

Citizen Petition: Standard of Identity for Olive Oil and
Olive-Pomace Oil

July 5, 2022

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Citizen Petition

The American Olive Oil Producers Association (“AOOPA”), Deoleo, and the North American Olive Oil Association (“NAOOA”) (collectively, the “Petitioners”) submit this petition (the “Petition”) pursuant to 21 C.F.R. § 10.30, requesting that the Commissioner of the U.S. Food and Drug Administration (“FDA”) promulgate regulations for the standard of identity for olive oil and olive-pomace oil pursuant to Section 401 of the Federal Food, Drug, and Cosmetic Act.

1. Action Requested

Petitioners request that FDA promulgate regulations for the standard of identity for olive oil and olive-pomace oil set forth in Appendix 1.

2. Statement of Grounds

2.1 Introduction

The U.S. has no enforceable standard of identity for olive oil products. Olive oil consumption rates in the U.S. have grown steadily since the 1990s and are among the highest in the world.¹ The U.S. has also become a globally important producer of olive oils, particularly extra virgin olive oil.² American consumers deserve science-based mandatory olive oil standards to empower them with the knowledge they need to make confident, informed choices for a healthier diet as well as facilitate enforcement to protect all consumers from fraud and promote a vibrant competitive and fair-dealing industry.

There is so much differentiation within the “olive oil” retail category and as a consequence this fails to provide consumers with any benchmark for assessing quality or pricing.³ In order to ensure authenticity and correct labeling, new standards must be implemented to regulate various grades of olive oil (e.g., extra virgin olive oil, virgin olive oil, olive oil) and olive-pomace oil.

The Senate and House Committees on Appropriations in FY 2020 directed the FDA “to develop a science-based Standard of Identity” for olive oil.⁴ Accordingly, the House Committee elaborated that the establishment of a uniform set of standards would better protect and inform consumers. It is notable that the House Committee on Appropriations has provided a directive to the FDA to establish a Standard of Identity for the various grades of olive oil from FY 2019 through FY 2022.

By promulgating enforceable standards of identity that incorporate current analytical testing methodologies for olive oil and olive-pomace oil that allow for truthful product differentiation, FDA will promote honesty and fair dealing in the interest of consumers.

¹ United States International Trade Commission, Olive Oil: Conditions of Competition between U.S. and Major Foreign Supplier Industries, Investigation No. 332-537, USITC Pub. No. 4419, August 2013 (“USITC Investigation 332-537”), at xii. <https://www.usitc.gov/publications/332/pub4419.pdf>

² S. Rep. 115-259 (May 24, 2018), at 103.

³ USITC Investigation 332-537, at 1-6.

⁴ H. Rept. 116-107 - Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Bill at 80 (2020) at 80; S. Rept. 116-110 - Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Bill (2020) at 113.

2.2 Basis for Petition

Pursuant to Section 401 of the Federal Food, Drug, and Cosmetic Act, the Secretary of the U.S. Department of Health & Human Services “shall promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity” whenever in his judgment such action will promote honesty and fair dealing in the interest of consumers.⁵ As set forth below, this Petition for the issuance of a standard of identity for olive oil and olive-pomace oil states the factual and legal grounds for the proposed standard, including all relevant information and views relied upon and representative information regarding contrary views to the petitioners’ position.⁶ The Petition further delineates how the proposed standard deviates from existing international standards and summarizes the scientific data and studies that provide reasonable grounds for such deviation.⁷ Throughout, the Petition demonstrates how the proposed standard will promote honesty and fair dealing in the interest of consumers.⁸

The proposed standard of identity has been developed in collaboration with industry representatives, AOOPA, Deoleo and NAOOA. Indeed, this Petition substantially harmonizes two previously filed citizen petitions, one filed jointly by AOOPA and Deoleo (FDA-2019-P-5191) in November 2019 (amended June 2020) and the other filed by NAOOA (FDA-2020-P-1423) in May 2020. On December 1, 2020, in response to a letter from the Honorable Kevin McCarthy inquiring about the status of the petitions, FDA stated that the existence of two divergent petitions “complicates the Agency’s review and increases the time needed to reach a decision. FDA is reviewing the petitions and will continue to discuss this matter with industry representatives.”⁹

Therefore, to facilitate and expedite FDA’s consideration of the need to implement an olive oil and olive-pomace oil standard, in the Petition the Petitioners have reached alignment on the vast majority (approximately 90% to 95%) of the proposed standard, including having reached agreement on such key elements of the standard as:

- Labeling: simplified and agreed alignment on mandatory provisions
- Physical chemical and sensorial parameters: harmonization reached between the two previous petitions on all quality parameters with the inclusion of Pyropheophytin A and 1,2-Diacylglycerols and substantial alignment of purity parameters
- Statement of Identity: alignment reached that the product statement of identity on the principal display panel should correspond with the defined grades of olive and olive-pomace oils
- Safe Harbor Clause addressing certain dynamic quality parameters.

