§ 73.30 Georgia [Amended]

■ 2. Section 73.30 is amended as follows:

* * * * *

R–3004A Fort Gordon, GA [Amended]

Boundaries. Beginning at lat. 33°25′03″N, long. 82°12′15″W;
to lat. 33°23′48″N, long. 82°08′56″W;
to lat. 33°22′20″N, long. 82°08′33″W;
to lat. 33°21′33″N, long. 82°09′10″W;
to lat. 33°20′15″N, long. 82°10′57″W.,
to lat. 33°17′41″N, long. 82°16′11″W;
to lat. 33°18′23″N, long. 82°16′17″W;
to lat. 33°18′22″N, long. 82°16′39″W;
to lat. 33°17′29″N, long. 82°16′52″W;
to lat. 33°16′57″N, long. 82°17′39″W;
to lat. 33°16′56″N, long. 82°18′50″W;
to lat. 33°17′27″N, long. 82°21′19″W;
to lat. 33°17′41″N, long. 82°22′35″W;
to lat. 33°19′26″N, long. 82°22′15″W;
to lat. 33°22′37″N, long. 82°16′58″W;
to lat. 33°23′50″N, long. 82°14′03″W;
to the point of beginning.

Designated Altitudes. Surface to but not including 2,500 feet MSL.

Time of designation. By NOTAM 24 hours in advance.

Controlling agency. FAA, Atlanta ARTCC.

Using agency. U.S. Army, Commanding Officer, Fort Gordon, GA.

Remarks. Aircraft activities must not be conducted on national holidays or from the Sunday prior to the Masters Golf Tournament through the Monday after (and subsequent weather days if required).

R–3004B Fort Gordon, GA [Amended]

Boundaries. Beginning at lat. 33°25′03″N, long. 82°12′15″W;
to lat. 33°23′48″N, long. 82°08′56″W;
to lat. 33°22′20″N, long. 82°08′33″W;
to lat. 33°21′33″N, long. 82°09′10″W;
to lat. 33°20′15″N, long. 82°10′57″W;
to lat. 33°17′41″N, long. 82°16′11″W;
to lat. 33°18′23″N, long. 82°16′17″W;
to lat. 33°18′22″N, long. 82°16′39″W;
to lat. 33°17′29″N, long. 82°16′52″W;
to lat. 33°16′57″N, long. 82°17′39″W;
to lat. 33°16′56″N, long. 82°18′50″W;
to lat. 33°17′27″N, long. 82°21′19″W;
to lat. 33°17′41″N, long. 82°22′35″W;
to lat. 33°19′26″N, long. 82°22′15″W;
to lat. 33°22′37″N, long. 82°16′58″W;
to lat. 33°23′50″N, long. 82°14′03″W;
to the point of beginning.

Designated Altitudes. 2,500 feet MSL to but not including 10,000 feet MSL.

Time of designation. By NOTAM 24 hours in advance.

Controlling agency. FAA, Atlanta ARTCC.

Using agency. U.S. Army, Commanding Officer, Fort Gordon, GA.

Remarks. Aircraft activities must not be conducted on national holidays or from the Sunday prior to the Masters Golf Tournament through the Monday after (and subsequent weather days if required).

R–3004C Fort Gordon, GA [Amended]

Boundaries. Beginning at lat. 33°25′03″N, long. 82°12′15″W;
to lat. 33°23′48″N, long. 82°08′56″W;
to lat. 33°22′20″N, long. 82°08′33″W;
to lat. 33°21′33″N, long. 82°09′10″W;
to lat. 33°20′15″N, long. 82°10′57″W;
to lat. 33°17′41″N, long. 82°16′11″W;
to lat. 33°18′23″N, long. 82°16′17″W;
to lat. 33°18′22″N, long. 82°16′39″W;
to lat. 33°17′29″N, long. 82°16′52″W;
to lat. 33°16′57″N, long. 82°17′39″W;
to lat. 33°16′56″N, long. 82°18′50″W;
to lat. 33°17′27″N, long. 82°21′19″W;
to lat. 33°17′41″N, long. 82°22′35″W;
to lat. 33°19′26″N, long. 82°22′15″W;
to lat. 33°22′37″N, long. 82°16′58″W;
to lat. 33°23′50″N, long. 82°14′03″W;
to the point of beginning.

Designated Altitudes. 10,000 feet MSL to 16,000 feet MSL.

Times of designation. By NOTAM 24 hours in advance.

Controlling agency. FAA, Atlanta ARTCC.

Using agency. U.S. Army, Commanding Officer, Fort Gordon, GA.

Remarks. Aircraft activities must not be conducted on national holidays or from the Sunday prior to the Masters Golf Tournament through the Monday after (and subsequent weather days if required).

* * * * *

Issued in Washington, DC, on April 4, 2023.

Brian Konie,

Acting Manager, Airspace Rules and Regulations Group.

[FR Doc. 2023–07398 Filed 4–7–23; 8:45 am]

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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: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA or we) is proposing to amend our standard of identity (SOI) 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 leading cause of heart disease and stroke. The proposed rule, if finalized, would 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: Either electronic or written comments on the proposed rule must be submitted by August 8, 2023.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of August 8, 2023. Comments 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 comments in the following way:

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

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

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

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary

A. Purpose of the Proposed Rule

This proposed rule, if finalized, would amend 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. Foods for which FDA has established a SOI are referred to as ''standardized'' foods. The amendments would permit the use of safe and suitable salt substitutes to replace some or all of the salt used in the manufacture of standardized foods. The proposed rule would not list specific salt substitutes; instead, the proposed rule would cover ingredients or combinations of ingredients used as salt substitutes by food manufacturers currently or in the future. If finalized, the proposed rule would support efforts to reduce sodium content in standardized foods and may help to improve consumer dietary patterns by reducing sodium consumption. On average Americans consume 50% more sodium than the recommended limit for those aged 14 and older (Ref. 1). Reducing sodium consumption may help reduce the risk of hypertension, a leading cause of heart disease and stroke. The proposed rule would allow food manufacturers the flexibility to use salt substitutes and allow for innovation in producing healthier standardized foods. The proposed rule would promote honesty and fair dealing in the interest of consumers by accommodating their preferences for lower sodium varieties of foods. This, in turn, would make lower-sodium options available to them.

B. Summary of the Major Provisions of the Proposed Rule

FDA is proposing to amend 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 propose to amend 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 propose to amend 80 SOI to permit salt substitutes.

We also propose to update the incorporation by reference (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. For example, the proposed rule would update the referenced methods of analysis to those in the ''Official Methods of Analysis of AOAC INTERNATIONAL,'' 21st Ed. 2019. We also propose to make technical amendments to correct inconsistencies and typographical errors in some SOI regulations.

We tentatively conclude that the proposed 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 proposing this rule consistent with our authority in sections 201, 401, 402, 409, and 701 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 321, 341, 342, 348, 371). We

discuss our legal authority in greater detail in section IV.

D. Costs and Benefits

The proposed rule would amend SOI that specify salt as a required or optional ingredient, to permit the use of salt substitutes. The proposed rule would give manufacturers the flexibility to use salt substitutes in standardized foods, to reduce sodium content. If finalized, the proposed rule would not result in regulatory costs for firms. The proposal would not require manufacturers to replace salt with salt substitutes. Instead, manufacturers would have the option of using salt substitutes to replace salt in standardized foods. Should manufacturers choose to use this flexibility to reformulate some products by substituting some salt with salt substitutes, the primary benefits realized would result from lower sodium consumption by U.S. consumers who choose to purchase and consume the reformulated versions of such products, and increased profit (producer surplus) for manufacturers (or at least no decrease in profits). The primary cost of such voluntary market behavior would include reformulation and relabeling costs for the manufacturers.

II. Table of Abbreviations/Acronyms

Abbreviation/ acronym	What it means
CDRR	Chronic Disease Risk Reduction Intake
CFR	Code of Federal Regulations
FD&C Act	Federal Food, Drug, and Cosmetic Act
FDA	Food and Drug Administration
FR	FEDERAL REGISTER
GRAS	Generally Recognized as Safe
IBR	Incorporation by Reference
mg	Milligram
SOI	Standard(s) of Identity
U.S.C.	United States Code

III. Background

A. Introduction

As a public health agency, FDA seeks to improve dietary patterns in the United States to help reduce the burden of diet-related chronic diseases and advance health equity as nutrition-related chronic diseases are experienced disproportionately by certain racial and ethnic minority groups, those living in rural communities, and those with lower socioeconomic status. We are committed to accomplishing this, in part, by creating a healthier food supply for all. One way FDA is working towards this goal is by helping to reduce sodium across the food supply.

Americans consume, on average, 3,400 milligrams of sodium per day (mg/day) (Ref. 1). This is nearly 50 percent more than the sodium Chronic Disease Risk Reduction Intake (CDRR) established by the National Academies of Sciences, Engineering and Medicine, which sets the limit for sodium for individuals 14 years and older at 2,300 mg/day. This CDRR was adopted as a recommendation by the Dietary Guidelines for Americans, 2020–2025 (Refs. 1 and 2). Reducing sodium intake to below the CDRR level is expected to help reduce the risk of chronic disease. Excess sodium intake increases risk for hypertension, commonly referred to as high blood pressure, a leading cause of heart disease and stroke and the first and fifth leading cause of mortality in 2020 in the United States (Refs. 2–6). Decreasing sodium intake is, therefore, expected to reduce the rate of hypertension. It has been estimated that sufficient reductions in the population average sodium intake could potentially result in tens of thousands fewer cases of heart disease and stroke and associated mortality each year (Refs. 7–9).

Reducing sodium in processed, packaged and prepared foods will help create a healthier food supply. A healthier food supply has the potential to contribute to better health outcomes and reduce preventable death and disease related to poor nutrition; many of which are experienced at higher rates by certain racial and ethnic groups (Ref. 10). For example, more than 4 in 10 American adults have hypertension and that number increases to nearly 6 in 10 for non-Hispanic Black Americans (Ref. 11). African American women are almost 60 percent more likely to have hypertension when compared to non-Hispanic white women, and African American adults are 30% more likely than non-Hispanic white Americans to die from coronary heart disease (CHD) (Refs. 12 and 13); further, American Indians/Alaskan Natives are 50% more like to be diagnosed with CHD than non-Hispanic Whites (Ref. 13). The proposed rule's likely effect on increasing the availability of lower sodium products may contribute to government-wide efforts to reduce health disparities.

Reducing sodium in processed, packaged and prepared food is a critical step in helping to improve consumer dietary patterns. More than 70 percent of sodium consumed in the United States comes from sodium added during manufacturing and commercial food preparation (Ref. 14). This makes it challenging for consumers to reduce their sodium consumption. Further, because salt (sodium chloride) serves various functions in processed, packaged, and prepared foods, industry must balance sodium reduction efforts while manufacturing products that maintain the properties of a certain food and still meet the preferences of consumers.

