develop data collection protocols and standards for machine readability. Other federal financial regulators will push this requirement to its registrants and supervised entities to collect, maintain, and submit data pursuant to these data transparency protocols and standards. This will impact registrants in our space that are dual registered with those financial regulators, and who will need to comply with those protocols and standards.

I look forward to hearing from members of industry, investor and consumer advocates, academics, and other stakeholders on these questions. I thank the staff for their work on this issue.

Appendix 5—Statement of Commissioner Caroline D. Pham

I support the Notice of Proposed Rulemaking on Swap Confirmation Requirements for Swap Execution Facilities (SEF Confirmation Proposal) because the Commission is finally fixing unworkable rules that have defied the reality of market structure, legal documentation, and operational processes since they were first issued in 2013. I would like to thank Roger Smith, Nora Flood, and Vince McGonagle in the Division of Market Oversight for their work on the SEF Confirmation Proposal.

As I previously stated, the Commission must take action to fix unworkable rules by codifying ''perpetual'' no-action relief through notice-and-comment rulemaking as required by the Administrative Procedure Act.[1] I am pleased that we are doing so today.

The Dodd-Frank Act amended the Commodity Exchange Act (CEA) to establish the SEF regulatory framework in order to reduce risk, promote transparency, and enhance market integrity for over-the-counter (OTC) derivatives.[2] Following that mandate, the CFTC implemented Part 37, which requires, among other things, that SEFs provide written final confirmation for uncleared swaps at the time of execution.[3] Moreover, Rule 37.6(b) requires that SEFs provide each counterparty ''a written record of all of the terms of the transaction which shall legally supersede any previous agreement and serve as a confirmation of the transaction.'' Contrary to its intent, this requirement actually *undermines* legal certainty by potentially voiding carefully negotiated and highly technical and complex legal agreements.[4] These provisions, while well-intentioned, have proven impracticable (if not impossible) for both SEFs and market participants. In fact, the requirement to provide SEF confirmation at the time of execution is temporally impossible for block trades, which are executed away from the SEF and then submitted to the SEF afterwards.

After hearing from the public, CFTC staff provided no-action relief in 2014 that has been extended repeatedly in order to provide a practical solution that could be implemented and would still support the CFTC's public and regulatory transparency requirements. For example, the no-action relief provided that SEFs could incorporate prior agreements to a transaction by reference, instead of receiving hundreds of thousands of pages of legal agreements, such as bilateral counterparty swap trading relationship documentation, and then attaching hundreds of pages to SEF confirmations.[5] This requirement was unworkable in light of Part 23 rules for swap dealers, and for a SEF to collect such legal documentation from swap counterparties and then to maintain it continuously on an ongoing basis (since these bilateral agreements are occasionally revised), turns SEFs into giant legal document repositories of questionable benefit.

Once CFTC staff realized the unrealistic nature of these SEF confirmation requirements, I believe the staff very prudently issued no-action relief. And I believe that this was an appropriate exercise of no-action relief because in the rush to implement the Dodd-Frank Act, the Commission did not always get it right.

When we don't get it right, it is incumbent upon the Commission to acknowledge technical and operational issues and fix them. I look forward to public comment, particularly whether this proposal sufficiently fixes the unworkable aspects of our existing rules. Thank you.

[FR Doc. 2023–17747 Filed 8–24–23; 8:45 am]

BILLING CODE 6351–01–P

[1] Statement of Commissioner Caroline D. Pham on Conditional Order of SEF Registration, U.S. Commodity Futures Trading Commission (July 20, 2022), *https://www.cftc.gov/PressRoom/SpeechesTestimony/phamstatement072022.*

[2] Core Principles and Other Requirements for Swap Execution Facilities, 76 FR 1213, 1214 (Jan. 7, 2011) (codified at 17 CFR part 37).

[3] *See* 17 CFR 37.6(b) (''The confirmation of all terms of the transaction shall take place at the same time as execution.'').

[4] *Id.*

[5] *See, e.g.,* NAL No. 17–17, Re: Extension of No-Action Relief for Swap Execution Facility Confirmation and Recordkeeping Requirements under Commodity Futures Trading Commission Regulations 37.6(b), 37.1000, 37.1001, 45.2, and 45.3(a) (Mar. 24, 2017).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 161

[Docket No. FDA–2016–P–0147]

RIN 0910–AI74

Fish and Shellfish; Canned Tuna Standard of Identity and Standard of Fill of Container

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA or we) is proposing to amend the standard of identity and standard of fill of container for canned tuna. This action partially responds to a citizen petition submitted by Bumble Bee Foods, LLC, StarKist Co., and Tri Union Seafoods, LLC (doing business as Chicken of the Sea International). We tentatively conclude that this action, if finalized, will promote honesty and fair dealing in the interest of consumers.

DATES: Either electronic or written comments on the proposed rule must be submitted by November 24, 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 November 24, 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: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 *https://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, we 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–2016–P–0147 for ''Fish and Shellfish; Canned Tuna Standard of Identity and Standard of Fill of Container.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

• Confidential Submissions—To submit 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 *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

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

FOR FURTHER INFORMATION CONTACT: Jennifer Shemansky, Center for Food Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2371, or Holli Kubicki, 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 and Coverage of the Proposed Rule

FDA is proposing to revise the canned tuna standard of identity and standard of fill of container established at § 161.190 (21 CFR 161.190). The proposed rule, if finalized, will modernize and update these food standards and is in partial response to a citizen petition submitted by Bumble Bee Foods, LLC, StarKist Co., and Tri Union Seafoods, LLC (doing business as (dba) Chicken of the Sea International) (the petitioners). The proposed rule would:

• replace the pressed cake weight method with the drained weight method to determine the standard fill of container (see proposed § 161.190(a)(3)(ii) and (iii), (a)(7), and (c));

• revise the introductory text in § 161.190(a)(5) thereby clarifying that use of a packing medium is optional;

• remove provisions for specific flavorings and spices (*i.e.,* monosodium glutamate currently in § 161.190(a)(6)(ii), spices or spice oils or spice extracts currently in § 161.190(a)(6)(iv), garlic currently in § 161.190(a)(6)(vi), and lemon flavoring currently in § 161.190(a)(6)(vii)), which are covered under § 101.22(a) (21 CFR 101.22(a)), to avoid redundancy;

• revise § 161.190(a)(6)(ii) to allow use of safe and suitable optional ingredients in accordance with § 101.22, and remove the discussion of safe and suitable carriers, solubilizing, or dispersing ingredients that may be used in combination with a flavoring or spice ingredient currently in § 161.190(a)(6)(vii);

• revise § 161.190(a)(1) to move the optional ingredient of sodium acid pyrophosphate to proposed § 161.190(a)(6)(v) and revise § 161.190(a)(8)(vii) regarding the labeling of canned tuna products containing sodium acid pyrophosphate to update the cross-reference from paragraph (a)(1) to paragraph (a)(6)(v);

• revise the upper and lower limits of vegetable extractives under § 161.190(a)(6)(iii) pertaining to amount of vegetable broth allowed to be used as an optional ingredient;

• amend § 161.190(a)(8)(vi) for clarity and consistency with other label declaration provisions in the Code of Federal Regulations (CFR);

• add a provision at § 161.190(a)(8)(x) for clarity and consistency with food standards in 21 CFR parts 131 through 169, which include a similar provision for label declaration information;

• revise § 161.190(a)(7) to update the method for determining the Munsell value and remove the incorporation by reference text regarding the Journal of the Optical Society of America (in current § 161.190(a)(7)(iii));

• add paragraph (d) to § 161.190 to update the incorporation by reference information (currently found in § 161.190(a)(7)); and

• revise language throughout the section to improve clarity and readability.