To support this Petition, the Petitioners sought the opinions of numerous industry, academic and regulatory groups throughout the United States and the world as outlined in their respective previous petitions. The principal area of non-alignment concerns authenticity requirements and the extent to which they take into account genuine

⁵ 21 U.S.C. § 341.

⁶ See 21 C.F.R. § 10.30.

⁷ See 21 C.F.R. § 130.6.

⁸ See 21 C.F.R. § 130.5.

⁹ FDA letter from Susan T. Mayne, Ph.D., Director of CFSAN to The Honorable Kevin McCarthy, December 2, 2020.

deviations due to conditions such as geography and climate. The ways in which the positions of the Petitioners diverge on this are summarized in Appendix 3.

As outlined in the previous citizen petitions, there are voluntary olive oil standards and legislated regulations at state, national and international levels around the world. The various standards have been considered throughout the development process of this Petition. Chief among those is the olive oil and olive-pomace oil standard (the “Codex Standard”) (See Exhibit 1) established by the Codex Alimentarius Commission (“Codex”), the standards-setting body recognized by the World Trade Organization, through which member countries formulate and harmonize international food standards. Codex members may choose to adopt Codex standards if they do not have a national standard, but adoption of the standards is voluntary.¹⁰

2.3 Proposed Olive Oil and Olive-Pomace Oil Standard of Identity

The proposed regulations in Appendix 1 reflect quality and purity standards and advancements in analytical testing methodologies that are already widely used and have been proven in efficacy by academic studies. The proposed definitions, grades, and physico-chemical and organoleptic parameters are in use in other standards. The reasoning behind the proposed standards, and how they differ from the Codex Standard are outlined in Appendix 2 of this Petition.

3. Environmental Impact

Pursuant to 21 C.F.R. § 25.32(a), Petitioners hereby claim a categorical exclusion from the environmental assessment/environmental impact survey requirement applicable to actions involving the issuance or amendment of a food standard.

4. Economic Impact

We invite any requests for information related to FDA’s economic impact analysis.

¹⁰ <https://www.fao.org/fao-who-codexalimentarius/about-codex/en/> Nature of Codex Standards

5. Certification

The undersigned Petitioners certify, that, to the best of their knowledge and belief, this Petition includes all information and views on which the Petition relies, and that it includes favorable and unfavorable representative information relevant to the Petition.

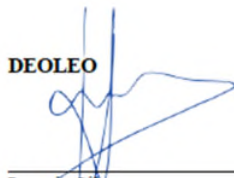
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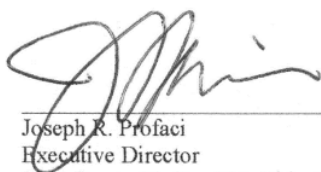
Founded in 2012, the American Olive Oil Producers Association is the unified voice for American olive oil producers and their state associations. *“AOOPA advocates in Washington, DC, state capitols and with partners around the world for policies for fair global market access for all producers; to support effective testing, standards and regulations; and to promote education about the quality and culinary and health benefits of olive oil.”*



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Deoleo is the world's largest olive oil company selling brands in more than 70 countries. With award winning brands such as Bertolli, Carbonell and Carapelli. *“Our sole purpose is to provide outstanding products that deliver premium quality to our customers and consumers. By taking a global leadership role in the Olive Oil business, we aim to inspire all stakeholders at every stage to commit to a process of adding value to the product, from the farm to the market shelf, thus ensuring sustainable growth in the future.”*

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The North American Olive Oil Association (NAOOA) established in 1989, is a trade association of 78 companies interested in the marketing of olive oils in the U.S., including but not limited to producers, packagers and importers of olive oil, as well as laboratories and export associations. NAOOA members hail from 11 countries, including all the major olive oil producing countries, and include leading brands Pompeian, Filippo Berio, Colavita, Star, Botticelli, Cento and Goya among many others, and many smaller specialty extra virgin olive oil brands. NAOOA's members account for approximately half of all olive oil sold in the U.S. and including all grades.

