169.140 Mayonnaise.

* * * * *

(d) * * *

(1) Salt or salt substitute.

* * * * *

129. In § 169.150, revise paragraph (e)(1) to read as follows:

§ 169.150 Salad dressing.

* * * * *

(e) * * *

(1) Salt or salt substitute.

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Robert F. Kennedy, Jr.,

Secretary,

Department of Health and Human Services