B. Legal Authority

We are issuing this proposed rule under section 401 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 341), which grants FDA the authority to establish a reasonable definition and standard of identity, a reasonable standard of quality, or reasonable standards of fill of container if such actions will promote honesty and fair dealing in the interest of consumers. There are already standards of identity and fill of container in place for canned tuna (§ 161.190(a) and (c), respectively). We tentatively conclude that revising these food standards will promote honesty and fair dealing in the interest of consumers. Allowing for

more flexibility and for the use of modern methods in the standards will allow for production of a wider range of products to meet consumer tastes and preferences.

C. Costs and Benefits

We estimate benefits of the proposed rule, if finalized. We estimate ongoing annual cost savings ranging from approximately $4 million to $15.9 million at a 3 percent discount rate, and approximately $3.9 million to $15.8 million at a 7 percent discount rate. Our primary annualized estimates are approximately $7.9 million at both the 3 percent and 7 percent discount rates. The primary estimate of the present value of total cost savings in the 10 years following any final rule that may be issued based on the proposed rule is $67.6 million at a 3 percent rate of discount and $55.4 million at a 7 percent rate of discount. Manufacturers and consumers may benefit from other provisions of the proposed rule, if finalized, but these impacts are harder to quantify.

The costs of the proposed rule, if finalized, are associated with costs to industry for reading and understanding the rule, training employees on new requirements, and the purchase of new equipment. These are one-time costs that industry incurs immediately after any final rule that may be issued based on this proposed rule passes its compliance date. When annualized over a period of 10 years, we estimate these costs range from approximately $3,800 to $6,000 at a 3 percent discount rate, and approximately $4,500 to $7,100 at a 7 percent discount rate. Our primary annualized estimates are approximately $4,900 at a 3 percent discount rate and $5,800 at a 7 percent discount rate. The primary estimate of total costs in the 10 years following any final rule that may be issued based on this proposed rule is $41,600 at a 3 percent discount rate and $40,600 at a 7 percent discount rate.

II. Background

A. Need for the Regulation—Citizen Petition and Temporary Marketing Permits

Bumble Bee Foods, LLC, StarKist Co., and Tri Union Seafoods, LLC (dba Chicken of the Sea) submitted a citizen petition (FDA–2016–P–0147) requesting that we amend § 161.190 to:

- base the standard of fill of container on the product's drained weight rather than the pressed cake weight;
- require that the net contents declaration include both the net weight and drained weight;
- provide that use of a packing medium is optional;
- permit the use of any flavoring;
- limit the amount of vegetable broth that may be added as a flavoring based on the dry weight of the vegetable extractives;
- provide that a label statement about added salt is optional; and
- specify that canned tuna is packed in hermetically sealed rigid metal cans to clarify that pouch tuna products are not covered by the standard of identity.

(See Citizen Petition from Steven Mavity, Senior Vice President, Technical Services & Corporate Quality, Bumble Bee Foods, LLC, Nabil Salib, Vice President of Operations, StarKist Co., and John DeBeer, Vice President, Tri-Union Seafoods, LLC (dba Chicken of the Sea International), to Division of Dockets Management, Food and Drug Administration, dated September 3, 2015 (''petition'') at page 1.) The proposed rule would revise the canned tuna standard of fill of container and standard of identity in partial response to the petition.

In addition to submitting a citizen petition, the petitioners submitted applications for temporary marketing permits (TMP) to market test products (designated as ''canned tuna'' products) that deviate from the requirements in § 161.190. We issued the temporary permits to each applicant in accordance with 21 CFR 130.17 (see 79 FR 35362, June 20, 2014). The temporary permits covered limited interstate marketing tests of products identified as ''canned tuna.'' These test products deviated from § 161.190 in that they did not meet the standard of fill of container and were not labeled with the statement ''Below Standard in Fill'' as required in § 161.190(c)(4) and 21 CFR 130.14(b). The TMPs allowed applicants to test market canned tuna products using a standard fill of container based on the drained weight rather than the pressed cake weight. The TMPs also allowed applicants to provide a net quantity of contents declaration that includes both the net and drained weight. In the **Federal Register** of March 7, 2016 (81 FR 11813), we announced an extension of the temporary permits. The extension allowed the applicants to continue to measure consumer acceptance of the products and assess the commercial feasibility of the products, in support of the petition to amend § 161.190. The new expiration date for the permits is either the effective date of a final rule amending § 161.190 that may result from the petition or 30 days after denial of the petition. All other conditions and terms of the permits remained the same (see 81 FR 11813). In the March 7, 2016, notice, we invited other interested parties to participate in the market test (id.). To date, FDA has approved several firms to participate in the market test. In the **Federal Register** of March 5, 2021 (86 FR 12954), we published a notice amending StarKist Co.'s temporary permit to add three manufacturing locations and to increase the amount of test product. More recently, in the **Federal Register** of December 28, 2021 (86 FR 73789), we published a notice adding a manufacturing location for both Bumble Bee Foods, LLC and StarKist Co. and to increase the amount of test product that could be marketed by StarKist Co. We also published a notice in the **Federal Register** of December 21, 2022 (87 FR 78110), allowing StarKist Co. to manufacture test product at one additional plant.

These active TMPs for canned tuna products allowed applicants to deviate from § 161.190 so the standard fill of container is based on the drained weight method rather than the pressed cake weight method. Based on input from the industry, we understand that use of the pressed weight method is outdated. Products using the drained weight method appear to have gained consumer acceptance since becoming available. Our proposed amendments to § 161.190 will modernize multiple aspects and requirements of the standards, including allowing use of the drained weight method.

B. FDA's Food Standards Modernization

Section 401 of the FD&C Act specifically states that standards are meant to promote honesty and fair dealing in the interest of the consumer. Food standards typically set forth permitted ingredients, both mandatory and optional, and sometimes specify the amount or proportion of each ingredient. Many food standards also designate the method of production. Since we established many food standards decades ago, various stakeholders have expressed concerns that many food standards are out of date and may impede innovation. The goal in updating or modernizing food standards is to maintain the basic nature and essential characteristics of standardized foods, while permitting flexibility for more modern methods, technologies, or new ingredients, as well as continued innovations (see *https://www.fda.gov/food/food-labeling-nutrition/standards-identity-food*). We seek to modernize food standards in a manner that will: (1) protect consumers against economic adulteration; (2) maintain the food's basic nature, essential characteristics, and nutritional integrity; and (3) promote industry innovation and provide flexibility to encourage manufacturers to produce more healthy

foods (see 84 FR 45497 at 45499, August 29, 2019).