Appendix 1: Proposed Regulations

Part 167. Olive Oils and Olive-Pomace Oils

Subpart A. General Provisions

167.1 Scope

This Part applies to all grades of olive oil and olive-pomace oil, as defined in Subpart C of this Part, and to the labeling of combinations of olive oils or olive-pomace oils with other edible oils, as defined in Subpart F of this Part.

Subpart B. Definitions

167.2 Olive Oil

Olive oil is the oil obtained solely from the fruit of the olive tree (*Olea europaea* L.) by mechanical or other physical means under conditions, including thermal conditions, that do not lead to alterations in the oil, and which has not undergone any treatment other than washing, crushing, malaxing, decantation, pressing, centrifugation, filtration, or refining. This term does not include oils obtained by re-esterification processes or using solvents, nor does it include any combination of olive oil with other types of oils.

167.3 Olive-Pomace Oil

Olive-pomace oil is the oil obtained by treating olive-pomace, which is the product remaining after the mechanical extraction of olive oil, with solvents other than halogenated solvents or other physical treatments. This term does not include oils obtained by re-esterification processes, nor does it include any combination of olive-pomace oil with other types of oils, with the exception of olive oils.

Subpart C. Grades of Olive Oils and Olive-Pomace Oils

167.4 Olive Oil Grades

167.4.1 Extra Virgin Olive Oil

Extra Virgin Olive Oil grade is olive oil obtained directly from olives and solely by mechanical means, having a maximum free acidity of 0.5g per 100g measured as oleic acid, a degree of fruitiness greater than 0.0, a median of defects equal to 0.0, and the other characteristics which correspond to the limits fixed for this standard of identity.

167.4.2 Virgin Olive Oil

Virgin Olive Oil grade is olive oil obtained directly from olives and solely by mechanical means, having a maximum free acidity of 2.0g per 100g measured as oleic acid, fruitiness greater than 0.0, a median of defects less than or equal to 2.5, and the other characteristics which correspond to the limits fixed for this standard of identity.

167.4.3 Olive Oil

Olive Oil grade is olive oil composed of Refined Olive Oil and Extra Virgin or Virgin Olive Oils, having a free acidity content of not more than ≤ 1.0 per 100g measured as oleic acid and other characteristics that correspond to those fixed for this standard of identity. The addition of alpha-tocopherol is permitted to restore natural tocopherol lost in the refining process.

167.4.4 Refined Olive Oil

Refined Olive Oil grade is olive oil that has been subject to additional processing steps by refining methods including but not limited to: degumming, neutralization, bleaching, or

deodorization (including soft-column deodorization and similar processes) that do not lead to alterations in the initial glyceridic structure (basic glycerin-fatty acid structure). This term does not include oils obtained using solvents or re-esterification processes. Refined Olive Oil has a free acidity, expressed as oleic acid, of not more than 0.30g per 100g measured as oleic acid and other characteristics fixed for standard of identity. The addition of alpha-tocopherol is permitted to restore natural tocopherol lost in the refining process.

167.4.5 Lampante Olive Oil

Lampante Olive Oil grade is olive oil obtained directly from olives and solely by mechanical means that has a free acidity of more than 2.0g per 100g measured as oleic acid and/or a median of defects greater than 2.5 and meets the characteristics which correspond to those fixed for this category in this standard of identity. Lampante Olive Oil is not suitable for human consumption without further processing and is intended to be used for refining or for technical use.

167.5 Olive-Pomace Oil Grades

167.5.1 Olive-Pomace Oil

Olive-Pomace Oil grade is composed of Refined Olive-Pomace Oil and Extra Virgin or Virgin Olive Oils, has a free acidity of not more than 0.5g per 100g measured as oleic acid, and meets the other characteristics fixed for this standard of identity. The addition of alpha-tocopherol is permitted to restore natural tocopherol lost in the refining process.

167.5.2 Refined Olive-Pomace Oil

Refined Olive-Pomace Oil grade is olive-pomace oil obtained from Crude Olive-Pomace oil by refining methods which do not lead to alterations in the initial glyceridic structure. It has a free acidity of not more than 0.30g per 100g measured as oleic acid and meets the other characteristics fixed for this standard of identity. The addition of alpha-tocopherol is permitted to restore natural tocopherol lost in the refining process.

