United States Tuna Foundation
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May 6, 2001

Dockets Management Branch
Food and Drug Administration
U.S. Department of Health
and Human Services
5600 Fishers Lane
Rockville, MD 20857

Docket # 94P-0286

Dear Dockets Management:

On July 25, 1994, we filed a Citizens Petition (Petition of 1994) to amend the Canned Tuna Standard of Identity (the Standard) (21 CFR 161.190). The Petition of 1994 was submitted on behalf of all processing members of the United States Tuna Foundation (USTF), who collectively manufacture approximately 95% of all canned tuna processed in the United States. The Petition of 1994 was primarily submitted in an effort to have the Standard basis changed from a "pressed cake" methodology to a "drained weight methodology.

A substantial period of time has expired since we filed our Petition of 1994, with no action having been taken by the Food and Drug Administration. Our processing members recently agreed upon further amendments to the Standard in an effort to harmonize the Standard with Standards maintained in other major canned tuna markets of the world. The proposed changes to the Standard contained in this letter, along with those referred to herein as being contained in the Petition of 1994, will better define fill of container requirements, greatly improve the consumers ability to measure the fill of container and modify ingredient usage for the purpose of improving product quality.

We hereby request that the following modifications be made to the Standard (new text is in italics and bold face for ease in identification only) and be treated as amendments to our Petition of 1994:

1. In section 161.190 (a) *Identity,* paragraph (1), change the next to the last sentence to the following:

> "It is packed in hermetically sealed ***rigid metal*** containers and so processed by heat as to prevent spoilage."

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This change clarifies that the Standard applies to canned tuna products only and not to tuna packed in flexible pouches or other types of packaging.

2. In section 161.190 (a) *Identity,* paragraphs (3) (ii), (3) (iii), and (7), replace the word "pressed" with "***drained***".

The requested changes ensure that the drained weight methodology is used for all fill weight and color determinations, rather than the pressed weight methodology.

3. Modify section 161.190 (a) Identity, paragraph (6), as follows:

a. Delete paragraph (ii) Monosodium glutamate
b. Delete paragraph (iii) Hydrolyzed protein declared in accordance with the applicable provisions of Sec. 101.22.
c. Renumber paragraphs (6) (iv) through (6) (viii) as paragraphs (6) (ii) through (6) (vi) respectively.
d. Revise new paragraph (iii) as follows:

> ***"Vegetable broth in aqueous solution in an amount not to exceed 10% of the labeled net weight of the container. The dry weight of vegetable extractives in the aqueous broth solution shall be at least 0.025% but no more than 0.6% of the labeled net weight of the container. Vegetable extractives shall 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."***

The changes to paragraph (a) (6) will eliminate the use of hydrolyzed vegetable protein, eliminate ingredients sometimes associated with allergens, and significantly reduce vegetable broth levels commonly used today, thereby eliminating their overuse. As a result of these changes, the overall appearance and quality of the product will significantly improve.

Dry vegetable extractives must be made into aqueous solution before being dispensed into cans. Newer more sophisticated broth dispensing equipment in use today requires the broth to be of a certain viscosity for optimal equipment performance. The 10% of net weight broth solution will meet viscosity requirements. Also, basing the broth solution on the labeled net weight of the container, rather than on the container water capacity, will provide an easier reference measurement.

4. Replace section 161.190 (c) *Fill of Container,* paragraph (1) with the following:

> ***"The standard of fill of container for canned tuna is a fill such that the average weight of the drained tuna from 24 cans, as determined by the***

draining method of the Association of Official Analytical Chemists, is not less than 72 % of the labeled net weight of the container."

The change will provide harmonization with the European Union, the largest canned tuna market in the world and will conform to the current commercial practice in Canada and other major international canned tuna markets. The change, along with other changes proposed in this letter, will result in a higher quality product with increased fish fills. It is also consistent with consumer expectation that canned tuna pack styles (solid, chunk, flaked, and grated) are distinguished by product appearance and piece size rather than fill of container.