FDA is engaged in several efforts aimed at encouraging gradual, efficient reduction of overall sodium content in processed, packaged and prepared food products. We recently issued two guidance documents for industry to support voluntary industry efforts to reduce sodium in the food supply and facilitate industry innovation toward creating healthier foods. The December 2020 guidance for industry entitled ''The Use of an Alternate Name for Potassium Chloride in Food Labeling'' (Potassium Chloride guidance) (Ref. 15) sets forth FDA's enforcement discretion policy with respect to declaring potassium chloride as ''potassium salt'' in the ingredient statement in the labeling of food products. In October 2021, we issued guidance for industry entitled ''Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods'' (Voluntary Sodium Reduction Goals guidance) (Ref. 16). The guidance document finalizes the short-term (2.5 year) voluntary sodium reduction targets in over 160 categories of packaged and restaurant prepared food. These short-term targets are based on a reduction of average sodium intake from current levels of 3,400 mg/day to 3,000 mg/day, and they serve as initial benchmarks for a broad and gradual reduction of sodium in the food supply (Ref. 16 and 17). Through the two guidance documents and this rulemaking, our intent is to support the gradual reduction of sodium across the food supply.

Under our authority in section 401 of the FD&C Act, FDA establishes SOI to promote honesty and fair dealing in the interest of consumers. SOI are established under the common or usual name of a food. Such foods are said to be ''standardized.'' SOI define the food and typically provide the types of ingredients that it must contain (*i.e.,* mandatory ingredients) and that it may contain (*i.e.,* optional ingredients). They sometimes specify the amount or proportion of each ingredient. Many SOI also designate methods of production. We have over 250 SOI for a wide variety of food products.

B. Need for the Regulation

Salt substitutes are ingredients that can help reduce sodium in processed, packaged and prepared foods. Food 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, food 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. Various stakeholders have expressed concern that many SOI are out of date and may impede innovation, including the ability to produce healthier foods (Ref. 18). 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. In this way, the SOI may become a barrier to innovation.

Permitting the use of salt substitutes is aligned with FDA's goal to reduce sodium across the food supply and our work to reduce sodium consumption. Research suggests that consumers usually do not notice small reductions in sodium and, over time, consumer palates adjust to lower sodium levels (Ref. 19). Through our work on the Voluntary Sodium Reduction Goals guidance and the Potassium Chloride guidance, we learned that stakeholders, including industry, consumers, consumer advocacy, scientific and professional health organizations, generally support allowing the use of salt substitutes. In another public engagement, some stakeholders discussed modernizing SOI to allow the use of salt substitutes using a ''horizontal approach'' (Ref. 18). 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. We considered several options for permitting salt substitutes in standardized foods and evaluated how to apply this change across multiple SOI. The proposed rule, if finalized, would adopt a horizontal approach to amending the applicable SOI. The proposed rule would permit the use of salt substitutes in SOI that specify salt as a required or optional ingredient, to reduce sodium in the food. Because the use of salt substitutes in these SOI is currently precluded, 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 would contribute to our goal to reduce sodium across the food supply. It would facilitate voluntary industry efforts toward sodium reduction by providing flexibility and supporting innovation in the production of healthier standardized foods, which may help some consumers to gradually reduce the sodium in their diet and contribute to better health outcomes. The proposed rule may have the potential to contribute to government-wide efforts to reduce health disparities if the use of salt substitutes helps populations disproportionately affected by hypertension to consume less sodium.

C. FDA's Current Regulatory Framework

The FD&C Act gives us the authority to establish definitions and standards for foods with respect to identity, quality, and fill of container (21 U.S.C. 341). SOI specify the permitted ingredients, both mandatory and optional, and sometimes describe the amount or proportion of each ingredient. Many SOI also prescribe a method of production or formulation. Foods for which FDA has established a SOI must conform to the applicable definition and standard. A food is misbranded if it purports to be or is represented as a food for which a SOI has been established but fails to conform to the definition and standard (21 U.S.C. 343(g)).

SOI are codified in parts 130 to 169 (21 CFR parts 130 to 169). Part 130 outlines general provisions, including the use of food additives in food standards. Part 130 also includes the general definition and SOI (*i.e.,* § 130.10). Parts 131 to 169 set forward SOI for foods in 21 food product categories.

We have long interpreted the term ''salt'' in the food standards in parts 131 to 169 to refer to sodium chloride. Salt is specified as a required or optional ingredient in 80 SOI across these parts. Some SOI cross reference other SOI. For example, in part 136 (21 CFR part 136), salt is an optional ingredient in the SOI for bread, rolls, and buns (§ 136.110) which is referenced in several other SOI, including: enriched bread, rolls, and buns (§ 136.115), milk bread, rolls, and buns (§ 136.130), raisin bread, rolls, and buns (§ 136.160), and whole wheat bread, rolls, and buns (§ 136.180). The result of such cross referencing is that salt is a required or an optional ingredient in 140 SOI.

Manufacturers of standardized foods have few options for reducing the sodium content of their products. If salt is a required ingredient, they may generally use less salt. If salt is an optional ingredient, they may either use no salt or less salt. However, they cannot replace salt with another ingredient unless the standard permits the use of another ingredient. Most SOI do not provide for a substitute for salt. In some instances, we established separate SOI for low sodium foods, thereby allowing manufacturers to reduce the amount of salt used and to substitute other ingredients. Manufacturers may also modify the sodium content of standardized foods under the general definition and SOI in § 130.10 (Requirements for foods named by use of a nutrient content claim and a standardized item), provided that certain conditions are met.

Deviation from a SOI is permitted under the general definition and SOI in § 130.10. The deviation must be due to a modification described by an expressed nutrient content claim defined by regulation. Expressed nutrient content claims for the sodium content of foods (*e.g.,* ''low sodium'') are provided under § 101.61 (21 CFR 101.61) (Nutrient content claims for the sodium content of foods). Thus, sodium modifications to a standardized food are permitted if the modification meets the requirements for a nutrient content claim under § 101.61. The modified food becomes a new standardized food under § 130.10 and is named with the nutrient content claim and the name of the standardized food from which it deviates (*e.g.,* ''low sodium provolone cheese''). It may be impracticable for manufacturers to reduce the sodium content in standardized foods to the extent required by a nutrient content claim. For example, to meet the requirements for a ''reduced sodium'' nutrient content claim, manufacturers must decrease the sodium in the food by at least 25 percent. Certain foods do not retain the same characteristics when the amount of sodium is reduced to this degree, and therefore, the general definition and SOI does not facilitate the production of lower sodium varieties. This proposed rule would allow manufacturers to reduce the sodium in standardized foods in amounts less than the amounts prescribed in § 101.61. This would provide manufacturers greater flexibility when reformulating standardized foods to lower the sodium content.

Presently, three SOI specifically permit the use of a salt substitute. The SOI for low sodium cheddar cheese (§ 133.116) and low sodium colby

cheese (§ 133.121) permit the use of a salt substitute. The SOI for low sodium colby cheese prohibits the use of salt and permits the use of a salt substitute that contains no sodium (§ 133.121(a)). The SOI for margarine (§ 166.110) specifically permits the use of potassium chloride in the manufacture of dietary margarine. Potassium chloride, in some instances, can be used as a partial substitute for sodium chloride in food processing and manufacturing.

If finalized, the proposed rule would provide a new means for manufacturers to reduce the sodium content of standardized foods. Salt substitutes would be permitted in any food for which an SOI has been established and that specifies salt as a required or an optional ingredient. This would be achieved without requiring the minimum reductions in sodium content under § 101.61 and renaming of food products as is required for modifications under § 130.10.

IV. Legal Authority

We are issuing this proposed rule consistent with our authority in sections 201, 401, 402, 409, and 701of the 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 tentatively conclude that permitting the use of salt substitutes to replace some or all of the salt used in the production of standardized foods would promote honesty and fair dealing in the interest of consumers. Consumers desire more nutritious and healthy food options, such as lower sodium versions of foods. This proposed rule, if finalized, would allow for industry development and sale of such foods while ensuring that standardized foods meet consumer expectations and preferences with respect to lower-sodium varieties.

FDA has codified food standards in parts 130 to 169. These regulations do not provide either an authorization or exemption from regulation as a food additive under section 409 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 its becoming a component of food, if such substance is not generally recognized by experts as safe under the conditions of its intended use (section 201(s) of the FD&C Act). The definition of ''food additive'' exempts any uses that are the subject of prior sanction (section 201(s)(4) of the FD&C Act)). Food additives are deemed unsafe except to the extent that FDA approves their use (section 409(a) 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).

We also are issuing this proposed 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) ''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 would effectuate 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 rule may help provide more options to consumers while ensuring that the foods maintain their basic nature and essential characteristics. The proposed amendments to the SOI for dairy products under parts 131, 133, and 135 are issued under section 701(e) of the FD&C Act.

V. Description of the Proposed Rule

The proposed rule, if finalized, would:

- Amend part 130 to add a new subpart C entitled ''Flexibility in Standardized Foods.''
- Add a new § 130.30 to provide for ''Ingredient Flexibility in Standardized Foods'' and define ''salt substitute'' as 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.
- Amend the 80 SOI that specify salt as a required or an optional ingredient to add regulatory text to permit the use of salt substitute, as defined in proposed § 130.30.
- Update 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. The proposed rule would also update the referenced methods of analysis to those in the ''Official Methods of Analysis of AOAC INTERNATIONAL,'' 21st Ed. 2019.
- Make technical amendments to correct inconsistencies and typographical errors in some SOI regulations.

A. Scope/Applicability

The proposed rule, if finalized, would amend SOI in parts 131 to 169. Specifically, the proposed rule would permit the use of salt substitutes in the foods covered by 80 SOI that include salt as a required or an optional ingredient. The proposal would also permit the use of salt substitutes in foods covered by SOI that reference some of the 80 SOI.

This rule does not propose to amend the SOI for oysters (§ 161.130). The SOI in § 161.130 provides for the optional use of salt water in the shucking of oysters. We understand that it is not standard industry practice to constitute a salt and water solution for this process. Rather, seawater accessible at the processing location is collected and used in the shucking process. Because salt is not an ingredient added by the manufacturer, we are not proposing to amend this SOI. We request comments on this approach and our understanding of current industry practice.

B. The Basic Nature and Essential Characteristics of a Standardized Food

Proposed § 130.30(b) would require that ingredients used as salt substitutes do not change the basic nature and essential characteristics of the standardized food. FDA previously discussed its understanding about the basic nature of a food in a proposed rule entitled ''Food Standards; General Principles and Food Standards Modernization,'' (70 FR 29214, May 20, 2005). The basic nature of a food is generally what the food is. It concerns the general attributes of the product. For example, the basic nature of a particular type of cheese is that it is a milk-derived food of a certain form and consistency. The essential characteristics of a food may contribute to achieving the basic nature of the food, but consumers may not be aware of the essential characteristics. The essential characteristics of a food are those that distinguish a food. Foods may be distinguished by their ingredients, compositional characteristics, physical characteristics, or levels of certain nutrients or the way they are produced—all of which are the essential characteristics of the food. For example, the essential characteristics of a particular type of cheese may include the bacterial culture used, the processing method, or the fat and moisture content that contribute to the unique characteristics of that cheese.