167.5.3 Crude Olive-Pomace Oil

Crude Olive-Pomace Oil grade is olive-pomace oil that meets the characteristics fixed for this standard of identity. It is not fit for human consumption without further processing and is intended to be used for refining or for technical use.

Subpart D. Quality and Purity Parameters

167.6 Generic chemical composition and purity parameters

The chemical composition requirements set forth in Tables 1 to 4 are applicable to all olive oils and olive-pomace oils unless otherwise specified.

167.7 Quality parameters

Each grade of olive oil or olive-pomace oil must comply with the limits specified in Table 5.

167.8 Classification of Grades.

Any analysis or characterization of the grades of olive oils or olive-pomace oils found in the stream of commerce shall be conducted in accordance with this Part and based on the most recently published version of the methods of analysis set forth in Subpart E of this Part. Analyses conducted for purposes of this regulation must be full analyses of all quality and purity parameters, and with respect to the organoleptic assessments, must specifically identify the median of defect for rancidity.

167.9 Safe Harbor Provision for Extra Virgin Olive Oil

If an Extra Virgin Olive Oil product fails to comply with the standards for one or more of the following parameters, Pyropheophytin A (PPP), 1,2- Diacylglycerols (DAGS) and median of defects (MeD) for Extra Virgin Olive Oil for Rancidity as set out in Table 5 of this standard of identity, the product will nonetheless be considered in compliance with the labeling requirements in Subpart F of this Part if it can be established that the label includes a best-if-used-by date that is no more than 18 months from bottling and that the product met or exceeded the following quality parameters at bottling:

PPP: maximum 11%

1,2-DAGs: minimum 52%

K232: maximum 2.30

K270: maximum 0.18

PV: maximum 15

FAEE: maximum 30 ppm

Organoleptic median of defects equal to 0

Organoleptic median of fruitiness greater than or equal to 1

TABLE 1
GENERIC CHEMICAL COMPOSITION PARAMETERS - PURITY

		Extra Virgin Olive Oil	Virgin Olive Oil	Olive Oil	Refined Olive Oil	Lampante Olive Oil	Olive-Pomace Oil	Refined Olive-Pomace Oil	Crude Olive-Pomace Oil
Total sterol content (mg/kg)		≥1000	≥1000	≥1000	≥1000	≥1000	≥1600	≥1800	≥2500
Wax content (C ₄₂ + C ₄₄ + C ₄₆ (mg/kg))		≤150	≤150	N/A	N/A	N/A	N/A	N/A	N/A
Wax content (C ₄₀ + C ₄₂ + C ₄₄ + C ₄₆ (mg/kg))		N/A	N/A	≤350	≤350	≤300 (See Note 1)	>350	>350	>350 (See Note 2)
Trans fatty acid content (% trans fatty acids)	C18:1 T %	≤0.05	≤0.05	≤0.20	≤0.20	≤0.10	≤0.40	≤0.40	≤0.20
	C18:2 T + C18:3 T %	≤0.05	≤0.05	≤0.30	≤0.30	≤0.10	≤0.35	≤0.35	≤0.10
Maximum difference between the actual and theoretical ECN 42 triacylglycerol content		≤ 0.2	≤ 0.2	≤ 0.3	≤ 0.3	≤ 0.3	≤ 0.5	≤ 0.5	≤ 0.6
Stigmastadienes content (mg/kg)		≤0.05	≤0.05	N/A	N/A	≤0.50	N/A	N/A	N/A
Content of 2-glyceryl monopalmitate (%)		≤ 0.9% if C16:0 ≤ 14% ≤ 1.0 % if C16:0 ≥ 14%	≤ 0.9% if C16:0 ≤ 14% ≤ 1.0 % if C16:0 ≥ 14%	≤ 0.9% if C16:0 ≤ 14% ≤ 1.1 % if C16:0 ≥ 14%	≤ 0.9% if C16:0 ≤ 14% ≤ 1.1 % if C16:0 ≥ 14%	≤ 0.9% if C16:0 ≤ 14% ≤ 1.1 % if C16:0 ≥ 14%	≤1.2	≤1.4	≤1.4

NOTE:

- When the oil has a wax content between 300 mg/kg and 350 mg/kg, it is considered a Lampante Olive Oil if the erythrodiol + uvaol content is ≤3.5%.
- When the oil has a wax content between 300 mg/kg and 350 mg/kg, it is considered a Crude Olive-Pomace Oil if the erythrodiol + uvaol content is >3.5%.

