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

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Petition

1. Action Requested

Petitioners request that FDA promulgate regulations for the standards 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. The result is widespread mislabeling of grades, adulteration, consumer mistrust, and unfair and unethical industry business practices. As the U.S. International Trade Commission has recognized, the "lack of enforcement has resulted in a long history of fraudulent practices (adulteration and mislabeling) in the olive oil sector."[1] Olive oil consumption rates in the U.S. have grown steadily since the 1990s and are among the highest in the world.[2] The U.S. has also become a globally-important producer of olive oils, particularly extra virgin olive oil.[3] The Senate and House Committees on Appropriations in FY 2019 stated it is imperative that FDA implement "a uniform set" of standards for olive oil "to better inform and protect consumers."[4]

The continued absence of an enforceable standard is harming consumers. Off the shelf product testing demonstrates that U.S. consumers are frequently misled by mislabeling of grades and marketing tactics that leave them unable to differentiate between high quality extra virgin olive oil and low-quality, old or rancid oils, as well as cheap by-products that are chemically and mechanically refined and colored to resemble olive oil.[5] Indeed, there is so much differentiation within the "extra virgin olive oil" category that this grade fails to provide consumers with any benchmark for assessing quality or pricing.[6] 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 composed refined oils) and olive-pomace oil.

By promulgating enforceable standards of identity that incorporate the latest 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.

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.[7] As set forth below, this petition for the issuance of standards of identity for olive oil and olive-pomace oil states the factual and legal grounds for the proposed

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[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 xiii, 3-2.
[2] USITC Investigation 332-537, at xii.
[3] S. Rep. 115-259 (May 24, 2018), at 103.
[4] *Id.* at 104.
[5] Aparicio et al, *Authenticity of olive oil: Mapping and comparing official methods and promising alternatives*, Food Research International, 2025-2038, (Dec. 2013), *available at* https://doi.org/10.1016/j.foodres.2013.07.039.
[6] USITC Investigation 332-537, at 1-6.
[7] 21 U.S.C. § 341.

standards, including all relevant information and views relied upon and representative information regarding contrary views to the petitioners' position.[8] The petition further delineates how the proposed standards deviate from existing international standards and summarizes the scientific data and studies that provide reasonable grounds for such deviation.[9] Throughout, the petition demonstrates how the proposed standards of identity will promote honesty and fair dealing in the interest of consumers.[10]

The proposed standards of identity rely heavily on the standard for olive oil promulgated by the California Department of Food and Agriculture ("CDFA") and are supported by data collected by the CDFA in enforcing its standard. These new standards of identity highlight critical advancements in agronomy, harvest techniques, olive oil processing, storage and handling, and analytical technologies. These technological advancements are reflected in this petition.

Olive oil is also produced in an increasingly wide range of locations and varying climates and this naturally has increased the variability in the chemistry of olive oil. The proposed standards account for wider regional variation and current climatic conditions in new geographic olive oil producing countries.

Advancements in analytical methodologies have enabled improved definition among grades and monitoring of quality and freshness in retail markets. These methodologies have proven capabilities to deliver true-to-label quality and authentic olive oil products to consumers. Both the research and commercial practices outlined within this petition support the proposed standards to accurately regulate a category that has been plagued with controversy, assuring U.S. consumers that the grade of olive oil selected is in fact truthfully labeled.

2.3 Background

For context, this section discusses various olive oil standards in place worldwide. The new proposed standards build upon these existing frameworks and incorporate modern testing methodologies and accommodate geographical growing conditions. The quality and purity parameters contained in the proposed standards are most closely aligned with those in place in California, which have resulted in marked improvements in quality for olive oil products within that state.

2.3.1 IOC

The International Olive Council ("IOC") is an intergovernmental organization chartered by the United Nations that develops standards of quality used by olive oil producing countries including Spain, Italy, Greece, Portugal, Tunisia and Turkey.[11] The IOC standards designate nine grades in two primary categories, olive oil and olive-pomace oil.[12] These standards do not accommodate natural variations in chemistry associated with new geographic producing regions including the United States. In practice, IOC member producing countries apply the minimum IOC standard at the point of export, which gives no guarantee the olive oil will meet the standard at point of retail for consumers.