Use of salt substitutes that do not change the basic nature and essential characteristics of the standardized food under this proposed rule is necessary to ensure the availability of foods that promote honesty and fair dealing in the interest of consumers, in accordance with section 401 of the FD&C Act.

C. Definition of Salt Substitute

Under the FD&C Act, any substance that is intentionally added to food is a food additive that is subject to premarket review and approval by FDA unless that substance is excluded from the definition of a food additive. These excluded food substances include substances that are generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use (''generally recognized as safe'' or ''GRAS''), or the substances are prior sanctioned and excepted from the definition of a food additive. FDA considers salt a common food ingredient that is GRAS for its intended use (21 CFR 182.1(a)). A salt substitute that is added to a standardized food, to replace some or all of the salt, must be an approved food additive or GRAS for its intended use. For example, potassium chloride is a GRAS substance (21 CFR 184.1622).

The proposed rule would amend § 130.30(c)(1) to define salt substitute as a safe and suitable ingredient (see § 130.3(d)) or combination of ingredients that is used to replace some or all of the added salt (sodium chloride), to reduce the sodium in the food, and that serves the functions of salt in the food. We are proposing to define salt substitute broadly to provide flexibility and facilitate innovation in the future without the need for additional rulemaking. Thus, the proposed rule would not list specific salt substitutes; instead, the proposed rule would cover ingredients or combinations of ingredients currently used as salt substitutes and ingredients or combinations of ingredients that may be used as salt substitutes in the future, as a result of advances in food science and technological changes.

Salt is a required or optional ingredient in a wide range of standardized foods. The proposed rule also would allow manufacturers the flexibility to explore new ways to replace salt and reduce the sodium content of standardized foods while preserving the basic nature and essential characteristics of the food.

We recognize that salt serves various functions in standardized foods. For example, depending on the food, salt may be important for taste, microbial safety, and other functions. The proposed definition would require that the salt substitute be used to replace some or all of the added salt, to reduce the sodium in the food, and serve the functions of salt in the food. This would ensure that the salt substitute performs a similar function to salt in the standardized food, while helping to reduce the sodium content. 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. The proposed rule would not establish a minimum replacement level for salt. It would not prescribe the sodium content of the foods or any parameters pertaining to the production of the food. Manufacturers would determine the level of salt replacement appropriate for the particular standardized food.

Our intent is 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. To accomplish this, proposed § 130.30(c)(1) would limit the definition of salt substitute and therefore the use of salt substitutes to an ingredient or a combination of ingredients that serve the functions that salt served in the particular standardized food. The ingredient or combination of ingredients may include substances intended to mitigate the impact of removing salt and are needed to maintain the basic nature and essential characteristics of the food.

Some manufacturers are currently using salt substitutes to reduce sodium in foods in the marketplace. Scientific articles and reports have used several examples of salt substitutes when discussing sodium reduction efforts (Ref. 19, 20, 21). The use of potassium chloride is one example of a safe and suitable ingredient discussed in the scientific literature that, in some instances, serves as a partial substitute for sodium chloride in food processing and manufacturing (Ref. 15). Other examples of ingredients listed in the scientific literature include herbs and spices, yeast extracts, monosodium glutamate, amino acids, and dairy extracts (Ref. 19). The food industry is pursuing sodium reduction efforts, including the use of salt substitutes (*e.g.,* in products marketed as ''low'' or ''reduced'' sodium), in a variety of foods, including in canned fish and soups (Ref. 21). We request data and information on the types of salt substitutes currently being used in the U.S. market to support sodium reduction and on potential salt substitutes that may be used as a result of the new flexibility provided in this proposed rule.

D. Amending Standard of Identity Regulations to Permit Salt Substitutes

We propose to amend our regulations to permit the use of salt substitutes in SOI that specify salt as a required or an optional ingredient. Foods for which FDA has established a SOI must conform to the applicable standard. Consequently, without these amendments, most standardized foods cannot be modified to replace salt with salt substitutes unless salt can be reduced in sufficient quantity to meet a nutrient content claim under § 101.61 (see section III.C). As stated previously, amending 80 applicable SOI to permit the use of salt substitutes is necessary to give manufacturers the most flexibility to use salt substitutes in standardized foods. The proposed rule would permit the use of salt, salt substitute or a combination of the two in applicable standardized foods. Salt substitutes used would be declared on the label in accordance with section 403(i)(2) of the FD&C Act.

Where salt is permitted in our SOI, the use is not described uniformly in the provisions of the standards. This is largely due to the standards having been established with different structural formats. The lack of uniformity is also due to the use of salt differing across different standardized foods. In some foods, salt is a mandatory ingredient, and in other foods, salt is an optional ingredient. For some foods, salt is permitted at a specific point in the manufacturing process, whereas salt is permitted in other foods without regard to manufacturing time. These differences mean that different amendatory language in the individual standards is necessary to permit the use of salt substitutes. To address this, we propose four types of revisions to the current regulatory text in the applicable SOI.

In particular, there are differences in how the use of salt is prescribed in certain SOI for cheeses and related cheese products in part 133 (21 CFR part 133). For example, several SOI for cheeses use terms such as ''salted,'' ''salting,'' ''brine,'' or ''salt solution,'' to prescribe the application of salt in the cheesemaking process. For additional clarity, the proposed amendments for cheeses and related cheese products are grouped and discussed separately from other SOI.

There are 4 types of revisions to the applicable SOI in this proposed rule.

The third and fourth types only apply to SOI in part 133.

- Type 1: When the current text of the SOI lists ''salt'' as an optional ingredient, the proposed rule would amend the SOI to state, ''salt or salt substitute.''
- Type 2: When the current text of the SOI provides for the use of ''salt'' in a paragraph, the proposed rule would amend the SOI to state, ''salt or salt substitute.''
- Type 3: When the current text of the SOI uses terms such as ''salted,'' ''salted with dry salt or brine,'' or ''salting,'' to provide for use of salt in the food, but does not specify salt as an ingredient, the proposed rule would amend the optional ingredient list to add ''salt substitute.''
- Type 4: When the current text of the SOI uses terms such as ''salted,'' or ''salted in brine,'' to provide for the use of salt in the food, but does not provide a list of optional ingredients, the proposed rule would amend the SOI to add a paragraph stating that, ''During the cheesemaking process, where the curd is salted, salt substitute may be used.''

We summarize these changes in tables 1 and 2.

1. Amendments to SOI not in Part 133

We propose amendments to permit the use of salt substitutes in 39 SOI for products that are not cheeses or related cheese products prescribed in part 133. The amendments would occur through two types of revisions to the current regulatory text of the applicable SOI.

a. Type 1 revision for SOI not in part 133. Several SOI provide for the addition of salt by listing it as an ingredient (*e.g.,* as an ''optional ingredient,'' ''other optional ingredient,'' or including salt in a list of substances that could be added as a seasoning or flavoring.) We propose to amend these SOI to permit the addition of a salt substitute in addition to, or in place of, salt by replacing ''salt'' with ''salt or salt substitute.'' For example, the SOI for acidified milk (§ 131.111(e)(8)) lists ''salt'' under ''other optional ingredients;'' the proposed rule would replace ''salt'' with ''salt or salt substitute.'' As another example, the SOI for canned tuna (21 CFR 161.190) includes ''salt'' in a list of seasoning or flavoring ingredients (§ 161.190 (a)(6)(i)); the proposed rule would replace ''salt'' with ''salt or salt substitute.''

b. Type 2 revision for SOI not in part 133. Five SOI prescribe the use of salt in paragraphs that describe the food, rather than as part of an ingredient list. We propose to amend these SOI to permit the addition of a salt substitute in addition to, or in place of, salt by replacing ''salt'' with ''salt or salt substitute'' in the regulatory text. For example, the SOI for catsup (21 CFR 155.194) specifies the optional use of salt by stating, ''[t]he food may contain salt''; and the SOI for self-rising flour (21 CFR 137.180) specifies that the food ''is seasoned with salt.'' In both examples, we propose to replace ''salt'' with ''salt or salt substitute.''

Table 1 summarizes the amendments to the SOI for foods other than cheeses and related cheese products. We request comment on whether there would be safety concerns, technical infeasibilities, or other issues that would prevent the use of a salt substitute in any SOI listed in table 1.

TABLE 1—AMENDMENTS TO DEFINITIONS AND STANDARDS OF IDENTITY—FOODS OTHER THAN CHEESES AND RELATED CHEESE PRODUCTS

CFR section	Title	Paragraph	Type of revision
§ 131.111	Acidified milk	(e)(8)	Type 1; amends salt in optional ingredients to add salt substitute.
§ 131.112	Cultured milk	(d)(8)	Type 1; amends salt in other optional ingredients to add salt substitute.
§ 131.160	Sour cream	(b)(5)	Type 1; amends salt in optional ingredients to add salt substitute.
§ 131.162	Acidified sour cream	(b)(4)	Type 1; amends salt in optional ingredients to add salt substitute.
§ 131.170	Eggnog	(e)(2)	Type 1; amends salt in other optional ingredients to add salt substitute.
§ 136.110	Bread, rolls, and buns	(c)(4)	Type 1; amends salt in optional ingredients to add salt substitute.
§ 137.180	Self-rising flour	(a)	Type 2; amends paragraph that describes the food to add salt substitute.
§ 137.270	Self-rising white corn meal	(a)	Type 2; amends paragraph that describes the food to add salt substitute.
§ 139.110	Macaroni products	(a)(4)	Type 1; amends salt in optional ingredients to add salt substitute.
§ 139.150	Noodle products	(a)(2)	Type 1; amends salt in optional ingredients to add salt substitute.
§ 145.110	Canned applesauce	(a)(2)(iii)	Type 1; amends salt in optional ingredients to add salt substitute.
§ 145.130	Canned figs	(a)(5)	Type 1; amends salt in optional ingredients to add salt substitute.
§ 150.110	Fruit butter	(c)(4)	Type 1; amends salt in optional ingredients to add salt substitute.
§ 155.120	Canned green beans and canned wax beans.	(a)(3)(i)	Type 1; amends salt in optional ingredients to add salt substitute.
§ 155.130	Canned corn	(a)(3)(i)	Type 1; amends salt in optional ingredients to add salt substitute.
§ 155.170	Canned peas	(a)(2)(i)	Type 1; amends salt in optional ingredients to add salt substitute.
§ 155.190	Canned tomatoes	(a)(2)(iv)	Type 1; amends salt in optional ingredients to add salt substitute.
§ 155.191	Tomato concentrates	(a)(2)(i)	Type 1; amends salt in optional ingredients to add salt substitute.
§ 155.194	Catsup	(a)(1)(iv)	Type 2; amends paragraph that describes the food to add salt substitute.
§ 155.200	Certain other canned vegetables	(c)(4)(i)	Type 1; amends salt in optional ingredients to add salt substitute.
§ 155.201	Canned mushrooms	(a)(3)(i)	Type 1; amends salt in optional ingredients to add salt substitute.
§ 156.145	Tomato juice	(a)(1)	Type 2; amends paragraph that describes the food to add salt substitute.
§ 158.170	Frozen peas	(a)(1)(iv)	Type 1; amends salt in optional ingredients to add salt substitute.
§ 161.145	Canned oysters	(a)(1)	Type 2; amends paragraph that describes the food to add salt substitute.
§ 161.170	Canned Pacific salmon	(a)(4)(i)	Type 1; amends salt in optional ingredients to add salt substitute.
§ 161.173	Canned wet pack shrimp in transparent or nontransparent containers.	(a)(4)(i)	Type 1; amends salt in optional ingredients to add salt substitute.
§ 161.190	Canned tuna	(a)(6)(i)	Type 1; amends salt in seasoning and flavoring ingredients to add salt substitute.
§ 163.111	Chocolate liquor	(b)(6)	Type 1; amends salt in optional ingredients to add salt substitute.
§ 163.112	Breakfast cocoa	(b)(4)	Type 1; amends salt in optional ingredients to add salt substitute.
§ 163.123	Sweet chocolate	(b)(3)	Type 1; amends salt in optional ingredients to add salt substitute.
§ 163.124	White chocolate	(b)(4)	Type 1; amends salt in optional ingredients to add salt substitute.
§ 163.130	Milk chocolate	(b)(3)	Type 1; amends salt in optional ingredients to add salt substitute.
§ 166.110	Margarine	(b)(2)	Type 1; amends salt in optional ingredients to add salt substitute.