5. Change section 161.190 (c) (2) as set forth in the Petition of 1994.

6. Replace (c) (3) with the following:

"The principal display panel of the canned tuna label shall bear an accurate statement of the drained weight of the can. Any common fraction used in the statement shall be reduced to its lowest term and decimal fractions shall be carried out to a maximum of two decimal places."

Placing the drained weight declaration on the principal display panel, along with the net weight declaration, will clearly identify the fill of container for all can sizes and provide the consumer with a workable measurement method.

In summary, we submit these amendments, along with those referred to in our Petition of 1994 (a summary of the proposed amendments is attached), in an effort to harmonize the U.S. Canned Tuna Standard of Identity with other Standards worldwide. Currently, the United States is the only country in the world that bases its canned tuna standard on a pressed cake methodology rather than a drained weight methodology. In addition, we are requesting that the Standard be amended to eliminate the use of certain ingredients that have the potential to affect product quality. Finally, we are seeking to add the drained weight to the principal display panel in an effort to make the label more consumer-friendly.

David G. Burney
Executive Director
U.S. Tuna Foundation

[Code of Federal Regulations]
[Title 21, Volume 2, Parts 100 to 169]
[Revised as of April 1, 2000]
From the U.S. Government Printing Office via GPO Access
[CITE: **21CFR161.190**]

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TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES--CONTINUED

PART 161--FISH AND SHELLFISH--Table of Contents

Subpart B--Requirements for Specific Standardized Fish and Shellfish

(a) Identity. (1) Canned tuna is the food consisting of processed flesh of fish of the species enumerated 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, in one of the optional packing media specified in paragraph (a)(5) of this section, and may contain one or more of the seasonings and flavorings specified in paragraph (a)(6) of this section. For the purpose of inhibiting the development of struvite crystals, sodium acid pyrophosphate may be added in a quantity not in excess of 0.5 percent by weight of the finished food. It is packed in hermetically sealed ***rigid metal*** containers and so processed by heat as to prevent spoilage. It is labeled in accordance with the provisions of paragraph (a)(8) of this section.

(2) The fish included in the class known as tuna fish are:

Thunnus thynnus (Linnaeus, 1758)--Northern bluefin tuna
Thunnus maccoyii (Castelnau, 1872)--Southern bluefin tuna
Thunnus alalunga (Bonnaterre, 1788)--Albacore
Thunnus atlanticus (Lesson, 1830)--Blackfin tuna
Thunnus obesus (Lowe, 1839)--Bigeye tuna
Thunnus albacares (Bonnaterre, 1788)--Yellowfin tuna
Thunnus tonggol (Bleeker, 1851)--Longtail tuna
Katsuwonus pelamis (Linnaeus, 1758)--Skipjack tuna
Euthynnus alletteratus (Rafinesque, 1810)--Spotted tunny
Euthynnus lineatus Kishinouye, 1920--Black skipjack tuna
Euthynnus affinis (Cantor, 1849)--Kawakawa
Allothunnus fallai Serventy, 1948--Slender tuna
Auxis rochei (Risso, 1810)--Bullet tuna
Auxis thazard (Lacepede, 1800)--Frigate tuna

(3) 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 such muscle, which part (known anatomically as the median superficial

muscle) is highly vascular in structure, dark in color because of retained blood, and granular in form. Canned tuna is prepared in one of the following forms of pack, the identity of which is determined in accordance with 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

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of 1 pound or less of net contents, such 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 can with the planes of their transverse cut ends parallel to the ends of the can. 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 operation shall 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 weight of the ***drained*** contents of a container is retained on a ½-inch-mesh screen.

(iii) Flake or flakes consist of a mixture of pieces of tuna in which more than 50 percent of the weight of the ***drained*** contents of the container will pass through a ½-inch-mesh screen, 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-mesh screen, 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 shall be labeled in accordance with the provisions of paragraph (a)(8)(v) of this section.