Amending the canned tuna standards may help modernize these food standards and may provide consumers with a wider variety of choices of tuna products. Additional choices of tuna products could lead to increased consumption. The 2020–2025 Dietary Guidelines for Americans (Ref. 1 at page 34) (see also *https://www.dietaryguidelines.gov*) notes almost 90 percent of Americans do not meet the recommendation for seafood intake.

C. Incorporation by Reference

The proposed rule, if finalized, would incorporate by reference Definitions of Terms and Explanatory Notes from Table 1, Nominal Dimensions of Standard Test Sieves (U.S.A. Standard Series), in Official Methods of AOAC INTERNATIONAL, 22nd Ed. (2023). The Office of the Federal Register (OFR) has regulations concerning incorporation by reference (see 1 CFR part 51). These regulations require that, for a final rule, Agencies must discuss in the preamble to the rule the way in which materials that the Agency incorporates by reference are reasonably available to interested persons, and how interested parties can obtain the materials. Additionally, the preamble to the rule must summarize the material (see 1 CFR 51.5(b)).

In accordance with the OFR's requirements, the discussion in section IV.C. of this document summarizes the required provisions of the material that we propose to incorporate by reference. Interested persons 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. AOAC INTERNATIONAL provides access to table 1 at *https://academic.oup.com/aoac-publications/book/45491/chapter/392327291.*

III. Legal Authority

We are issuing this proposed rule under section 401 of the FD&C Act, which grants FDA the authority to establish a reasonable definition and standard of identity, a reasonable standard of quality, or reasonable standards of fill of container if such actions will promote honesty and fair dealing in the interest of consumers. Canned tuna is among the foods that FDA has standardized under this authority (see § 161.190). Standards of identity and fill of container were established for canned tuna in 1957 (see 22 FR 892, February 13, 1957). Although the standards have been amended several times, certain requirements appear to be outdated. We tentatively conclude that amending these requirements in the standards will promote honesty and fair dealing in the interest of consumers. Allowing for more flexibility and for the use of modern methods in the standards will allow for production of a wider range of products to meet consumer tastes and preferences.

IV. Description of the Proposed Rule

We are proposing to amend our canned tuna standard of identity and standard of fill of container (§ 161.190). The proposed rule would allow industry to use the internationally accepted drained weight method, further clarify the standards, and permit more flexibility. The proposed rule also would further clarify whether certain ingredients are optional within the standard of identity.

A. Proposed Amendments to the Standard of Fill of Container

The current standard of fill of container for canned tuna requires that the pressed cake weight method be used (see § 161.190(c)(1)). The petition requested, in part, that the pressed cake weight method be replaced with the drained weight method (petition at pages 1 and 9).

We agree that the pressed cake weight method should be replaced with the drained weight method. We do not agree with the petitioners' suggestion to base the drained weight method for canned tuna products solely on the AOAC Official Method 968.30 Canned Vegetables: Drained Weight Procedure (petition at page 7). This method is specific for canned vegetables and requires modification for canned tuna. We propose to use a drained weight method that is based on both the drained weight method specified in the Codex standard for canned tuna and bonito (CODEX STAN 70–1981) (Ref. 2) and the AOAC method 968.30 (Ref. 3). Although both methods are very similar, the Codex standard helps to provide necessary details to modify the AOAC method 968.30 for canned tuna.

The proposed rule would delete the text in § 161.190(c) ''*Fill of container*'' and replace it with text on the drained weight method. The proposed rule would, however, keep the provision currently at § 161.190(c)(4) for canned tuna that falls below the applicable standard of fill of container, but would redesignate it as § 161.190(c)(3) to be consistent with other proposed changes to the standard. The proposed rule also would update certain provisions in the canned tuna standard of identity to reflect the proposed change from the pressed cake weight method to the drained weight method. Specifically, the proposed rule would change the specifications for chunk and flake tuna in § 161.190(a)(3)(ii) and (iii), respectively, so they will be based on the ''drained weight of the contents of the container'' instead of the ''pressed contents'' of the container. Additionally, the proposed rule would amend § 161.190(a)(7) so that portions of the drained product are combined rather than starting with a pressed cake. To maintain the structure of the standard, the proposed rule would redesignate other sections of the current standard and replace the pressed cake weight method with the drained weight method in the redesignated paragraphs. Specifically, the proposed rule would redesignate the determination of free flakes in § 161.190(c)(2)(xi) as § 161.190(c)(2)(i) and revise the newly designated paragraph (c)(2)(i). The proposed rule would redesignate determination of particle size from § 161.190(c)(2)(xii) to § 161.190(c)(2)(ii) and revise newly designated paragraph (c)(2)(ii). The redesignated paragraphs in paragraphs (c)(2)(i) and (ii) would be revised to incorporate the drained weight method. The proposed rule also would redesignate the paragraph that describes a sieving device used for size separation in § 161.190(c)(3)(iv) as § 161.190(c)(2)(iii).

We are proposing these changes because the pressed cake weight method is only required in the U.S. canned tuna standards and does not align with current industry practice in the United States. For example, the pressed cake weight method relies upon using a 3-piece can, but the current industry practice is to use a 2-piece can. In comparison, the type of packaging is irrelevant when using the drained weight method. The pressed cake weight method relies on more complex instrumentation and requires more steps than the drained weight method, resulting in a more costly procedure with a wider margin of error than the drained weight method. The pressed cake weight method is therefore more difficult to perform, more prone to human error, and may produce inconsistent results compared with the drained weight method. The drained weight method is used in the production of many other foods, both

domestically and internationally. FDA food standards require the drained weight method in production of canned fruit cocktail, canned pineapple, canned green beans and canned wax beans, canned tomatoes, canned mushrooms, and canned oysters (see 21 CFR 145.135, 145.180, 155.120, 155.190, 155.201, and 161.145, respectively). Compared to the pressed cake weight method, the drained weight method is easier to perform, and produces more consistent and reliable results. The drained weight method can be performed using a balance or a food scale and a sieve or strainer.

The proposed amendments to § 161.190(c) differ from what the petition requested because we describe the drained weight method for use with canned tuna products in the standard. The proposed drained weight method is based on both the Codex standard for canned tuna and bonito (Ref. 2) and the AOAC drained weight method for canned vegetables (Ref. 3). Both the proposed drained weight method and the Codex standard contain more details than the AOAC drained weight method requested in the petition. The Codex standard gives clear, easy-to-follow instructions that are specific for canned tuna products. The proposed drained weight method aims for clarity, readability, and ease of implementation. As a result, the proposed canned tuna standard of fill incorporates much of the Codex standard, except the units are changed to include both the imperial system as well as the metric system (for example, including temperature ranges in both Fahrenheit and Celsius, and sieve sizes in inches and centimeters). However, we propose to maintain some components of the current pressed cake weight method, such as the temperature range. We are also proposing to maintain using the average weight from 24 cans but modifying it to use the average weight from a minimum of 24 containers to allow manufacturers to adjust their sampling amount for larger production volumes, if needed.