TABLE 1—AMENDMENTS TO DEFINITIONS AND STANDARDS OF IDENTITY—FOODS OTHER THAN CHEESES AND RELATED CHEESE PRODUCTS—Continued

CFR section	Title	Paragraph	Type of revision
§ 168.130	Cane sirup	(b)(1)	Type 1; amends salt in optional ingredients to add salt substitute.
§ 168.140	Maple sirup	(b)(1)	Type 1; amends salt in optional ingredients to add salt substitute.
§ 168.160	Sorghum sirup	(b)(1)	Type 1; amends salt in optional ingredients to add salt substitute.
§ 168.180	Table sirup	(b)(7)	Type 1; amends salt in optional ingredients to add salt substitute.
§ 169.140	Mayonnaise	(d)(1)	Type 1; amends salt in other optional ingredients to add salt substitute.
§ 169.150	Salad dressing	(e)(1)	Type 1; amends salt in other optional ingredients to add salt substitute.

2. Amendments to SOI in Part 133

Type 1 and type 2 amendments are also proposed for certain SOI for cheeses and related cheese products. We propose type 3 and type 4 amendments for the several SOI in part 133 that specify salt as an ingredient, using terms such as ''brine,'' ''salt brine,'' ''salt solution,'' ''salted,'' and ''salting.'' ''Brine,'' ''salt brine,'' and ''salt solution'' are solutions containing sodium chloride and ''salted'' and ''salting'' in the manufacture of cheese refer to the use of sodium chloride. The proposed rule would provide manufacturers of standardized cheeses and related cheese products, the flexibility to use salt substitutes to replace some or all of the salt prescribed in these processes.

We propose to permit the use of salt substitutes in 41 SOI for cheeses and related cheese products. Some SOI in part 133 list salt under ''optional ingredients'' or ''other optional ingredients,'' while others vary in how they prescribe the use of salt in the paragraph that describes the cheese or cheesemaking process. Because of these differences, we propose four types of revisions to the current regulatory text of the applicable SOI for cheeses and related cheese products.

a. Type 1 revision for SOI in part 133. Several SOI for cheeses and related cheese products provide for the addition of salt by listing it as an ingredient (*e.g.,* as an ''optional ingredient'' or ''other optional ingredient.'') We propose to amend these SOI to permit the addition of salt substitute in addition to, or in place of, salt by replacing ''salt'' in the list with ''salt or salt substitute.'' For example, the SOI for cold-pack and club cheese lists ''salt'' under ''optional ingredients'' (§ 133.123(c)(3)). The proposed rule would replace ''salt'' with ''salt or salt substitute.''

b. Type 2 revision for SOI in part 133. Five SOI provide for the use of salt in paragraphs that describe the cheese, rather than as part of an ingredient list. We propose to amend these SOI to permit the addition of a salt substitute in addition to, or in place of, salt by replacing ''salt'' in the paragraphs with ''salt or salt substitute.'' For example, the proposed rule would replace ''salt'' with ''salt or salt substitute'' in three paragraphs of the SOI for dry curd cottage cheese (§ 133.129(b)(1)(i) through (iii)) and in one paragraph of the SOI for sap sago cheese (§ 133.186 (a)(2)).

c. Type 3 revision for SOI in part 133. Some SOI for cheeses and related cheese products provide for the use of salt in a paragraph that describes the cheesemaking process, through terms such as ''salted,'' ''salted with dry salt or brine,'' or ''salting,'' and do not specify salt in a list of ingredients (*e.g.,* as an ''other optional ingredient''). We propose to amend these SOI to permit the addition of a salt substitute in addition to, or in place of, salt by adding ''salt substitute'' as a new subparagraph in the current list of other optional ingredients. For example, the SOI for cheddar cheese (§ 133.113(a)(3)) states that ''the curd is salted, stirred, further drained, and pressed into forms,'' but does not list salt in the optional ingredients in § 133.113(b)(3). The proposed rule would amend § 133.113(b)(3) by adding a new subparagraph, ''salt substitute'' (proposed § 133.113(b)(3)(vi)).

d. Type 4 revision for SOI in part 133. Several SOI for cheeses and related cheese products provide for the use of salt in a paragraph that describes the cheesemaking process through terms such as ''salted'' or ''salted in brine,'' but do not include a list of ingredients (*e.g.,* ''optional ingredient'' or ''other optional ingredient'') that could be amended to add salt substitute. We propose to amend these SOI to explicitly permit the use of a salt substitute in the cheesemaking process. For example, the SOI for asiago fresh and asiago soft cheese (§ 133.102(b)) provides that ''the curd is salted in brine and cured in a well-ventilated room,'' but does not have an optional ingredient list. The proposed rule would amend this SOI by adding a new subparagraph at § 133.102(c)(3) to state, ''During the cheesemaking process, where the curd is salted, salt substitute may be used.''

Table 2 summarizes the amendments to the SOI for cheeses and related cheese products. We request comment on whether there would be safety concerns, technical infeasibilities, or other issues that would prevent the use of salt substitute in any SOI listed in table 2.

TABLE 2—PROPOSED AMENDMENTS TO DEFINITIONS AND STANDARDS OF IDENTITY—CHEESES AND RELATED CHEESE PRODUCTS

CFR section	Title	Current paragraph	Revised or added paragraph designation	Type of revision
§ 133.102	Asiago fresh and asiago soft cheese.	(c)	(c)(3)	Type 4; amends SOI to add a new paragraph to permit salt substitute.
§ 133.106	Blue cheese	(b)(3)	(b)(3)(vii)	Type 3; amends other optional ingredients to add new paragraph to list salt substitute.
§ 133.108	Brick cheese	(b)(3)	(b)(3)(v)	Type 3; amends other optional ingredients to add new paragraph to list salt substitute.
§ 133.111	Caciocavallo siciliano cheese	(c)	(c)(3)	Type 4; amends SOI to add a new paragraph to permit salt substitute.

TABLE 2—PROPOSED AMENDMENTS TO DEFINITIONS AND STANDARDS OF IDENTITY—CHEESES AND RELATED CHEESE PRODUCTS—Continued

CFR section	Title	Current paragraph	Revised or added paragraph designation	Type of revision
§ 133.113	Cheddar cheese	(b)(3)	(b)(3)(vi)	Type 3; amends other optional ingredients to add new paragraph to list salt substitute.
§ 133.118	Colby cheese	(c)	(c)(4)	Type 4; amends SOI to add new paragraph to permit salt substitute.
§ 133.123	Cold-pack and club cheese ...	(c)(3)	N/A	Type 1; amends salt in optional ingredients to add salt substitute.
§ 133.124	Cold-pack cheese food	(e)(3)	N/A	Type 1; amends salt in other optional ingredients to add salt substitute.
§ 133.127	Cook cheese, koch kaese	(b)(3)(v)	N/A	Type 1; amends salt in other optional ingredients to add salt substitute.
§ 133.129	Dry curd cottage cheese	(b)(1)(i)–(iii)	N/A	Type 2; amends paragraph that describes the food to add salt substitute.
§ 133.133	Cream cheese	(b)(3)(i)	N/A	Type 1; amends salt in other optional ingredients to add salt substitute.
§ 133.136	Washed curd and soaked curd cheese.	(b)(3)	(b)(3)(vi)	Type 3; amends other optional ingredients to add new paragraph to list salt substitute.
§ 133.138	Edam cheese	(b)(3)	(b)(3)(v)	Type 3; amends other optional ingredients to add new paragraph to list salt substitute.
§ 133.141	Gorgonzola cheese	(b)(3)	(b)(3)(vii)	Type 3; amends other optional ingredients to add new paragraph to list salt substitute.
§ 133.144	Granular and stirred curd cheese.	(b)(3)	(b)(3)(vi)	Type 3; amends other optional ingredients to add a new paragraph to list salt substitute.
§ 133.147	Grated American cheese food	(c)(5)	N/A	Type 1; amend salt in other optional ingredients to add salt substitute.
§ 133.148	Hard grating cheeses	(c)	(c)(1) and (2)	Type 4; amends SOI to add a new paragraph to permit salt substitute.
§ 133.149	Gruyere cheese	(b)(3)	(b)(3)(iv)	Type 3; amends other optional ingredients to add a new paragraph to list salt substitute.
§ 133.150	Hard cheeses	(c)	(c)(3)	Type 4; amends SOI to add a new paragraph to permit salt substitute.
§ 133.152	Limburger cheese	(b)(3)	(b)(3)(iv)	Type 3; amends other optional ingredients to add new paragraph to list salt substitute.
§ 133.153	Monterey cheese and monterey jack cheese.	(b)(3)(iii)	N/A	Type 1; amends salt in other optional ingredients to add salt substitute.
§ 133.155	Mozzarella cheese and scamorza cheese.	(b)(3)(iii)	N/A	Type 1; amends salt in other optional ingredients to add salt substitute.
§ 133.156	Low-moisture mozzarella and scamorza cheese.	(b)(3)(iii)	N/A	Type 1; amends salt in other optional ingredients to add salt substitute.
§ 133.160	Muenster and munster cheese.	(b)(3)	(b)(3)(vi)	Type 3; amends other optional ingredients to add a new paragraph to list salt substitute.
§ 133.162	Neufchatel cheese	(b)(3)(i)	N/A	Type 1; amends salt in other optional ingredients to add salt substitute.
§ 133.164	Nuworld cheese	(b)(3)	(b)(3)(iv)	Type 3; amends other optional ingredients to add a new paragraph to list salt substitute.
§ 133.165	Parmesan and reggiano cheese.	(c)	(c)(3)	Type 4; amends SOI to add a new paragraph to permit salt substitute.
§ 133.169	Pasteurized process cheese ..	(d)(4)	N/A	Type 1; amends salt in optional ingredients to add salt substitute.
§ 133.173	Pasteurized process cheese food.	(e)(4) Salt	N/A	Type 1; amends salt in other optional ingredients to add salt substitute.
§ 133.179	Pasteurized process cheese spread.	(f)(5) Salt	N/A	Type 1; amends salt in other optional ingredients to add salt substitute.
§ 133.181	Provolone cheese	(b)(3)	(b)(3)(vi)	Type 3; amends other optional ingredients to add a new paragraph to list salt substitute.
§ 133.182	Soft ripened cheeses	(b)	N/A	Type 2; amends paragraph that describes the food to add salt substitute.
§ 133.183	Romano cheese	(c)	(c)(3)	Type 4; amends SOI to add a new paragraph to permit salt substitute.
§ 133.184	Roquefort cheese, sheep's milk blue-mold, and blue-mold cheese from sheep's milk.	(b)(3)	(b)(3)(i) and (ii)	Type 3; amends other optional ingredients to add new paragraph to list salt substitute.
§ 133.185	Samsoe cheese	(b)(3)	(b)(3)(v)	Type 3; amends other optional ingredients to add new paragraph to list salt substitute.
§ 133.186	Sap sago cheese	(a)	N/A	Type 2; amends paragraph that describes the food to add salt substitute.
§ 133.187	Semisoft cheeses	(b)	N/A	Type 2; amends paragraph that describes the food to add salt substitute.