(4) Canned tuna, in any of the forms of pack specified in paragraph (a)(3) of this section, falls within one of the following color designations, measured by visual comparison with matte surface neutral reflectance standards corresponding to the specified Munsell units of value, determined in accordance with paragraph (a)(7) of this section.

(i) White. This color designation is limited to the species Thunnus alalunga (albacore), and is not darker than Munsell value 6.3.

(ii) Light. This color designation includes any tuna not darker than Munsell value 5.3.

(iii) Dark. This color designation includes all tuna darker than Munsell value 5.3.

(iv) Blended. This color designation may be applied only to tuna flakes specified in paragraph (a)(3)(iii) of this section, consisting

of a mixture of tuna flakes of which not less than 20 percent by weight meet the color standard for either white tuna or light tuna, and the remainder of which fall within the color standard for dark tuna. The color designation for blended tuna is determined in accordance with paragraph (a)(7) of this section.

(5) Canned tuna is packed in one of the following optional packing

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

(ii) Olive oil.

(iii) Water.

(6) Canned tuna may be seasoned or flavored with one or more of the following:

(i) Salt.

(ii) Spices or spice oils or spice extracts.

(iii) Vegetable broth in ***aqueous solution in*** an amount not ***to exceed 10*** percent of the ***labeled net weight*** of the container. ***The dry weight of vegetable extractives in the aqueous broth solution shall be at least 0.25 percent but no more than 0.6 percent of the label net weight of the container. Vegetable*** extractives ***shall*** 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) Garlic.

(v) Lemon flavoring to be prepared from lemon oil and citric acid together with safe and suitable carriers for the lemon oil which are present at nonfunctional and insignificant levels in the finished canned food. When lemon flavoring is added, a safe and suitable solubilizing and dispersing ingredient may be added in a quantity not exceeding 0.005 percent by weight of the finished food. A substance used in accordance with this paragraph is deemed to be suitable if it is used in an amount no greater than necessary to achieve the intended flavor effect, and is

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deemed to be safe if it is not a food additive as defined in section 201(s) of the Federal Food, Drug, and Cosmetic Act (the act), or if it is a food additive as so defined, it is used in conformity with regulations established pursuant to section 409 of the act.

(vi) Edible vegetable oil or partially hydrogenated vegetable oil, excluding olive oil, used alone or in combination in an amount not to exceed 5 percent of the volume capacity of the container, with or without any suitable form of emulsifying and suspending ingredients that has been affirmed as GRAS or approved as a food additive to aid in dispersion of the oil, as seasoning in canned tuna packed in water.

(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 ***drained*** ***tuna*** 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 of the Association of Official Analytical Chemists,'' 13th Ed. (1980), Table 1, ``Nominal Dimensions of Standard Test Sieves (U.S.A. Standard Series),'' under the heading ``Definitions of Terms and Explanatory Notes,'' which is incorporated by reference. Copies may be obtained from the Association of Official Analytical Chemists International, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877-2504, or may be examined at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC. Mix the sieved material and place a sufficient quantity into a 307 x 113 size container (bearing a top seam and having a false bottom approximately \1/2\-inch deep and painted flat black inside and outside) so that after tamping and smoothing the surface of the sample the material will be 1/8-inch to 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.