TABLE 2[‡]
FATTY ACID COMPOSITION - PURITY
(EXPRESSED AS % m/m METHYL ESTERS)

Parameter	Extra Virgin, Virgin and Lampante Olive Oils	All other olive oils and olive-pomace oils
Myristic acid (C14:0)	≤0.03	≤0.03
Palmitic acid (C16:0)	7.50–20.00	7.50–20.00
Palmitoleic acid (C16:1)	0.30–3.50	0.30–3.50
Heptadecanoic acid (C17:0)	≤0.40	≤0.40
Heptadecenoic acid (C17:1)	≤0.60	≤0.60
Stearic acid (C18:0)	0.50–5.00	0.50–5.00
Oleic acid (C18:1)	53.00–85.00	55.00–85.00
Linoleic acid (C18:2)	2.50–22.00	2.50–21.00
Linolenic acid (C18:3)	*	≤1.00
Arachidic acid (C20:0)	≤0.60	≤0.60
Gadoleic acid (eicosenoic) (C20:1)	≤0.50	≤0.50
Behenic acid (C22:0)	≤0.20	≤0.20 (See Note)
Lignoceric acid (C24:0)	≤0.20	≤0.20

NOTE: ≤0.30 for olive-pomace oils

‡The Petitioners were unable to reach consensus on the provisions marked with an asterisk as will be explained in Appendix 3.

TABLE 3[‡]
STEROL AND TRITERPENE DIALCOHOLS COMPOSITION - PURITY
(EXPRESSED AS % OF TOTAL STEROLS)

Parameter	Extra Virgin, Virgin and Lampante Olive Oils	All other olive oils and olive-pomace oils
Cholesterol	≤0.5	≤0.5
Brassicasterol	≤0.1	(See Note)
Campesterol	*	≤4.0
Stigmasterol	≤1.9	< campesterol
Delta-7-stigmastenol	≤0.5*	≤0.5*
Apparent Beta-sitosterol	≥92.5	≥93.0
Erythrodiol + Uvaol (Olive oils)	≤4.5	≤4.5 for olive oil
Erythrodiol + Uvaol (Olive-pomace oils)	N/A	>4.5

NOTE: ≤0.2 for olive-pomace oils

‡The Petitioners were unable to reach consensus on the provisions marked with an asterisk as will be explained in Appendix 3.

TABLE 4
TRACE METALS AND HALOGENATED SOLVENTS
(EXPRESSED AS mg/kg)

Iron (Fe)	≤3.0
Copper (Cu)	≤0.1
Lead (Pb)	≤0.1
Arsenic (As)	≤0.1
Halogenated solvents	Each solvent ≤0.1; sum of all solvents ≤0.2

TABLE 5
QUALITY PARAMETERS

		Extra virgin Olive Oil	Virgin Olive Oil	Lampante Olive oil	Refined Olive Oil	Olive Oil	Crude Olive-Pomace Oil	Refined Olive-Pomace Oil	Olive-Pomace Oil
Free fatty acid content (FFA) (% m/m):		≤0.5	≤2.0	>2.0	≤0.30	≤1.0	N/A	≤0.30	≤1.0
Peroxide value (PV) (meq O ₂ /kg oil)		≤20.0	≤20.0	no limit	≤5.0	≤15.0	N/A	≤5.0	≤15.0
Absorbency in ultraviolet	K ₂₃₂	≤2.50	≤2.60	N/A	N/A	N/A	N/A	N/A	N/A
	K ₂₇₀	≤0.22	≤0.25	N/A	≤1.25	≤1.15	N/A	≤2.00	≤1.70
	Delta K	≤0.01	≤0.01	N/A	≤0.16	≤0.15	N/A	≤0.20	≤0.18
Moisture and volatile matter (MOI) (% m/m)		≤0.2	≤0.2	≤0.3	≤0.1	≤0.1	≤1.5	≤0.1	≤0.1
Insoluble impurities (INI) (% m/m)		≤0.1	≤0.1	≤0.2	≤0.05	≤0.05	N/A	≤0.05	≤0.05
Pyropheophytin A (PPP) (%)		≤21	N/A	N/A	N/A	N/A	N/A	N/A	N/A
1,2-Diacylglycerols (DAGs) (%)		≥35	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Fatty acid ethyl esters (FAEE) (mg/kg)		≤35	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Organoleptic analysis	Median of defects (MeD)	= 0.0	0.0 <MeD ≤2.5	>2.5	N/A	N/A	N/A	N/A	N/A
	Median of fruitiness (MeF)	>0.0	>0.0	N/A	N/A	N/A	N/A	N/A	

Subpart E. Methods of Analysis

167.10 Methods of Analysis

167.10.1 General

The following methods shall be used to determine the characteristics of olive oils and olive-pomace oils.