TABLE 2—PROPOSED AMENDMENTS TO DEFINITIONS AND STANDARDS OF IDENTITY—CHEESES AND RELATED CHEESE PRODUCTS—Continued

CFR section	Title	Current paragraph	Revised or added paragraph designation	Type of revision
§ 133.188	Semisoft part-skim cheeses ...	(b)	N/A	Type 2; amends paragraph that describes the food to add salt substitute.
§ 133.189	Skim milk cheese for manufacturing.	(d)	(d)(1) and (2)	Type 4; amends SOI to add a new paragraph to permit salt substitute.
§ 133.190	Spiced cheeses	(b)(3)(iii)	N/A	Type 1; amends salt in other optional ingredients to add salt substitute.
§ 133.195	Swiss and emmentaler cheese.	(b)(3)	(b)(3)(vii)	Type 3; amends other optional ingredients to add a new paragraph to list salt substitute.

E. Update Incorporation by Reference

Several of the 80 SOI that specify salt as a required or optional ingredient contain outdated references. We propose to update the IBR paragraphs in these 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 propose to add IBR paragraphs to subparts A of parts 131, 137, 139, 150, 155, and 161. SOI in subparts B of these parts would reference applicable IBR paragraphs in subpart A. We also propose to update the IBR paragraphs in the SOI under parts 136, 145, and 166 which would not have IBR paragraphs in subparts A of these parts. The revised format is for administrative efficiency. Specifically, the proposed rule would update the IBR information for §§ 131.111, 131.112, 131.160, 131.162, 131.170, 136.110, 137.180, 137.270, 139.110, 139.150, 145.110, 150.110, 155.120, 155.130, 155.170, 161.145, 161.173,161.190, and 166.110. These SOI list methods of analysis that are from the 13th or 15th editions of ''Official Methods of Analysis of the Association of Official Analytical Chemists.'' Additionally, § 155.170 lists an incorrect section number for the method for alcohol insoluble solids in canned peas. We propose to update the referenced methods of analysis to those in the ''Official Methods of Analysis of AOAC INTERNATIONAL,'' 21st Ed. 2019. These proposed changes will ensure that the reference materials are current, accessible, and meet Federal requirements pertaining to IBR (see 1 CFR part 51).

- Definition of Terms and Explanatory Notes; Table 1. Nominal Dimensions of Standard Test Sieves (USA Standard Series). The reference lists the test sieve designations and their nominal dimensions.
- AOAC Reference Table 909.04; Correction Factors for Gasometric Determination of Carbon Dioxide. The reference lists the correction factors of carbon dioxide measurements for different atmospheric conditions.
- AOAC Official Method 923.02A; Reagent under Carbon Dioxide (Total) in Baking Powders-Gasometric Determination. The reference describes the reagent used in measuring the amount of carbon dioxide released from a sample.
- AOAC Official Method 923.02B; Apparatus under Carbon Dioxide (Total) in Baking Powders-Gasometric Determination. The reference describes the apparatus used in measuring the amount of carbon dioxide released from a sample.
- AOAC Official method 926.07A; Vacuum Oven Method, under 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. 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 932.14C; By Means of Refractometer under Solids in Syrups. The reference provides the method for measuring the percentage of soluble solids in a sample.
- AOAC Official method 935.36(a); Solids (Total) in Bread. The reference provides the method for measuring the percentage of solids in a sample.
- AOAC Official method 938.06A; Indirect Method, under 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 945.48G; under 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; Solid-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. You may inspect a copy at Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500, between 9 a.m. and 4 p.m., Monday through Friday.

F. Technical Amendments

We also propose to make technical amendments to correct inconsistencies and typographical errors in several of the 80 SOI regulations that specify salt as a required or optional ingredient. The corrections are non-substantive. The proposed rule would:

- Amend § 133.118(c)(2) to replace ''143'' with ''145.''
- Amend § 133.150(c)(2) to replace ''143'' with ''145.''
- Amend § 133.150(e)(1) to replace ''unusual'' with ''usual.''
- Amend § 133.182(c)(2) to replace ''143'' with ''145.''

- Amend § 133.184(b) to replace ''Operational'' with ''Optional.''
- Amend § 133.186(c) to replace ''Nonmenclature'' with ''Nomenclature.''
- Amend § 133.187(c)(2) to replace ''143'' with ''145.''
- Amend § 133.188(c)(2) to replace ''143'' with ''145.''
- Amend § 155.170(b)(1)(iii) to replace ''shrivelled'' with ''shriveled.''
- Amend § 158.170(b)(1)(iii) to replace ''shrivelled'' with ''shriveled.''
- Amend § 168.140(a) to replace ''mapel'' with ''maple.''

VI. Proposed Effective/Compliance Dates

We propose that any final rule resulting from this rulemaking be effective 30 days after the final rule's date of publication in the **Federal Register** insofar as it amends non-dairy SOI. We believe that this effective date is appropriate because it will provide industry the flexibility to use salt substitutes to reduce the sodium content in standardized foods. Some manufacturers are already exploring ways to reduce sodium in standardized foods, and this proposed rule, if finalized, will assist in those efforts. For the same reasons, FDA proposes that any dairy SOI that may be amended based on this proposal, unless stayed by the filing of proper objections, will also be effective 30 days after the final rule's date of publication in the **Federal Register**.

VII. Preliminary Economic Analysis of Impacts

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), 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 (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Office of Information and Regulatory Affairs has determined that this proposed rule is a significant regulatory action as defined by Executive Order 12866 Section 3(f)(1).[1]

[1] We note that this Executive Order 12866 applies only to the non-dairy SOI portions of this rulemaking; the dairy SOI covered by this rulemaking are ''regulations or rules issued in accordance with the formal rulemaking provisions of 5 U.S.C. 556, 557'' (see 21 U.S.C. 701(e)(1)) and therefore excluded by section (d)(1) of Executive Order (E.O.) 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. We do not anticipate the proposed rule would generate regulatory impacts on small entities. As with any voluntary market behavior, larger firms may have certain advantages over small firms in some areas, while smaller firms may have advantages in other areas. As a result, we propose to certify that the proposed 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 an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $165 million, using the most current (2021) Implicit Price Deflator for the Gross Domestic Product. The proposed rule would not result in a mandated expenditure in any year that meets or exceeds this amount.

The proposed rule would permit, but not require, manufacturers to use salt substitutes to replace salt where salt is a required or optional ingredient in standardized foods. If finalized, the benefits of this rule would be additional flexibility in the manufacture of standardized foods and the potential for reduced salt consumption by consumers which may contribute to better health outcomes. We have no information to suggest the use of currently available salt substitutes would lead to improved product characteristics (*e.g.,* shelf life) or would lead to reduced production costs and potentially lower prices. We request comment on such potential benefits of reformulation for manufacturers and on how many standardized foods manufacturers might choose to reformulate, either in the relatively near or longer-run future.

The proposed rule, if finalized, would not impose requirements resulting in regulatory costs on firms or consumers. Manufacturers would have the *option* of using salt substitutes. There are no regulatory implications for not reading the rule or deciding not to use salt substitutes. Should manufacturers choose to use this flexibility to reformulate some products by substituting some salt with salt substitutes, the primary benefits realized would result from lower sodium consumption on average by U.S. consumers, assuming they choose to purchase and consume the reformulated versions of such products, and increased profit (producer surplus) for manufacturers, assuming they find offering reformulated versions of such products consistent with maximizing firm profits. The primary costs of such voluntary market behavior would be reformulation and relabeling costs for manufacturers. We currently lack data to estimate any net social benefits from voluntary market behavior relating to future use of salt substitutes made possible by this rule, but cite some published analyses below related to meeting voluntary sodium reduction targets that could partially be addressed via the flexibility provided by this rule. We request public comment on possible producer response (*e.g.,* how many manufacturers may choose to take voluntary action in response to this rule, what share of standardized food products may get reformulated) and on possible consumer willingness to purchase and consume such products with various types of salt substitutes at various levels, which would allow us to provide a range of net social benefit estimates when this rule is finalized.

A. Economic Analysis of Impacts

1. Background

There are 80 SOI that specify salt as a mandatory or optional ingredient. Some of these standards are referenced by other SOI, resulting in salt as an ingredient in 140 SOI. The salt in the foods covered by these 140 SOI may serve a variety of functions such as taste, texture, moisture control, and microbial safety. FDA has a public health interest in reducing sodium across the food supply. Therefore, we propose to give manufacturers the flexibility to use salt substitutes in standardized foods where salt is a required or optional ingredient, to reduce the sodium content. While there may be potential data sources (*e.g.,* IRI, Label Insight, Mintel, NHANES, Syndigo) that could provide market or consumption share (*e.g.,* contribution of sodium and/or caloric intake) for foods covered by these 140 SOI, FDA does not currently have sufficient estimates to further extrapolate impacts at this time. We request public comment on additional potential data sources for estimates of market share and/or caloric and/or sodium consumption share of the products included in these SOI.

We request comment on potential regulatory alternatives including allowing the use of only specified salt substitutes, at only specified levels of substitution, for only specified

purposes, for only specified products, in conjunction with only specified ancillary formulation changes, or with specified labeling requirements. More generally, we request comments on potential regulatory approaches to reducing salt in food or the dietary intake of salt that do not involve allowing the use of salt substitutes in standardized foods.