Additionally, we disagree with the petitioners' request to limit the standard to rigid metal cans (petition at pages 1, 2, and 10). The proposed drained weight method may be used for any type of hermetically sealed container (*e.g.,* can, pouch, jar), in contrast to the pressed cake method, which required the use of rigid metal cans to meet the requirements. Accordingly, we have not proposed any conforming changes to limit the standard of identity to rigid metal containers in § 161.190(a)(1) as the petition requested. In addition, to help make clear that hermetically sealed containers in which canned tuna is packed may include containers other than rigid metal cans, we are proposing to revise § 161.190(a)(3)(i) to consistently refer to ''container'' or ''containers'' rather than ''can'' or ''cans.''

Unlike the pressed cake weight method, the drained weight method is simple enough that a consumer could check the amount of tuna at home if they wanted to verify the amount of tuna in the package. The switch from the pressed cake weight method to the drained weight method may promote honesty and fair dealing in the interest of the consumer.

B. Proposed Amendments to the Standard of Identity

1. Clarification That a Packing Medium Is Optional

The petition requested that we provide that the use of a packing medium is optional (petition at pages 1 and 9). Under our current regulations, the use of packing media is optional (§ 161.190(a)(5)); however, to further clarify, the proposed rule would revise the introductory paragraph of § 161.190(a)(5) to read ''*Optional packing media.* Canned tuna may be in one or more of the following optional packing media:''. We propose to add a paragraph heading to help improve clarity of the section. We also propose a conforming revision to paragraph (a)(1) to read, in relevant part, ''. . . may be in one or more of the optional packing media specified in paragraph (a)(5) of this section, . . .''.

2. Revocation of the Requirement That Canned Tuna Bear a Label Statement When Salt Is Used as an Optional Ingredient

Under our current regulations, salt is an optional ingredient (see § 161.190(a)(6)(i)). If salt is used as an ingredient, the label of canned tuna must bear the statement ''seasoned with salt'' (§ 161.190(a)(8)(vi)). Alternatively, the label may bear any of the statements ''salted,'' ''with added salt,'' or ''salt added'' if salt is the only seasoning ingredient used. The petition requested that we make a label statement about added salt optional (petition at pages 1 and 10).

We agree that a label statement about salt should not be mandatory given that salt must be declared on the label in the ingredient statement (see section 403(i)(2) of the FD&C Act (21 U.S.C. 343(i)(2)) and § 101.4 (21 CFR 101.4(a))). We also note that salt is not a characterizing ingredient that differentiates canned tuna varieties such as those seasoned with flavorings and spices, vegetable broth, or vegetable oil(s). Consequently, we propose to amend § 161.190(a)(8)(vi) to only apply to the characterizing ingredients in § 161.190(a)(6)(ii) through (iv) and not to salt.

In addition, the proposed rule would clarify § 161.190(a)(6) so it is easily understood that salt is an optional ingredient. The proposed rule would amend the introductory paragraph in § 161.190(a)(6) to include the heading ''*Optional Ingredients.* One or more of the following safe and suitable optional ingredients may be used:''. This proposed change also would make the format in the canned tuna standard more consistent with other standards, such as the canned Pacific salmon and canned wet pack shrimp standards (see §§ 161.170 and 161.173, respectively).

3. Expand Optional Ingredients To Allow for Safe and Suitable Flavorings and Spices in Accordance With § 101.22

Our current regulations list seasonings and flavorings with which canned tuna may be seasoned or flavored (§ 161.190(a)(6)). The petition requested that FDA permit the use of any flavoring (petition at pages 1 and 9).

We agree that the canned tuna standard is restrictive regarding the use of flavorings. The proposed rule would amend § 161.190(a)(6)(ii) to permit flavorings and spices in accordance with § 101.22 as optional ingredients. The proposed rule would make corresponding revisions to § 161.190(a)(1) by changing ''seasonings and flavorings'' to ''safe and suitable optional ingredients.'' To avoid redundancy, the proposed rule would remove monosodium glutamate (currently listed in § 161.190(a)(6)(ii)), spices or spice oils or spice extracts (currently listed in § 161.190(a)(6)(iv)), garlic (currently listed in § 161.190(a)(6)(vi)), and lemon flavoring (currently listed in § 161.190(a)(6)(vii)) because these ingredients are covered under § 101.22 (Foods; labeling of spices, flavorings, colorings and chemical preservatives).

The proposed rule would remove spices or spice oils or spice extracts from § 161.190(a)(6)(iv) and would group them with flavorings and spices in § 161.190(a)(6)(ii). Spice oils and spice extracts would still be permitted as optional ingredients in canned tuna because they are covered under proposed § 161.190(a)(6)(ii). Spice oils and spice extracts are covered under natural flavorings as defined in § 101.22(a)(3).

The proposed rule also would remove hydrolyzed protein (currently listed in § 161.190(a)(6)(iii)) because hydrolyzed

protein is a flavor and a flavor enhancer (see § 101.22(h)(7)) and therefore is covered under proposed § 161.190(a)(6)(ii).

The proposed rule would remove the text regarding sodium acid pyrophosphate currently in § 161.190(a)(1) and move it to proposed § 161.190(a)(6)(v). This revision would consolidate the optional ingredients in the standard and better clarify that sodium acid pyrophosphate is also an optional ingredient. The proposed rule would also revise § 161.190(a)(8)(vii) regarding labeling of canned tuna products that contain sodium acid pyrophosphate to update the cross-reference for the new location of the sodium acid phosphate optional ingredient provision from paragraph (a)(1) to paragraph (a)(6)(v). As for lemon flavoring, as stated earlier, the proposed rule would remove the lemon flavoring paragraph in § 161.190(a)(6)(vii), and it also would remove the language specific to lemon flavoring in § 161.190(a)(8)(vi) and (viii) and renumber the remaining paragraphs accordingly.

To further effectuate the changes proposed in § 161.190(a)(6)(ii) through (iv), the proposed rule would include conforming changes to the label declaration provisions in proposed § 161.190(a)(8)(vi). Specifically, we propose revising § 161.190(a)(8)(vi) to state that ''[i]f the canned tuna contains one or more of the optional ingredients in paragraphs (a)(6)(ii) through (iv) of this section, the label must appropriately declare the ingredients by the common or usual name in accordance with § 101.22. If the ingredients designated in paragraph (a)(6)(iii) of this section are used, the term 'vegetable broth' must be declared.'' The proposed rule would also add that the label statements declare the ingredients by the common or usual name ''in accordance with 21 CFR 101.22'' for clarity and consistency with our other regulations (proposed § 161.190(a)(8)(vi)) (see, for example, 21 CFR 163.111(c)(3) (Chocolate liquor) and 21 CFR 163.124(c) (White chocolate)). In addition, the proposed rule would add a provision in § 161.190(a)(8)(x) that states that ''Each of the ingredients used in the food must be declared on the label as required by the applicable sections of parts 101 and 130 of this chapter.'' The proposed revision would be consistent with other food standards (see, for example, 21 CFR 145.175(a)(4)(iv) (Canned pears) and 21 CFR 161.145(a)(4) (Canned oysters)).