167.10.2 Determination of fatty acid composition

Preparation of methyl esters in accordance with AOCS Ce 2-66 or ISO 5509 or COI/T.20/Doc.24. Methyl esters of fatty acids shall be analyzed by gas chromatography in accordance with ISO 5508 or AOCS Ch 2-91. Or COI/T.20/DOC.33.

167.10.3 Determination of the composition and content of sterols, triterpenic dialcohols and aliphatic alcohols by capillary column gas chromatography
COI/T.20/Doc. no.26.

167.10.4 Determination of wax content and alkyl esters

According to COI/T.20/Doc. No 28, "Determination of the content of waxes, fatty acid methyl esters and fatty acid ethyl esters by capillary gas chromatography" or IOC/T.20/Doc.31 Determination of the content of waxes, fatty acid methyl esters and fatty acid ethyl esters by capillary gas chromatography using 3 grams of silica.

167.10.5 Determination of the stigmastadiene content

According to COI/T.20/Doc. No 11, "Determination of stigmastadienes in vegetable oils", or COI/T.20/Doc. no. 16, "Determination of sterenes in refined vegetable oils", or ISO 15788-1 or AOCS Cd 26-96.

167.10.6 Determination of the content of 2-glyceryl monopalmitate

According to COI /T.20/Doc.23.

167.10.7 Determination of the difference between the actual and theoretical ECN 42 triglyceride content

The difference between the actual and theoretical ECN 42 triglyceride content shall be determined in accordance with AOCS Ce 5b-89 or COI /T.20/Doc.20.

167.10.8 Determination of organoleptic characteristics

Organoleptic characteristics shall be determined in accordance with COI/T.20/Doc. 15.

167.10.9 Determination of free fatty acid content

Free fatty acid content shall be determined in accordance with ISO 660 or AOCS Ca 5a-40 Or IOC/T.20/Doc.34.

167.10.10 Determination of the peroxide value

Peroxide value shall be determined in accordance with AOCS Cd 8b-90 or ISO 3960 or IOC/T.20/Doc.35.

167.10.11 Determination of absorbency in ultraviolet

Absorbency in ultraviolet shall be determined in accordance with ISO 3656 or AOCS Ch 5-91 or-COI/T.20/DOC. 19.

167.10.12 Determination of moisture and volatile matter

Moisture and volatile matter shall be determined in accordance with ISO 662 or AOCS Ca 2c-25.

167.10.13 Determination of insoluble impurities in light petroleum

Insoluble impurities shall be determined in accordance with ISO 663 or AOCS Ca 3a-46.

167.10.14 Determination of trace metals

Determination of copper and iron by direct graphite furnace atomic absorption spectrometry shall be in accordance with ISO 8294.13

167.10.15 Determination of alpha-tocopherol

Tocopherols and tocotrienols contents, using high-performance liquid chromatography, shall be determined in accordance with ISO 9936.

167.10.16 Determination of pyropheophytins

The degradation products of chlorophylls a and a' (pheophytins a, a' and pyropheophytins) shall be determined in accordance with ISO 29841.

167.10.17 Determination of 1,2-Diacylglycerol content

Relative amounts of 1,2- and 1,3-diacylglycerols shall be determined in accordance with ISO 29822.

167.10.18 Determination of composition of triacylglycerols and composition and content of di- acylglycerols by capillary gas chromatography, in vegetable oils

COI/T.20/Doc. No 32.

167.10.19 Detection of traces of halogenated solvents

As determined by the method prescribed in COI/T.20/Doc. no. 8.

167.10.20 Trace metals (arsenic)

As determined by the method prescribed in AOAC 952.13 or AOAC 942.17 or AOAC 985.16.

167.10.21 Trace metals (lead)

As determined by the method prescribed in ISO 12193 or AOCS Ca 18c-91 or AOAC 994.02.