2. Benefits of the Proposed Rule

The benefit of this proposed rule is that manufacturers would have additional flexibility in producing standardized foods covered by 140 SOI, which may lead to social benefits in the form of increased consumer satisfaction (consumer surplus), increased profits (producer surplus), or both. In addition, a change in voluntary market behavior relating to patterns of food consumption, or to use a potassium-based salt as a salt substitute and consumers who would benefit from increasing their potassium intake choose to consume those products, those consumers may experience positive health effects.

Salt is a relatively inexpensive ingredient, and we would not expect manufacturers to begin using salt substitutes based on cost cutting considerations alone at this time. To explore the possibility of manufacturers voluntarily replacing salt with salt substitutes to improve the healthfulness of their standardized foods, one would need to identify the costs and level of potential substitution, and extent of consumer acceptance of salt substitutes at differing levels in different standardized foods in order to estimate the number of manufacturers who would decide to use salt substitutes. We currently lack data on these potential industry responses and request public comment from manufactures, suppliers, and consumers on the extent to which the additional flexibility provided by this rule would be used by manufacturers, hence also desired or tolerated by consumers, and viable in the supply chain.

As discussed in the preamble of this rule, on average, Americans consume approximately 3,400 milligrams of sodium per day (mg/day), which is nearly 50 percent more than the recommended daily limit on sodium intake for individuals 14 years and older (Refs. 1 and 2). Excess sodium intake increases the risk for hypertension, or high blood pressure, a leading cause of heart disease and stroke (Refs. 2–6). Decreasing sodium consumption is expected to reduce hypertension and potentially result in fewer cases of heart disease and stroke (Refs. 7–9 [2]). More than 70 percent of sodium consumed in the U.S. comes from sodium added during manufacturing and commercial food preparation (Ref. 14). The health benefits from reducing sodium consumption are expected to be higher for populations that currently have higher sodium consumption or that are more sensitive to any given level of sodium consumption than other populations. Hence, there may be potential health equity effects to any regulation that generates or facilitates reduced intake of sodium. In order to estimate such health benefits, we would need data and information on the complex pathway between allowing manufactures to use salt substitutes, the extent to which manufactures will develop products of interest to those at highest risk of hypertension, the likely demographic patterns of consumers purchasing those new products, and eventually, the extent of the reduction in sodium uptake among those at most risk of hypertension.

In the absence of necessary data to fully estimate the impacts of this rule, we refer to published literature on the health benefits of sodium reduction targets to provide broader context of potential impacts of this rule. A 2018 study by Pearson-Stuttard, et al. looked at the health and economic effects of FDA's 2016 draft voluntary sodium reduction guidance (Refs. 8 and 22) and estimated benefits of meeting sodium reduction targets in the form of medical cost savings and consumer health improvements, net of producer reformulation costs and some government administrative and monitoring costs. Over a 20-year period, the authors of the study find net social benefits from only consumer health effects to be roughly $12 billion (uncertainty range of $0 billion to $28 billion) under what it described as the most pessimistic scenario relating to potential sodium reduction among the three presented (Ref. 8). This roughly $12 billion *net* benefit arises from roughly $19 billion in estimated health cost savings (benefits) and just over $7 billion of estimated reformulation, administrative and monitoring costs.[3]

Since these benefit estimates are not comprehensive, we would need additional data on possible producer and consumer response to fully assess health benefits. Moreover, benefits might be higher or lower than what would be indicated by estimates that focus on the subset of effects tracked by Pearson-Stuttard et al. Benefits might be higher if firms were to realize additional profits or producer surplus from any product reformulation (since we assume firms would use salt substitutes only if profits would remain the same or increase). Benefits might also be higher due to possible changes in consumer surplus from consumers willing to buy reformulated products whose valuation includes factors beyond medical cost savings or health state utility. Benefits might be lower if some consumers experience disutility associated with the reformulated product and adjust their consumption pattern accordingly, which could partially offset the estimated health benefits presented above.

In addition, as mentioned above, we currently lack data to determine how much, if any, of the aggregate effects that Pearson-Stuttard et al. attribute to broader voluntary sodium reduction efforts could be directly connected to the flexibility provided by this rule. The rule does not cover all foods analyzed in the Pearson-Stuttard, et al. scenarios, which included many non-standardized foods. With comprehensive data on the share of foods affected by this rule, we could estimate health benefits across only such products as a subset of the Pearson-Stuttard, et al. estimate. We request such data and also data on possible consumer and producer response to the flexibility provided by this rule.

3. Costs of the Proposed Rule

The proposed rule, if finalized would not impose *regulatory* costs on manufacturers or consumers. There would be no regulatory requirements or regulatory penalties relative to the baseline of taking no regulatory action. Manufacturers would be required to use safe and suitable ingredients regardless of the amount or type of salt substitutes they choose to use. The flexibility provided by this rule creates parity for use of existing salt substitutes in both standardized and non-standardized foods (see section V.C. for discussion of examples of current salt substitutes in use) and such uses are already required to be disclosed and labeled. It is

[2] These studies may be sensitive to assumptions regarding consumer response. If some consumers experience disutility associated with the reformulated product and adjust their consumption pattern accordingly, this could partially offset some of the estimated health benefits.

[3] These results may be sensitive to assumptions regarding consumer response to product reformulation. For example, benefits might be lower if some consumers experience disutility associated with the reformulated product and adjust their consumption pattern accordingly, which could partially offset the estimated health benefits presented above. Ref. 9, for instance, indicates that its cost-effectiveness results are highly sensitive to such issues.

possible that a change in voluntary market behavior relating to food consumption may generate health costs. For example, to the extent manufacturers choose to use potassium chloride as a salt substitute and consumers choose to consume those products, consumers who may need to limit their potassium intake may see negative health effects that should be accounted for in cost estimates. We request comments on evidence that could contribute to a more thorough assessment (including possible quantification) of such costs. The agency will continue to monitor the use of salt substitutes in the U.S. food supply.

The economic rationale for food standards involves reducing consumers' search costs; in particular, their ability to infer certain product characteristics from representation as certain standardized foods. The proposed rule may affect product characteristics by allowing manufacturers to use salt substitutes that replace any one or any combination of the functions of added salt. However, the proposed rule would preclude ingredient substitutions that change the basic nature and essential characteristics of a standardized food. The basic nature of a food concerns the general attributes of the product that is offered for sale to consumers. The essential characteristics of a food may contribute to achieving the basic nature of the food, but consumers may not be aware of the essential characteristics. Use of safe and suitable salt substitutes that do not change the basic nature and essential characteristics of the standardized food ensures that products on the market retain their general attributes. For purposes of this analysis, we assume products that retain their general attributes will also retain consistency with consumer beliefs and expectations relating to those products and that the use of salt substitutes will therefore not generate consumer dissatisfaction relating to the identity of the standardized food. To the extent that this assumption may not be accurate, we request comment on the degree to which consumers may be willing to purchase and consume such products after salt substitutes are used.

If finalized, manufacturers may choose to take advantage of the flexibility provided in this proposed rule. As discussed above, the primary potential costs of that voluntary market behavior would arise from producers choosing to use the flexibility afforded to them to reformulate some products such as reformulation, consumer testing, labeling, and possibly marketing costs. Pearson-Stuttard, et al., estimate that reformulation costs (using the FDA model, Ref. 23) corresponding to the draft voluntary short term sodium reduction targets could range from $2.7 to $15 billion over a 20-year time period and that these costs would comprise roughly 95 percent of the costs related to reaching short term sodium reduction targets (Ref. 8). Producers may voluntarily choose to reformulate some products in response to this rule's added flexibility and the magnitude of such costs would depend on the number of products reformulated. The more firms choose to reformulate using salt substitutes given the flexibility provided by this rule, the greater the share of sodium reduction efforts (and associated reformulation costs) that could be attributed to this rule. Regardless of what amount of reformulation producers voluntarily choose to undertake, they will only do so if their private benefits in the form of increased revenue are at least as much as their private costs. We request comment on the number of manufacturers who may choose to reformulate standardized food products and the extent to which manufacturers may choose to reformulate those products given this new flexibility. We also request comment on all other considerations relating to manufacturers' voluntary market decision to use salt substitutes including cost of reformulation, ability to source substitute ingredients, expected impact on sales, profits, and consumer acceptance or lack of acceptance.

B. Initial Small Entity Analysis

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. If finalized, we do not expect the proposed rule would generate impacts on small entities. The rule would not impose regulatory costs on small entities. There would be no regulatory requirements or regulatory penalties relative to the baseline of taking no regulatory action. We have no basis to suppose or estimate any other impacts on small entities. As a result, we propose to certify that the proposed rule will not have a significant economic impact on a substantial number of small entities. This analysis, as well as other sections in this document, serves as the Initial Regulatory Flexibility Analysis, as required under the Regulatory Flexibility Act.

This analysis is also available in the docket for this proposed rule (Ref. 24) and at *https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations.*

VIII. Analysis of Environmental Impact

We have determined under 21 CFR 25.32(a) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IX. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed 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.

X. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. We have determined that the proposed 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 proposed rule in accordance with the principles set forth in Executive Order 13175. We have tentatively determined that the rule does not contain policies that would have a substantial direct effect 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. We invite comments from tribal officials on any potential impact on Indian tribes from this proposed action.

XII. References

The following references marked with an asterisk (*) are on display with 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 *http://www.regulations.gov.* References without asterisks are not on public