Use of additional flavor profiles, along with the use of more modern methods, may help industry in producing canned tuna products that better meet evolving tastes and consumer preferences. This may help encourage tuna consumption consistent with the seafood recommendations outlined in the 2020–2025 Dietary Guidelines for Americans (Ref. 1).

We note that a notice of proposed rulemaking, ''Use of Salt Substitutes to Reduce the Sodium Content in Standardized Foods,'' proposes additional changes that would amend § 161.190(a)(6)(i) to allow the use of salt substitutes, if finalized (see 88 FR 21148, April 10, 2023). Additionally, we note that a direct final rule, ''Revocation of Uses of Partially Hydrogenated Oil in Foods'' (see 88 FR 53764, August 9, 2023), and companion notice of proposed rulemaking, ''Revocation of Uses of Partially Hydrogenated Oil in Foods; Companion Document to Direct Final Rule'' (see 88 FR 53827, August 9, 2023), revised § 161.190(a)(6)(viii) to remove partially hydrogenated vegetable oil. This proposed rulemaking would redesignate § 161.190(a)(6)(viii) as § 161.190(a)(6)(iv) to accommodate other proposed changes to § 161.190(a)(6) and proposes minor editorial changes to the language in the paragraph.

4. Revise the Upper and Lower Limits of Vegetable Extractives for Vegetable Broth Used as an Optional Flavoring Ingredient

Our current regulations state that canned tuna may be seasoned or flavored with vegetable broth in an amount not in excess of 5 percent of the volume capacity of the container, such broth to consist of a minimum of 0.5 percent by weight of vegetable extractives and to be prepared from two more of the following vegetables: beans, cabbage, carrots, garlic, onions, parsley, peas, potatoes, green bell peppers, red bell peppers, spinach, and tomatoes (see § 161.190(a)(6)(v)). The petition requested, among other things, that we revise this paragraph to limit the amount of vegetable broth that may be added as a flavoring based on the dry weight of the vegetable extractives, as well as revise the wording to reflect current industry practices and terminology (petition at pages 1, 3, and 10).

We generally agree with the petitioners' suggested rephrasing. Vegetable broth is no longer added directly to the can; it is added as extractives and water, separately. Shifting the range of permitted vegetable extractives would result in a reduction in the concentration of permitted vegetable broth in standardized canned tuna products.

We understand that the current upper limit of 5 percent vegetable extractives is likely not used due to flavor and gelling issues. We support lowering the upper limit of vegetable extractives to 2.5 percent as the petition requested (petition at page 3). However, we seek additional information regarding the rationale for the lower limit of 0.025 percent vegetable extractives requested in the petition (id.). The proposed rule would revise the upper limit range of vegetable extractives to 2.5 percent and remove the lower limit of vegetable extractives. The petition's requested lower limit of 0.025 percent vegetable extractives would add a small amount of vegetable extractives, similar to tuna packed in water. If a firm adds any vegetable extractives, regardless of the percentage, the firm must disclose the ingredients on the label (§ 101.4). We invite comments on the petitioners' request for a lower limit of 0.025 percent vegetable extractives (petition at page 3).

The proposed rule also would redesignate § 161.190(a)(6)(v) as § 161.190(a)(6)(iii) to accommodate other proposed changes to paragraph (a)(6) regarding optional ingredients.

5. Revise and Update the Method for Color Determination

The proposed rule would revise and update the method for color determination in § 161.190(a)(7). Currently, the regulation describes use of an optical comparator for determining the Munsell values for the color designations for canned tuna in § 161.190(a)(4). We propose removing the portions of § 161.190(a)(7) that are specific to the use of an optical comparator as this change will accommodate the use of electronic color meters to determine the Munsell values. Electronic color meters are likely faster, more widely used, and more objective than using an optical comparator. These proposed changes would align the level of detail for the canned tuna method for color determination with other regulations that rely on Munsell values (see, *e.g.,* Canned tomatoes (21 CFR 155.190) and Vegetable Juices (21 CFR part 156)).

Additionally, we propose to remove the incorporation by reference in § 161.190(a)(7)(iii) of the 1943 report regarding the spacing of Munsell colors published in the *Journal of the Optical Society of America.* Removing the 1943 *Journal of the Optical Society of America* reference would be consistent with other U.S. food standards, which refer to the Munsell value without citing

a source or otherwise incorporating an article by reference in support.

C. Proposed Update of Incorporation by Reference

To help with readability of the section, we propose to add a new paragraph (d) ''*Incorporation by reference.*'' for the proposed updates to the IBR paragraphs in § 161.190(a)(7).

Currently, § 161.190(a)(7) incorporates by reference the ''Official Methods of Analysis of the Association of Official Analytical Chemists,'' 13th Edition (1980), Table 1, ''Nominal Dimensions of Standard Test Sieves (U.S.A. Standard Series),'' under the heading ''Definitions of Terms and Explanatory Notes.'' We propose to update the regulation to refer to the 22nd Edition of the same table. Table 1 provides information about international and USA standard sieve sizes, including sieve designations, the nominal sieve opening (in inches), and the nominal wire diameter (in millimeters) for each sieve.

We propose several updates to the contact information for access to the IBR materials. Specifically, we propose updating the National Archives and Records Administration's (NARA's) contact information by removing the phone number, revising the URL, and adding an email address. We propose adding FDA's Dockets Management Staff contact for information regarding the availability of copies of the material incorporated by reference in proposed § 161.190(d). We also propose to update the address and to add a phone number for AOAC INTERNATIONAL.

These proposed changes will ensure that the reference materials are accessible, if needed, and in accordance with the specified requirements for incorporation by reference in the CFR. We note that a notice of proposed rulemaking, ''Use of Salt Substitutes to Reduce the Sodium Content in Standardized Foods,'' proposes a new section (§ 161.10) for the incorporation by reference information for all of part 161 (see 88 FR 21148). There is no substantive difference between the material we propose to incorporate by reference in this proposal and the proposed material incorporated by reference in the salt substitutes proposed rule.

D. Proposed Additional Revisions

We are proposing additional revisions throughout the section to improve the clarity and readability of the section and to use plain language. For example, we are proposing to add paragraph headings for paragraphs (a)(1) through (8), and we are proposing editorial changes to simplify phrasing and to use consistent terminology throughout the section.

V. Proposed Effective and Compliance Dates

We propose that any final rule that may be issued based on this proposed rule become effective 30 days after publication of the final rule in the **Federal Register**. The final rule would apply to affected products initially produced or initially delivered for introduction into interstate commerce on or after the effective date. We propose that the compliance date for any final rule that may be issued based on this proposed rule be 1 year after publication of the final rule in the **Federal Register**.