167.10.22 Sampling

According to ISO 661 and ISO 5555.

Subpart F. Labeling

167.11 Mandatory Labelling

167.11.1 General

The name of the product shall be consistent with the descriptions of the product set out in this Part. In addition to the requirements set out herein, sellers of olive oils and olive-pomace oils shall comply with the requirements of 21 C.F.R Part 101, Subchapters A, B, D, E, F.

167.11.2 Designation of Region

Labeling statements regarding the country of origin of the source of the oil must be compliant with all federal laws governing country of origin labeling.

167.11.3 Varietal Names

If olive varietal names are used in the labeling of the product, then varieties comprising 85% of the oil by weight shall be listed in their order of dominance.

167.11.4 Harvest Date(s)

If reference is made to harvest date in the labeling of the product, it shall be the earliest month and year of harvest among all lots comprising the product. When oils from multiple years are combined, the label of the product may alternatively indicate that there are multiple harvest dates by stating the earliest month and year of harvest for each year contained therein (e.g. Harvest Dates: October 2021 and May 2022 or Oct 2021 & May 2022).

167.11.5 Lot Identification

All bottles, packaging and containers shall be permanently marked to indicate the producing factory and lot allocation with full traceability, in compliance with all applicable laws and regulations.

167.11.6 Best If Used By Date

If a product label includes a date that signifies the end of the period during which the intact package of oil will retain any specified qualities for which express or implied claims have been made, it shall be referred to as a “Best If Used By” date, and the label shall state the expected storage and handling conditions for the product on which the date has been based.

167.11.7 Prohibited Descriptions

The use of terms that describe products covered by this Part on packaging shall be restricted to avoid inappropriate and misleading messages under Part 101 as follows: the terms “light” or “lite” may only be used expressly to describe the flavor or color of the oil, and the terms “extra” and “pure” may only be used to describe a product that is 100% extra virgin olive oil as defined in Subpart C (except that the word “pure” shall never be used on the principal display panel).

167.11.8 Ingredient Statement

If a product governed by this Part contains Refined Olive Oil or Refined Olive-Pomace Oil, the label shall include an ingredient statement consistent with section 101.4, Subpart A of Part 101 that identifies the grade (as defined in Subpart C of this Part) of any and all component oils in the product.

167.11.9 Mixtures of Edible Oils and Fats with Olive Oils and Olive-Pomace Oils.

When a product constituting a blend of an olive oil or olive-pomace oil with a different edible oil or fat indicates on the label either by words (other than in the ingredient statement) or by suggestive images, that it contains oil derived from olives, the name of the food on the principal display panel must clearly: (a) indicate common or usual name in letter fonts equivalent in size and prominence of the component oils in the blend in order of predominance by volume; and (b) indicate the percentage of each component oil in the blend (e.g., “Canola Oil (90%) and Virgin Olive Oil (10%);” “Blend of Vegetable (40%), Refined Olive-Pomace (35%) and Extra Virgin Olive (25%) Oils”). If such a blend does not indicate or suggest the presence of olive oil by words or images, an appropriately descriptive name of the blend (e.g., “Cooking Oil Blend”) may be used provided the component oils are identified by common or usual name and olive oil grade in the ingredient statement. Notwithstanding the foregoing, the label of an olive oil blend

may not indicate or suggest the presence of olive oil by images unless the blend contains more than 50% olive oils.

167.11.10 Labeling of Non-Retail Containers.

Information on the above labeling requirements shall be given either on the container or in accompanying documents, except that the name of the food, lot identification and the name and address of the manufacturer or packer shall appear on the container. However, lot identification and the name and address of the manufacturer or packer may be replaced by an identification mark, provided that such a mark is clearly identifiable with the accompanying documents.

Subpart G: Food Additives

167.12 Olive oils and crude olive-pomace oil.

Olive oils and crude olive-pomace oils shall not contain food additives.

167.13 Refined-olive oils, olive-pomace oil and refined olive-pomace oil.

Tocopherols may be added to refined-olive oil, olive-pomace oil and refined olive-pomace oil to restore the natural tocopherols lost in the refining process up to a maximum level of 200mg/kg of total alphanatocopherol in the final product. Use of tocopherols shall be in compliance with the B, Parts 170, 178, and 182 of this Subchapter.

167.14 Processing aids.

Processing aids are allowed to be used during oil extraction to the extent allowed by the agency pursuant to Part 178 of this Subchapter.