display at *http://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. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. * U.S. Department of Agriculture and U.S. Department of Health and Human Services. ''Dietary Guidelines for Americans, 2020–2025.'' 9th Edition. December 2020. Available at *https://www.dietaryguidelines.gov;* accessed February 23, 2022.
2. National Academies of Sciences, Engineering and Medicine. ''Dietary Reference Intakes for Sodium and Potassium'' (March 2019). Washington, DC: The National Academies Press.
3. Sacks, F. M., L. P. Svetkey, W. M. Vollmer, L. J. Appel, et al., ''Effects on Blood Pressure of Reduced Dietary Sodium and the Dietary Approaches to Stop Hypertension (DASH) diet.'' DASH—Sodium Collaborative Research Group. *New England Journal of Medicine.* 2001; 344(1): pp 3–10.
4. Graudal, N. A., T. Hubeck-Graudal, and G. Jürgens, ''Effects of Low-Sodium Diet vs. High-Sodium Diet on Blood Pressure, Renin, Aldosterone, Catecholamines, Cholesterol, and Triglyceride (Cochrane Review).'' *American Journal of Hypertension.* 2012; 25(1): pp. 1–15. *https://www.ncbi.nlm.nih.gov/pubmed/22068710,* accessed December 9, 2020.
5. Eckel, R. H., J. M. Jakicic, J. D. Ard, J. M. de Jesus, et al., ''2013 AHA/ACC Guideline on Lifestyle Management to Reduce Cardiovascular Risk: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines.'' *Journal of the American College of Cardiology.* 2014; 63(25 Pt B): pp. 2960–84. *https://www.ncbi.nlm.nih.gov/pubmed/24239922;* accessed December 9, 2020.
6. * Murphy, S. L., K. D. Kochanek, J. Q. Xu, and E. Arias, ''Mortality in the United States, 2020.'' NCHS Data Brief, no 427. Hyattsville, MD: National Center for Health Statistics. 2021; *https://www.cdc.gov/nchs/products/databriefs/db427.htm;* accessed Feb 23, 2022.
7. Coxson, P. G., N. R. Cook, M. Joffres, Y. Hong, et al., ''Mortality Benefits From U.S. Population-Wide Reduction in Sodium Consumption: Projections From 3 Modeling Approaches.'' *Hypertension.* 2013; 61(3): pp. 564–570.
8. Pearson-Stuttard, J., C. Kypridemos, B, Collins, D. Mozaffarian, et al., ''Estimating the Health and Economic Effects of the Proposed U.S. Food and Drug Administration Voluntary Sodium Reformulation: Microsimulation Cost-Effectiveness Analysis.'' *PLoS Medicine.* 2018; 15(4): pp. 1–18.
9. Smith-Spangler C. M., J. L. Juusola, E. A. Enns, D. K. Owens, and A. M. Garber, ''Population Strategies to Decrease Sodium Intake and the Burden of Cardiovascular Disease: A Cost-Effectiveness Analysis.'' *Annals of Internal Medicine.* 2010; 152(8): pp. 481–487.
10. Micha, R., J. L. Peñalvo, F. Cudhea, F. Imamura, et al., ''Association Between Dietary Factors and Mortality from Heart Disease, Stroke, and Type 2 Diabetes in the United States.'' *Journal of the American Medical Association.* 2017; 317(9): pp. 912–924.
11. * Ostchega, Y., C.D. Fryar, T. Nwankwo, and D.T. Nguyen, ''Hypertension Prevalence Among Adults Aged 18 and Over: United States, 2017–2018.'' NCHS Data Brief, no 364. Hyattsville, MD: National Center for Health Statistics. 2020; *https://www.cdc.gov/nchs/products/databriefs/db364.htm;* accessed March 21, 2023.
12. * Centers for Disease Control and Prevention, ''Deaths: Final Data for 2018'' *National Vital Statistics Report.* 2021; 69 (13). Table 10: p. 52. Available at *https://www.cdc.gov/nchs/data/nvsr/nvsr69/nvsr69-13-508.pdf;* accessed December 20, 2022.
13. * Centers for Disease Control and Prevention, ''Summary of Health Statistics'' *National Health Interview Survey.* 2018; Table A–1a. Available at *http://www.cdc.gov/nchs/nhis/shs/tables.htm;* accessed December 20, 2022.
14. Harnack, L.J., M. E. Cogswell, J. M. Shikany, C. D. Gardner, et al., ''Sources of Sodium in U.S. Adults from 3 Geographic Regions.'' *Circulation.* 2017; 135: pp. 1775–1783.
15. * FDA, ''The Use of an Alternate Name for Potassium Chloride in Food Labeling: Guidance for Industry.'' December 2020. Available at *https://www.fda.gov/media/125081/download* (Docket number FDA–2019–D–0892), accessed February 23, 2022.
16. * 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. Available at *https://www.fda.gov/media/98264/download* (Docket number FDA–2014–D–0055), accessed February 23, 2022.
17. Mayne, S. T., R. A. McKinnon, and J. Woodcock, ''Reducing Sodium Intake in the U.S. Healthier Lives, Healthier Future.'' *Journal of the American Medical Association.* 2021; 326(17): pp. 1675–1676.
18. * 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.*
19. Institute of Medicine. ''Strategies to Reduce Sodium Intake in the United States'' (2010). Washington, DC: The National Academies Press.
20. Dötsch, M., J. Busch, M. Batenburg, G. Liem, et al., ''Strategies to Reduce Sodium Consumption: A Food Industry Perspective.'' *Critical Reviews in Food Science and Nutrition.* 2009; 49(10): pp. 841–851.
21. Taylor, C., M. Doyle, D. Webb, ''The Safety of Sodium Reduction in the Food Supply: A Cross-Discipline Balancing Act—Workshop Proceedings.'' *Critical Reviews in Food Science and Nutrition.* 2018; 58(10): pp. 1650–1659.
22. * FDA, ''Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods: Guidance for Industry. Draft Guidance.'' June 2016.
23. Muth, M. K., S. Bradley, J. Brophy, K. Capogrossi, S. Karns, and C. Viator. Reformulation cost model. Contract No. HHSF–223–2011–10005B, Task Order 20. Final report. Research Triangle Park (NC): RTI International; 2015.
24. * FDA, ''Use of Salt Substitutes to Reduce the Sodium Content in Standardized Foods'' Preliminary Regulatory Impact Analysis, Initial Regulatory Flexibility Analysis, Unfunded Mandates Reform Act Analysis. Available at *https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations.*

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, we propose that 21 CFR parts 130, 131, 133, 136, 137, 139, 145, 150, 155, 156, 158, 161, 163, 166, 168, and 169 be 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 to read as follows:

* * * * *

Subpart C—Flexibility in Standardized Foods

§ 130.30 Ingredient flexibility in standardized foods.

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

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

(c) *Definitions.*

(1) Salt substitute means 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.

(2) [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 § 131.10 to read as follows:

§ 131.10 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. 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:

(a) Official Methods of Analysis, 21st Ed. (2019);

(1) AOAC Official Method 945.48G, under Evaporated Milk (Unsweetened); IBR §§ 131.160(c); 131.162(c).

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

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

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

(b) [Reserved]

■ 5. 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.* Referenced methods are from ''Official Methods of Analysis'' (incorporated by reference, see § 131.10):

(1) Milkfat content—As determined by the method prescribed in AOAC Official Method 989.05, Fat in Milk Modified Mojonnier Ether Extraction Method.

(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, Solid-Not-Fat in Milk By Difference between Total Solids and Fat Contents.

(3) Titratable acidity—As determined by the methods prescribed in AOAC Official Method 947.05, Acidity of Milk Titrimetric Method or by an equivalent potentiometric method.

* * * * *

■ 6. 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.* Referenced methods are from ''Official Methods of Analysis'' (incorporated by reference, see § 131.10):

(1) Milkfat content—As determined by the method prescribed in AOAC Official Method 989.05, Fat in Milk Modified Mojonnier Ether Extraction Method.

(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, Solid-Not-Fat in Milk By Difference between Total Solids and Fat Contents.

(3) Titratable acidity—As determined by the methods prescribed in AOAC Official Method 947.05, Acidity of Milk Titrimetric Method or by an equivalent potentiometric method.

* * * * *

■ 7. 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.* Referenced methods are from ''Official Methods of Analysis'' (incorporated by reference, see § 131.10).

(1) Milkfat content—AOAC Official Method 945.48G, under Evaporated Milk (Unsweetened).

(2) Titratable acidity—AOAC Official Method 947.05, Acidity of Milk Titrimetric Method.

* * * * *

■ 8. 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.* Referenced methods are from ''Official Methods of Analysis'' (incorporated by reference, see § 131.10).

(1) Milkfat content—AOAC Official Method 945.48G, under Evaporated Milk (Unsweetened).

(2) Titratable acidity—AOAC Official Method 947.05, Acidity of Milk Titrimetric Method.

* * * * *

■ 9. 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.* Referenced methods are from ''Official Methods of Analysis'' (incorporated by reference, see § 131.10).

(1) Milkfat content—As determined by the method prescribed in AOAC Official Method 989.05, Fat in Milk Modified Mojonnier Ether Extraction Method.

(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, Solid-Not-Fat in Milk By Difference between Total Solids and Fat Contents.

* * * * *

PART 133—CHEESES AND RELATED CHEESE PRODUCTS

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

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

■ 11. 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.

* * * * *

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

§ 133.106 Blue cheese.

* * * * *

(b) * * *

(3) * * *

(vii) Salt substitute.

* * * * *

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

§ 133.108 Brick cheese.

* * * * *

(b) * * *

(3) * * *

(v) Salt substitute.

* * * * *

■ 14. 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.

* * * * *

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

§ 133.113 Cheddar cheese.

* * * * *

(b) * * *

(3) * * *

(vi) Salt substitute.

* * * * *

■ 16. 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.

* * * * *

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

§ 133.123 Cold-pack and club cheese.

* * * * *

(c) * * *

(3) Salt or salt substitute.

* * * * *

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

§ 133.124 Cold-pack cheese food.

* * * * *

(e) * * *

(3) Salt or salt substitute.

* * * * *

■ 19. 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.

* * * * *

■ 20. In § 133.129, revise paragraphs (b)(1)(i) through (b)(1)(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; 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.

* * * * *

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

§ 133.133 Cream cheese.

* * * * *

(b) * * *

(3) * * *

(i) Salt or salt substitute.

* * * * *

■ 22. 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.

* * * * *

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

§ 133.138 Edam cheese.

* * * * *

(b) * * *

(3) * * *

(v) Salt substitute.

* * * * *

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

§ 133.141 Gorgonzola cheese.

* * * * *

(b) * * *

(3) * * *

(vii) Salt substitute.

* * * * *

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

§ 133.144 Granular and stirred curd cheese.

* * * * *

(b) * * *

(3) * * *

(vi) Salt substitute.

* * * * *

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

§ 133.147 Grated American cheese food.

* * * * *

(c) * * *

(5) Salt or salt substitute.

* * * * *

■ 27. 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.

* * * * *

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

§ 133.149 Gruyere cheese.

* * * * *

(b) * * *

(3) * * *

(iv) Salt substitute.

* * * * *

■ 29. 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

* * * * *

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

§ 133.152 Limburger cheese.

* * * * *

(b) * * *

(3) * * *

(iv) Salt substitute.

* * * * *

■ 31. 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.

* * * * *

■ 32. 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.

* * * * *

■ 33. 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.

* * * * *

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

§ 133.160 Muenster and munster cheese.

* * * * *

(b) * * *

(3) * * *

(vi) Salt substitute.

* * * * *

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

§ 133.162 Neufchatel cheese.

* * * * *

(b) * * *

(3) * * *

(i) Salt or salt substitute.

* * * * *

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

§ 133.164 Nuworld cheese.

* * * * *

(b) * * *

(3) * * *

(iv) Salt substitute.

* * * * *

■ 37. 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.

* * * * *

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

§ 133.169 Pasteurized process cheese.

* * * * *

(d) * * *

(4) Salt or salt substitute.

* * * * *

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

§ 133.173 Pasteurized process cheese food.

* * * * *

(e) * * *

(4) Salt or salt substitute.

* * * * *

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

§ 133.179 Pasteurized process cheese spread.

* * * * *

(f) * * *

(5) Salt or salt substitute.

* * * * *

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

§ 133.181 Provolone cheese.

* * * * *

(b) * * *

(3) * * *

(vi) Salt substitute.