VI. Request for Information

The petition requested that we limit the amount of vegetable broth that may be added as a flavoring based on the dry weight of the vegetable extractives used (petition at page 1). The standard of identity currently states the vegetable extractives are not to exceed 5 percent of the volume capacity of the container, with a minimum broth consisting of 0.5 percent by weight of vegetable extractives (§ 161.190(a)(6)(v)). The petition requested that the dry weight of the vegetable extractives in the aqueous broth is at least 0.025 percent and not more than 2.5 percent of the labeled net weight of the container (petition at pages 3 and 10).

The proposed rule would revise the upper limit range of vegetable extractives to 2.5 percent but remove the lower limit of vegetable extractives (see proposed § 161.190(a)(6)(iii)). Thus, in addition to comments on the proposed rule itself, we request comments on whether there should be a lower limit of vegetable extractives and if so, whether the lower limit should be 0.025 percent as the petition requested (petition at page 3) or another percentage. Please provide data to support a lower limit.

VII. Preliminary Economic Analysis of Impacts

We have examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, Executive Order 14094, 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, 13563, and 14094 direct us to assess all benefits, costs, and transfers 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). Rules are ''significant'' under Executive Order 12866 Section 3(f)(1) (as amended by Executive Order 14094) if they ''have an annual effect on the economy of $200 million or more (adjusted every 3 years by the Administrator of [the Office of Information and Regulatory Affairs (OIRA)] for changes in gross domestic product); or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities.'' OIRA has determined that this proposed rule is not a significant regulatory action under Executive Order 12866 Section 3(f)(1).

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the proposed rule would not significantly increase costs to manufacturers, 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 estimates of anticipated impacts, 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 $177 million, using the most current (2022) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

The proposed rule, if finalized, would amend existing requirements for the canned tuna standard of identity and standard of fill of container. These include changes to methods for determining the fill of a container, expanding the list of optional flavorings and spices, and reducing the maximum amount of vegetable broth that can be used as an ingredient. The proposed rule is in partial response to a 2015 citizen petition submitted by Bumble Bee Foods, LLC, StarKist Co., and Tri Union Seafoods, LLC (dba Chicken of the Sea).

To estimate costs and benefits associated with the proposed rule, we assume that the appropriate baseline is the state of the world with the current standard of identity and standard of fill

of container for canned tuna. We then compare the likely impacts of the proposed rule against this baseline. The quantifiable benefits of the proposed rule accrue to canned tuna manufacturers. These firms benefit from switching to a less costly method for determining the fill of a container. We estimate ongoing annual cost savings ranging from approximately $4 million to $15.9 million at a 3 percent discount rate, and approximately $3.9 million to $15.8 million at a 7 percent discount rate. Our primary annualized estimates are approximately $7.9 million at both the 3 percent and 7 percent discount rates. The primary estimate of the present value of total cost savings in the 10 years following any final rule that may be issued based on the proposed rule is $67.6 million at a 3 percent rate of discount and $55.4 million at a 7 percent rate of discount. Manufacturers and consumers may benefit from other provisions of the proposed rule, if finalized, but these impacts are harder to quantify. We summarize quantified benefits in table 1.

The costs of the proposed rule, if finalized, are associated with costs to industry for reading and understanding the rule, training employees on new requirements, and the purchase of new equipment. These are one-time costs that industry incurs immediately after any final rule that may be issued based on the proposed rule passes its compliance date. When annualized over a period of 10 years, we estimate these costs range from approximately $3,800 to $6,000 at a 3 percent discount rate, and approximately $4,500 to $7,100 at a 7 percent discount rate. Our primary annualized estimates are approximately $4,900 at a 3 percent discount rate and $5,800 at a 7 percent discount rate. The primary estimate of the present value of total costs in the 10 years following any final rule that may be issued based on the proposed rule is $41,600 at a 3 percent discount rate and $40,600 at a 7 percent discount rate.

TABLE 1—SUMMARY OF BENEFITS, COSTS AND DISTRIBUTIONAL EFFECTS OF PROPOSED RULE

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered (years)	
Benefits:							
Annualized Monetized $millions/year	$7.9	$3.9	$15.8	2022	7	10	
	7.9	4	15.9	2022	3	10	
Annualized Quantified					7		
					3		
Qualitative							
Costs:							
Annualized Monetized $millions/year	0.01	0.00	0.01	2022	7	10	
	0.00	0.00	0.01	2022	3	10	
Annualized Quantified					7		
					3		
Qualitative							
Transfers:							
Federal Annualized Monetized $millions/year					7		
					3		
From/To	From:			To:			
Other Annualized Monetized $millions/year					7		
					3		
From/To	From:			To:			

Effects:
State, Local or Tribal Government: None.
Small Business: None.
Wages: None.
Growth: None.

We have developed a comprehensive Preliminary Economic Analysis of Impacts that assesses the impacts of the proposed rule. The full preliminary analysis of economic impacts is available in the docket for this proposed rule (Ref. 4) 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

While FDA tentatively concludes that this proposed rule contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required. The previously approved collections of information are

subject to review by OMB under the PRA. The collections of information in 21 CFR part 101 have been approved under OMB control number 0910–0381.

X. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. We have determined that this 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 proposed 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 proposed 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. FDA solicits 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 at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.* References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available 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 of Americans, 2020–2025,'' 9th ed.

* 2. Codex Alimentarius, International Food Standards, Codex standard for canned tuna and bonito (CODEX STAN 70–1981, R (Adopted in 1981. Revised in 1995. Amended in 2011, 2013, 2016, 2018.). *https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXS%2B70-1981%252FCXS_070e.pdf.* Accessed June 8, 2023.

3. Official Methods of Analysis of AOAC INTERNATIONAL (2023. 22nd ed., AOAC INTERNATIONAL, Rockville, MD, Official Method 968.30.

* 4. Fish and Shellfish; Amendments to the Canned Tuna Standard of Identity and Standard of Fill of Container, Docket No. FDA–2016–P–0147, Preliminary Regulatory Impact Analysis, Initial Regulatory Flexibility Analysis, Unfunded Mandates Reform Act Analysis. *https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations.*

List of Subjects in 21 CFR Part 161

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

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, the FDA proposes that 21 CFR part 161 be amended as follows:

PART 161—FISH AND SHELLFISH

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

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

■ 2. In § 161.190:
■ a. Revise paragraph (a)(1);
■ b. Add a heading to paragraph (a)(2);
■ c. Revise paragraph (a)(3);
■ d. Add a heading to paragraph (a)(4);
■ e. Revise paragraphs (a)(5) through (7);
■ f. Add a heading to paragraph (a)(8);
■ g. Revise paragraphs (a)(8)(i), (iii), and (v) through (ix);
■ h. Add paragraph (a)(8)(x);
■ i. Revise paragraph (c); and
■ j. Add paragraph (d).

The revisions and additions read as follows:

§ 161.190 Canned tuna.