(i) Determine the Munsell value of the sample surface so prepared. The following method may be used, employing an optical comparator, consisting of a lens and prism system which brings two beams of light, reflected from equal areas of sample surface and standard surface, respectively, together, within an eyepiece, so as to show an equally divided optical field. The scanned areas of sample and standard surface are not smaller than 2 square inches. Light reaching the eye is rendered sufficiently diffuse, by design of eyepiece and comparator, so that detail of the sample surface will remain undefined, to a degree such as to avoid visual confusion in observation of a match of over-all intensity of reflected light. The eyepiece contains a color filter centering at a wavelength between 550 mμ and 560 mμ. The filter does not pass appreciable visible radiation of wavelengths below 540 mμ or above 570 mμ The passed wavelength band is of a monochromaticity sufficient to cause a sample and a neutral standard of equal reflectance to appear of the same hue. The comparator is rigidly mounted on a vertical stand attached to a base in which arrangement is provided for securely and accurately positioning two cans of size 307 x 113 in the two fields of view. Mounted on the base are two shaded lamps, which direct the center of their beams of light at about a 45 deg. angle to the plane of the sample and standard surfaces. The lamps are so positioned that light from one bears mainly upon the sample surface and light from the other mainly on the standard surface, and are so placed in relation to sample and standard that no shadows, as from the can rims, appear in the fields of view. The lamps are strong enough to furnish adequate and convenient illumination through eyepiece and filter. Means are provided to alter the light intensity of one lamp in relation to the other, as may conveniently be achieved by using a 100-watt tungsten filament bulb in one lamp and using, in the other, a similar 150-watt bulb connected with the power source through a suitable rheostat. The stand is equipped with non-glossy black curtains on the side of the observer, to exclude variation in extraneous light reflected from the person of the observer.

(ii) To adjust the comparator, place a pair of matte surface standards of

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Munsell value 5.3, mounted as described in paragraph (a)(7)(iv) of this section, in position in the comparator base, and adjust the intensity of the variable lamp until the two halves of the optical field, viewed through the eyepiece, are of equal brightness. Then remove one of the standards and replace it with the prepared sample. Without altering any other adjustments, observe through the eyepiece whether the sample appears lighter or darker than the standard. In case of examination of albacore designated ``white'', conduct the procedure using standards of Munsell value 6.3.

(iii) The standards with which comparisons are made are essentially neutral matte-finish standards, equivalent in luminous reflectance of light of 555μ wavelength to 33.7 percent of the luminous reflectance of magnesium oxide (for Munsell value 6.3) and 22.6 percent of the luminous reflectance of magnesium oxide (for Munsell value 5.3), as given by the relationship between Munsell value and luminous reflectance derived by a subcommittee of the Optical Society of America and published in the ``Journal of the Optical Society of America,'' Vol. 33, page 406 (1943), which is incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS-150), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(iv) These standards shall be cut in circles 3 1/4-inches in diameter and shall be mounted in 307 x 113 size containers, bearing a top seam and painted flat black inside and outside, so that the surfaces of the standards are 3/16-inch below the top of the containers in which they are mounted.

(v) In the case of blended tuna, the foregoing method shall be varied by first separating the tuna flakes of the two different colors before passing them through the ¼-inch mesh sieve, then proceeding with each portion separately for the determination of its color value, employing, if necessary, a sample container with false bottom greater than ½- inch deep.

(8)(i) The specified names of the canned tuna for which definitions and standards of identity are prescribed by this section, except where water is the packing medium or where the tuna is smoked, are 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. In the case of blended tuna, there shall be used both applicable color designations of the blended flakes, in precedence determined in accordance with the predominating portion found in the container; for example, ``Blended white and dark tuna flakes'', ``Blended dark and light tuna flakes''.

(ii) The specified name of canned tuna when water is used as the packing medium is formed as described in paragraph (a)(8)(i) of this section, followed by the words ``in water''; for example, ``Grated light tuna in water''.

(iii) When the packing medium is vegetable oil or olive oil, the label shall bear the name of the optional packing medium used, as specified in paragraph (a)(5) of this section, preceded by the word ``in'' or the words ``packed in''. In case of the optional ingredient specified in paragraph (a)(5)(i) of this section, the name or names of the oil used may be stated, or the general term ``vegetable oil'' may be used.

(iv) In case solid pack tuna is packed in olive oil, the designation ``Tonno'' may also appear.