* * * * *

■ 42. In § 133.182, revise the tenth sentence in paragraph (b) and revise paragraph (c)(2) to read as follows:

§ 133.182 Soft ripened cheeses.

* * * * *

(b) * * * Salt or salt substitute may be added during the procedure. * * *

* * * * *

(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.

* * * * *

■ 43. 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.

* * * * *

■ 44. 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.

* * * * *

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

§ 133.185 Samsoe cheese.

* * * * *

(b) * * *

(3) * * *

(v) Salt substitute.

* * * * *

■ 46. 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.''

* * * * *

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

§ 133.187 Semisoft cheeses.

* * * * *

(b) * * * Salt or salt substitute may be added during the procedure. * * *

* * * * *

(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. * * *

* * * * *

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

§ 133.188 Semisoft part-skim cheeses.

* * * * *

(b) * * * Salt or salt substitute may be added during the procedure. * * *

* * * * *

(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. * * *

* * * * *

■ 49. 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.

* * * * *

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

§ 133.190 Spiced cheeses.

* * * * *

(b) * * *

(3) * * *

(iii) Salt or salt substitute.

* * * * *

■ 51. 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

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

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

■ 53. 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,'' 21st Ed. (2019), 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. 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.

* * * * *

PART 137—CEREAL FLOURS AND RELATED PRODUCTS

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

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

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

Subpart A—General Provisions.

Sec.

137.10 Incorporation by reference.

137.20 through 137.100 [Reserved]

Subpart A—General Provisions.

§ 137.10 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. 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:

(a) Official Methods of Analysis, 21st Ed. (2019);

(1) AOAC Official Method 923.02A, Reagent; IBR §§ 137.180(c); 137.270(b).

(2) AOAC Official Method 923.02B, Apparatus, under Carbon Dioxide (Total) in Baking Powders Gasometric Determination; IBR §§ 137.180(c); 137.270(b).

(3) Reference Table 909.04, Correction Factors for Gasometric Determination of Carbon Dioxide; IBR §§ 137.180(c); 137.270(b).

(b) [Reserved]

§§ 137.20 through 137.100 [Reserved]

■ 56. 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, Reagent, and 923.02B, Apparatus, under Carbon Dioxide (Total) in Baking Powders Gasometric Determination (incorporated by reference, see § 137.10): Instead of using AOAC Official Method 923.02C, Determination, 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, ''Correction Factors for Gasometric Determination of Carbon Dioxide'', incorporated by reference, see § 137.10) 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.

* * * * *

■ 57. 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, Reagent, and 923.02B, Apparatus, under Carbon Dioxide (Total) in Baking Powders Gasometric Determination (incorporated by reference, see § 137.10): Instead of using AOAC Official Method 923.02C, Determination, 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 bulk 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, ''Correction Factors for Gasometric Determination of Carbon Dioxide'' (incorporated by reference, see § 137.10) 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.

* * * * *

PART 139—MACARONI AND NOODLE PRODUCTS

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

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

■ 59. Add subpart A, consisting of §§ 1397.10 through 139.100, to read as follows:

Subpart A—General Provisions.

Sec.
139.10 Incorporation by reference.
139.20 through 139.100 [Reserved]

Subpart A—General Provisions.

§ 139.10 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. 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.

(a) Official Methods of Analysis, 21st Ed. (2019);

(1) AOAC Official Method 926.07A, Vacuum Oven Method, under Solids (Total) and Loss on Drying (Moisture) in Macaroni Products; IBR §§ 139.110(a); 139.150(a).

(2) [Reserved]

(b) [Reserved]

§§ 139.20 through 139.100 [Reserved]

■ 60. 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 § 139.10).

* * * * *

■ 61. 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 § 139.10). 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

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

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

■ 63. In § 145.110, revise paragraphs (a)(1) and (a)(2)(iii) to 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,'' in ''Official Methods of Analysis of AOAC INTERNATIONAL,'' 21st Ed. (2019), 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. 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.

(2) * * *

(iii) Salt or salt substitute.

* * * * *

■ 64. In § 145.130, revise paragraph (a)(5) to read as follows:

§ 145.130 Canned figs.

(a) * * *

(5) Salt or salt substitute.

* * * * *

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

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

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

■ 66. Add subpart A, consisting of §§ 150.10 through 150.100, to read as follows:

Subpart A—General Provisions.

Sec.
150.10 Incorporation by reference.
150.20 through 150.100 [Reserved]

Subpart A—General Provisions.

§ 150.10 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. 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.

(a) Official Methods of Analysis, 21st Ed. (2019);

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

(2) AOAC Official Method 932.14C, By Means of Refractometer, under Solids in Syrups; IBR § 150.110(d).

(b) [Reserved]

§§ 150.20 through 150.100 [Reserved]

■ 67. In § 150.110, revise paragraphs (c)(4), (d)(3), and (d)(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 § 150.10).

* * * * *

(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, under Solids in Syrups (incorporated by reference, see § 150.10); the weight of diluted concentrated juice from any other fruits is the original weight of the juice before it was diluted or concentrated.

* * * * *

PART 155—CANNED VEGETABLES

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

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

■ 69. Add § 155.10 to subpart A to read as follows:

§ 155.10 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. 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.

(a) Official Methods of Analysis, 21st Ed. (2019);

(1) Table 1, ''Nominal Dimensions of Standard Test Sieves (USA Standard Series),'' under the heading ''Definition of Terms and Explanatory Notes''; IBR §§ 155.120(b); 155.130(b).

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

(b) [Reserved]

■ 70. In § 155.120, revise paragraphs (a)(3)(i) and (b)(2)(i) to 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 lbs) and 30.5 cm (12 in) if such quantity is 1.36 kg (3 lbs) or more. The bottom of the sieve is woven-wire cloth that complies with the specifications of such cloth set forth in ''Official Methods of Analysis'', Table 1, ''Nominal Dimensions of Standard Test Sieves (USA Standard Series),'' under the heading ''Definition of Terms and Explanatory Notes,'' (incorporated by reference, see § 155.10). 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.

* * * * *

■ 71. In § 155.130, revise paragraphs (a)(3)(i) and (b)(2)(i) to 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 lbs), and 30.5 cm. (12 in) if such quantity is 1.36 kg. (3 lbs) or more. The bottom of the sieve is woven-wire cloth that complies with the specifications for such sieve set forth in ''Official Methods of Analysis'', Table 1, ''Nominal Dimensions of Standard Test Sieves (USA Standard Series),'' under the heading ''Definition of Terms and Explanatory Notes'' (incorporated by reference, see § 155.10). 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.

* * * * *

■ 72. In § 155.170, revise paragraph (a)(2)(i), and paragraphs (b)(1)(iii) and (vi) to 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 tAOAC Official Method 938.10(incorporated by reference, see § 155.10).

* * * * *

■ 73. In § 155.190, revise paragraph (a)(2)(iv) to read as follows:

§ 155.190 Canned tomatoes.

(a) * * *

(2) * * *

(iv) Salt or salt substitute.

* * * * *

■ 74. In § 155.191, revise paragraph (a)(2)(i) to read as follows:

§ 155.191 Tomato concentrates.

(a) * * *

(2) * * *

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

* * * * *

■ 75. In § 155.194, revise paragraph (a)(1)(iv) to read 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.

* * * * *

■ 76. 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.

* * * * *

■ 77. 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

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

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

■ 79. In § 156.145, revise paragraph (a)(1) to read 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

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

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

■ 81. In § 158.170, revise paragraphs (a)(1)(iv) and (b)(1)(iii) to 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

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

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

■ 83. Add § 161.10 to read as follows:

§ 161.10 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. For information on the availability of this material at NARA, visitn *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.

(a) Official Methods of Analysis, 21st Ed. (2019);

(1) Table 1, ''Nominal Dimensions of Standard Test Sieves (USA Standard Series),'' under the heading ''Definition of Terms and Explanatory Notes''; IBR §§ 161.145(c); 161.173(c); 161.190(a)(7).

(2) [Reserved]

(b) [Reserved]

■ 84. 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 ''Official Methods of Analysis,'' Table 1, ''Nominal Dimensions of Standard Test Sieves (USA Standard Series),'' under the heading ''Definition of Terms and Explanatory Notes,'' (incorporated by reference, see § 161.10). 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.

* * * * *

■ 85. In § 161.170, revise paragraph (a)(4)(i) to read as follows:

§ 161.170 Canned Pacific salmon.

(a) * * *

(4) * * *

(i) Salt or salt substitute.

* * * * *

■ 86. In § 161.173, revise paragraphs (a)(4)(i) and (c)(1) to 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 ''Official Methods of Analysis'' (incorporated by reference, see § 161.10), Table 1, ''Nominal Dimensions of Standard Test Sieves (USA Standard Series), under the heading ''Definition of Terms and Explanatory Notes'' (incorporated by reference, see § 161.10) 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.

* * * * *

■ 87. In § 161.190, revise paragraphs (a)(6)(i) and (a)(7) introductory text to 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 ¼-inch mesh complying with the specifications for such cloth set forth in ''Official Methods of Analysis'', Table 1, ''Nominal Dimensions of Standard Test Sieves (USA Standard Series),'' under the heading ''Definitions of Terms and Explanatory Notes'' (incorporated by reference, see § 161.10) 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 ½-inch deep and painted flat black inside and outside) so that after tamping and smoothing the surface of the sample the material will be ⅛-inch to ¼-inch below the top of the container. Within 10 minutes after sieving through the ¼-inch mesh woven-wire cloth, determine the Munsell value of sample surface.

* * * * *

PART 163—CACAO PRODUCTS

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

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

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

§ 163.111 Chocolate liquor.

* * * * *

(b) * * *

(6) Salt or salt substitute.

* * * * *

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

§ 163.112 Breakfast cocoa.

* * * * *

(b) * * *

(4) Salt or salt substitute.

* * * * *

■ 91. 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;

* * * * *

■ 92. 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;

* * * * *

■ 93. 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

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

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

■ 95. In § 166.110, revise paragraphs (a) and (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 938.06A, ''Indirect Method, under Fat in Butter,'' found in ''Official Methods of Analysis of AOAC INTERNATIONAL,'' 21st Ed. (2019), 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. 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. 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

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

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

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

§ 168.130 Cane sirup.

* * * * *

(b) * * *

(1) Salt or salt substitute.

* * * * *

■ 98. 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.

* * * * *

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

§ 168.160 Sorghum sirup.

* * * * *

(b) * * *

(1) Salt or salt substitute.

* * * * *

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

§ 168.180 Table sirup.

* * * * *

(b) * * *

(7) Salt or salt substitute.

* * * * *

PART 169—FOOD DRESSINGS AND FLAVORINGS

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

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

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

§ 169.140 Mayonnaise.

* * * * *

(d) * * *

(1) Salt or salt substitute.

* * * * *

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

§ 169.150 Salad dressing.

* * * * *

(e) * * *

(1) Salt or salt substitute.

* * * * *

Dated: March 23, 2023.

Robert M. Califf,

Commissioner of Food and Drugs.

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