(a) * * *

(1) *Description.* Canned tuna is the food consisting of processed fish of the species listed in paragraph (a)(2) of this section, prepared in one of the optional forms of pack specified in paragraph (a)(3) of this section, conforming to one of the color designations specified in paragraph (a)(4) of this section, may be in one or more of the optional packing media specified in paragraph (a)(5) of this section, and may contain one or more of the safe and suitable optional ingredients specified in paragraph (a)(6) of this section. It is packed in hermetically sealed containers and processed by heat to prevent spoilage. It is labeled per paragraph (a)(8) of this section.

(2) *Species.* * * *

(3) *Forms of pack.* The optional forms of processed tuna consist of loins and other striated muscular tissue of the fish. The loin is the longitudinal quarter of the great lateral muscle freed from skin, scales, visible blood clots, bones, gills, viscera and from the nonstriated part of the muscle, which part (known anatomically as the median superficial muscle) is highly vascular in structure, dark in color because of the retained blood, and granular in form. Canned tuna is prepared in one of the following forms of pack, determined following the methods prescribed in paragraph (c)(2) of this section.

(i) Solid or solid pack consists of loins freed from any surface tissue discolored by diffused hemolyzed blood, cut in transverse segments to which no free fragments are added. In containers of 1 pound or less of net contents, the segments are cut in lengths suitable for packing in one layer. In containers of more than 1 pound net contents, such segments may be cut in lengths suitable for packing in one or more layers of equal thickness. Segments are placed in the container with the planes of their transverse cut ends parallel to the ends of the container. A piece of a segment may be added if necessary to fill a container. The proportion of free flakes broken from loins in the canning process must not exceed 18 percent.

(ii) Chunk, chunks, chunk style consists of a mixture of pieces of tuna in which the original muscle structure is retained. The pieces may vary in size, but not less than 50 percent of the drained weight of the contents of the container is retained on a ½-inch (or 12.5-millimeter) mesh sieve.

(iii) Flake or flakes consist of a mixture of pieces of tuna in which more than 50 percent of the drained weight of the contents of the container will pass through a ½-inch (or 12.5-millimeter) mesh sieve, but in which the muscular structure of the flesh is retained.

(iv) Grated consists of a mixture of particles of tuna that have been reduced to uniform size, that will pass through a ½-inch (or 12.5-millimeter) mesh sieve, and in which the particles are discrete and do not comprise a paste.

(v) Any of the specified forms of pack of canned tuna may be smoked. Canned smoked tuna must be labeled per paragraph (a)(8)(v) of this section.

(4) *Colors of pack.* * * *

(5) *Optional packing media.* Canned tuna may be in one or more of the following optional packing media:

(i) Any edible vegetable oil other than olive oil, or any mixture of such oils not containing olive oil;

(ii) Olive oil; or

(iii) Water.

(6) *Optional ingredients.* One or more of the following safe and suitable optional ingredients may be used:

(i) Salt.

(ii) Flavorings and spices in accordance with § 101.22 of this chapter.

(iii) Vegetable broth added in an aqueous solution, such that the dry weight of the vegetable extractives in the broth must not be more than 2.5 percent of the labeled net weight of the container. The vegetable broth must be prepared from two or more of the following vegetables: Beans, cabbage, carrots, celery, garlic, onions, parsley, peas, potatoes, green bell peppers, red bell peppers, spinach, and tomatoes.

(iv) Edible vegetable oil, excluding olive oil. The amount of edible vegetable oil must not exceed 5 percent of the volume capacity of the container, with or without any suitable form of emulsifying and suspending ingredients that are generally recognized as safe per § 170.30 of this chapter or approved as a food additive to aid in dispersion of the oil, as seasoning in canned tuna packed in water.

(v) Sodium acid pyrophosphate added for the purpose of inhibiting the development of struvite crystals. Sodium acid pyrophosphate may be added in a quantity that must not exceed 0.5 percent by weight of the finished food.

(7) *Method of color determination.* For the color designations specified in paragraph (a)(4) of this section, the following method must be used: Recombine the separations of drained product resulting from the method prescribed in paragraph (c)(2) of this section. Pass the combined portions through a ¼-inch (or 6.3-millimeter) sieve complying with the specifications set forth in ''Official Methods of AOAC INTERNATIONAL,'' 22nd Ed. (2023), Table 1, ''Nominal Dimensions of Standard Test Sieves (U.S.A. Standard Series),'' under the heading ''Definitions of Terms and Explanatory Notes,'' (incorporated by reference, see paragraph (d) of this section). 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 (or 1.3-centimeter) 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 (or 0.3-centimeter) to ¼-inch (or 0.6-centimeter) below the top of the container. Within 10 minutes after draining through the ¼-inch (or 6.3-millimeter) sieve, determine the Munsell value of sample surface.

(i) Determine the Munsell value of the sample. The standards with which comparisons are made are essentially neutral matte-finish standards, equivalent in luminous reflectance of light at a wavelength of 555 nanometers and 33.7 percent of the luminous reflectance of magnesium oxide (for Munsell value 6.3); 22.6 percent of the luminous reflectance of magnesium oxide (for Munsell value 5.3). When examining albacore designated as ''white'', conduct the procedure using standards of Munsell value 6.3.

(ii) For blended tuna, vary the method by first separating the tuna flakes into the different colors before passing them through the ¼-inch (or 6.3-millimeter) sieve, then determining the color value of each portion separately. If necessary, use a sample container with a false bottom greater than ½ -inch (or 1.3 centimeter) deep.

(8) *Labeling.* (i) The specified name of the canned tuna described in this section, except for tuna packed in water or tuna that is smoked, is formed by combining the designation of form of pack with the color designation of the tuna; for example, ''Solid pack white tuna'', ''Grated dark tuna'', etc. For blended tuna, use both applicable color designations of the blended flakes with the predominant portion of the container first; for example, ''Blended white and dark tuna flakes'', ''Blended dark and light tuna flakes''.

* * * * *

(iii) For canned tuna packed in vegetable oil or olive oil, the label must include the name of any optional packing medium used, as specified in paragraph (a)(5) of this section, preceded by the word ''in'' or the words ''packed in''. If the tuna is packed in an optional vegetable oil, as specified in paragraph (a)(5)(i) of this section, the name or names of the oil or the general term ''vegetable oil'' may be used.

* * * * *

(v) If any of the specified forms of canned tuna are smoked, the word ''smoked'' must appear as a part of the name on the label, for example, ''Smoked light tuna flakes''.

(vi) If the canned tuna contains one or more of the optional ingredients in paragraph (a)(6)(ii) through (iv) of this section, the label must appropriately declare the ingredients by the common or usual name in accordance with § 101.22 of this chapter. If the ingredients designated in paragraph (a)(6)(iii) of this section are used, the term ''vegetable broth'' must be declared.

(vii) If the canned tuna contains the optional ingredient sodium acid pyrophosphate as provided in paragraph (a)(6)(v) of this section, the label must bear the statement ''pyrophosphate added'' or ''with added pyrophosphate''.