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

(vi) Where the canned tuna contains one or more of the ingredients provided for in paragraph (a)(6) of this section, the label shall bear the statement ``Seasoned with _____'', the blank being filled in with the name or names of the ingredient or ingredients used, except that if the ingredient designated in paragraph (a)(6)(v) of this section is used, the blank shall be filled in with the term ``vegetable broth'', and if the ingredients designated in paragraph (a)(6)(viii) of this section are used, the blank may be filled in with the term ``oil'', and if the ingredient designated in paragraph (a)(6)(iv) of this section is

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used alone, the label may alternatively bear either the statement ``spiced'' or the statement ``with added spice''; and if salt is the only seasoning ingredient used, the label may alternatively bear any of the statements ``salted'', ``with added salt'', or ``salt added''. If the flavoring ingredients designated in paragraph (a)(6)(vii) of this section are used, the words ``lemon flavored'' or ``with lemon flavoring'' shall appear as part of the name on the label; for example, ``lemon flavored chunk light tuna''. Citric acid and any optional solubilizing and dispersing agent used as specified in paragraph (a)(6)(vii) of this section in connection with lemon flavoring ingredients or emulsifying and suspending ingredients used as specified in paragraph (a)(6)(viii) of this section shall be designated on the label by their common or usual name.

(vii) Where the canned tuna contains the optional ingredient sodium acid pyrophosphate as provided in paragraph (a)(1) of this section, the label shall 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 (except if lemon flavoring is added, this subparagraph applies only to the terms ``lemon flavored'' or ``with lemon flavoring'', not to the constituent ingredients of that flavoring or to any optional solubilizing or dispersing ingredient used in connection with lemon flavoring ingredients), shall 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 employed 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 shall be set forth 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.

(b) [Reserved]

(c) Fill of container. (1) The standard of fill of container for canned tuna is a fill such that the average weight of the ***drained tuna*** from 24 cans, as determined by the ***draining*** method ***of the Association of Official Analytical Chemists, is not less than 72 percent of the labeled net weight of the container.***

(2) The methods referred to in paragraph (c)(1) of this section for determining the ***drained weight*** and referred to in paragraph (a)(3)(i) of this section for determining the percent of free flakes and the percent of pieces that pass through a ½-inch-mesh sieve are as follows:

(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 operations described in (c)***(1)*** or in other parts of this paragraph are to be weighed as free flakes. Only fragments that were broken in the canning procedure are considered to be free flakes.

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Using a spatula, scrape free flakes gently from the outside of the cake. Weigh the aggregate free flakes that were broken from the loin segments in the canning procedure and calculate their percentage of the total weight ***drained weight.***

(ii) Determination of particle size: If the optional form of tuna ingredient is chunks, flakes, or grated, the ***drained tuna*** resulting from the operations described in ***(c)(1)*** of this section, inclusive, 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)(3)(iv) 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 three top sieves (1 ½-inch, 1-inch, ½-inch screens), and determine the combined percentage retention by weight in relation to the total weight of the ***drained tuna.***

(3) The principal display panel of the canned tuna label shall bear an accurate statement of the drained weight of the can. Any common fraction used in the statement shall be reduced to its lowest term and decimal fractions shall be carried out to a maximum of two decimal places.

(4) If canned tuna falls below the applicable standard of fill of container prescribed in paragraph (c)(1) of this section, the label shall bear the general statement of substandard fill provided in Sec. 130.14(b) of this chapter, in the manner and form therein specified.

[42 FR 14464, Mar. 15, 1977, as amended at 47 FR 11833, Mar. 19, 1982; 49 FR 10102, Mar. 19, 1984; 54 FR 24896, June 12, 1989; 55 FR 45797, Oct. 31, 1990; 56 FR 6263, Feb. 15, 1991; 58 FR 2884, Jan. 6, 1993; 61 FR 14480, Apr. 2, 1996; 63 FR 14035, Mar. 24, 1998]

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2 Your Internal Billing Reference Information

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Total Packages	Total Weight	Total Declared Value*	Total Charges
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Credit Card Auth.

* When declaring a value higher than $100 per shipment, you pay an additional charge. See **SERVICE CONDITIONS, DECLARED VALUE, AND LIMIT OF LIABILITY** section for further information.

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WCSL 1297
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