(viii) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the names of the optional ingredients used, as specified in paragraphs (a)(8)(iii), (vi), and (vii) of this section, must immediately and conspicuously precede or follow such name without intervening, written, printed, or graphic matter except that the common name of the species of tuna fish may so intervene, but the species name ''albacore'' may be used only for canned tuna of that species which meets the color designation ''white'' as prescribed by paragraph (a)(4)(i) of this section.

(ix) Statements of optional ingredients present required by paragraph (a)(8)(vi) of this section, but not subject to the provisions of paragraph (a)(8)(viii) of this section, must be included on the label with such prominence and conspicuousness as to render them likely to be read and understood by the ordinary individual under customary conditions of purchase.

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

* * * * *

(c) *Fill of container.* (1) The standard of fill of container for canned tuna is a fill such that tuna must constitute at least 72 percent of the fill of the container. The general method for determining the fill of containers is specified in § 130.12(b) of this chapter. The drained weight method, as specified in paragraph (c)(2) of this section, must be used to verify the standard fill of container for canned tuna products. The drained weight of each container must be determined individually, and an average value must be determined based on an average taken from a minimum of 24 containers.

(2) Determine the drained weight of the tuna using unopened canned tuna containers left at 75 ± 5°F (or 24 ± 3 °C) for at least 12 hours immediately before testing. Empty the contents of one individual tuna container onto a previously weighed sieve and evenly distribute the contents across the bottom of the sieve. Without shifting any tuna,

tilt the sieve at a 17- to 20-degree angle to help facilitate drainage. Allow the tuna to drain for 2 minutes, starting when the product is applied to the sieve. The sieve containing the drained tuna is then reweighed, after excess packing media is gently removed from the bottom of the sieve with a paper towel. The drained weight is calculated by subtracting the difference in the weights as follows:

Final weight of sieve with tuna—Empty weight of sieve = Drained weight of tuna

If the contents of the tuna container weigh less than 3 pounds (1.36 kilograms), then a sieve with an 8-inch (20-centimeter) diameter must be used. If the contents of the tuna container weigh 3 pounds (1.36 kilograms) or more, then a sieve with a 12-inch (30-centimeter) diameter must be used. The bottom of the sieve has a woven-wire cloth mesh complying with the specifications set forth for the 2.80 mm (No. 7) sieve in the ''Official Methods of AOAC INTERNATIONAL,'' 22nd Ed. (2023), Table 1, ''Nominal Dimensions of Standard Test Sieves (U.S.A. Standard Series),'' under the heading ''Definitions of Terms and Explanatory Notes,'' (incorporated by reference, see paragraph (d) of this section).

(i) Determination of free flakes: If the optional form of tuna ingredient is solid pack, determine the percent of free flakes. Any flakes resulting from the drained weight procedure described in paragraph (c)(2) of this section are to be weighed as free flakes. Only fragments that were broken in the canning process are considered to be free flakes. Using a spatula, scrape free flakes gently from the outside of the drained tuna product. Weigh the aggregate free flakes that were broken from the loin segments in the canning process and calculate their percentage of the total drained weight.

(ii) Determination of particle size: If the optional form of tuna ingredient is chunks, flakes, or grated, the drained tuna product resulting from the drained weight procedure described in paragraph (c)(2) of this section, is gently separated by hand, care being taken to avoid breaking the pieces. The separated pieces are evenly distributed over the top sieve of the screen separation equipment described in paragraph (c)(2)(iii) of this section. Beginning with the top sieve, lift and drop each sieve by its open edge three times. Each time, the open edge of the sieve is lifted the full distance permitted by the device. Combine and weigh the material remaining on the top three sieves (1¼-inch (or 37.5-millimeter), 1-inch (or 25.0-millimeter), ½-inch (or 12.5-millimeter) meshes) and determine the combined percentage retention by weight in relation to the total drained weight.

(iii) The sieving device referred to in paragraph (c)(2)(ii) of this section consists of three sieves, each approximately 1 foot square, loosely mounted, one above another, in a metal frame. The mesh in the top sieve complies with the specifications for 1 ¼-inch (or 37.5-millimeter) woven-wire cloth mesh as prescribed in paragraph (a)(7) of this section. The meshes in the sieve below comply with similar specifications for 1-inch (or 25.0-millimeter) and ¼-inch (or 12.5-millimeter) mesh as set forth in AOAC Official Methods, Table 1, ''Nominal Dimensions of Standard Test Sieves (U.S.A. Standard Series)'' (incorporated by reference, see paragraph (d) of this section). The sides of each sieve are formed, in a raised rim, from ¾-inch (or 1.9-centimeters) × ⅛-inch (or 0.3-centimeter) metal strap. The frame has tracks made of ⅜-inch (or 1.0-centimeter) angle metal to support each sieve under each side. The tracks are positioned to permit each sieve a free vertical travel of 1¾-inches (or 4.4-centimeters).

(3) If canned tuna falls below the applicable standard of fill of container prescribed in paragraph (c)(1) of this section, the label must bear the general statement of substandard fill per § 130.14(b) of this chapter.

(d) *Incorporation by reference.* Table 1, Nominal Dimensions of Standard Test Sieves (U.S.A. Standard Series), Definitions of Terms and Explanatory Notes, Official Methods of Analysis of AOAC INTERNATIONAL, 22nd Ed., 2023 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.html* or email *fr.inspection@nara.gov.* The material may be obtained from AOAC INTERNATIONAL, 2275 Research Blvd., Suite 300, Rockville, MD 20850–3250; 1–800–379–2622.

Dated: August 14, 2023.

Robert M. Califf,

Commissioner of Food and Drugs.

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DEPARTMENT OF JUSTICE

Federal Bureau of Investigation

28 CFR Part 105

[Docket No. FBI–154; AG Order No. 5736–2023]

RIN 1110–AA33

Child Protection Improvements Act Criteria for Designated Entity Determinations

AGENCY: Federal Bureau of Investigation, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Department of Justice is proposing to promulgate regulations (''proposed rule'' or ''rule'') concerning the Child Protection Improvements Act of 2018 (''CPIA''). The CPIA provides a means by which authorized qualified entities can have access to national criminal history background checks for determinations of whether covered individuals have been convicted of, or are under pending indictment for, a crime that bears upon their fitness to have responsibility for the safety and well-being of children, the elderly, or individuals with disabilities. As required by the CPIA, these proposed regulations would establish the criteria to be utilized by an entity designated by the Federal Bureau of Investigation (FBI) to make these determinations.

DATES: Written comments must be postmarked and electronic comments must be submitted on or before September 25, 2023. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. eastern time on the last day of the comment period.

ADDRESSES: You may review this proposed rule on *https://www.regulations.gov* and use the electronic comment form for these regulations to submit your comments. Submit written comments by U.S. Postal Service or other commercial delivery services, addressing them to FBI, CPIA Comments, Attention, Betsy C. Taylor, Office of the General Counsel (OGC), FBI Criminal Justice Information Services (CJIS) Division, 1000 Custer Hollow Road, Module C3, Clarksburg, West Virginia 26306.