The IOC is largely governed by EU member countries based on participation shares. In the 2015 International Agreement on Olive Oil and Table Olives, the participation shares were restructured in a manner that calculates shares based on consumption as well as production. Under

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[8] *See* 21 C.F.R. § 10.30.
[9] *See* 21 C.F.R. § 130.6.
[10] *See* 21 C.F.R. § 130.5.
[11] International Olive Council, *Mission Statement*, http://www.internationaloliveoil.org/estaticos/view/100-mission-statement (last visited Nov. 1, 2019)
[12]

the 2015 agreement, the EU shares grew from 684[13] shares to 717 of the 1,000 participation shares,[14] with the next largest shareholder, Tunisia, holding 67 shares. The United States is not currently a member of the IOC. If it were, it would have a small number of shares and could not be effective in shaping policy. Therefore, the U.S. should not adopt the standard of an international organization in which it does not have representation.

2.3.2 Codex

The Codex Alimentarius Commission ("Codex") is a standards-setting body recognized by the World Trade Organization, through which member countries formulate and harmonize international food standards.[15] Codex members may choose to adopt Codex standards if they do not have a national standard, but adoption of the standard is voluntary.[16]

The Codex standard for olive oil, like the IOC standards, do not currently accommodate natural variations in chemistry associated with new geographic producing regions including the United States. Codex, and specifically the Codex Committee on Fats and Oils (CCFO), has recently begun work on the revision of Sections 3, 8 and the Appendix of the *Standard for Olive Oils and Olive Pomace Oils.* This represents the first time the standard has been reviewed in the past 15 years, despite considerable technological and scientific innovations, expansion of global growing regions, and the increase in volumes and value of trade. But because Codex and its subsidiary bodies typically seek to reach agreement on the adoption or amendment to standards by consensus, such revisions tend to involve a lengthy process. It is encouraging that the Committee is considering data and information in several areas, including parameters that are important to define olive oil quality and freshness, such as Diacylglycerols (DAGs), Pyropheophytins (PPPs). These analytical methods, discussed further below in Section 2.4.4, have been developed over the past 15 years and are used to measure the quality and freshness of extra virgin olive oil and predict shelf life. The information developed by the electronic working group for all areas under review will be considered at CCFO 27.

2.3.3 USDA

In 2010, the United States Department of Agriculture ("USDA") revised the United States Standards for Grades of Olive Oil.[17] These grade standards were largely based on IOC standards, but were modified at the request of the California Olive Oil Council to increase the limits for linolenic acid and campesterol and to remove the category for "ordinary olive oil" based on its limited recognition and unpalatability.[18] There is no mandated testing program for USDA standards; compliance is entirely voluntary.[19] In addition to being non-mandatory, USDA testing methods do not apply—and the USDA lacks the statutory authority to apply them—at the consumer level.[20]

2.3.4 CDFA

On September 26, 2014, the State of California Department of Food and Agriculture ("CDFA") enacted a mandatory standard to define the grades of olive oils, refined-olive oils, and

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[13] USITC Investigation 332-537, at 2-3.
[14] *International Agreement on Olive Oil and Table Olives,* United Nations, 2015.
[15] *Id.*
[16] Codex Alimentarius, *Standard for Olive Oils and Olive Pomace Oils - CODEX STAN 33-1981* (amended 2013), *available at* http://www.fao.org/fao-who-codexalimentarius/codex-texts/list-standards/en/ (last visited Nov. 1, 2019).
[17] 75 Fed. Reg. 22363, 22364 (Apr. 28, 2010).
[18] USITC Investigation 332-537, at 3-7 n.17 (citing 75 Fed. Reg. at 22363).
[19] *Id.* at 3-16.
[20] These USDA standards are subject to the inspection and certification procedures set forth in 7 C.F.R. 52.1-52.83. *See* 75 Fed. Reg. at 22368.

olive-pomace oils; specify purity and quality parameters for each grade; establish requirements for labeling and packaging; and list acceptable methods of analysis.[21] The CDFA standard was crafted to consider the natural variations in U.S. produced olive oils while maintaining restrictions on chemical and physical composition to ensure quality and prevent adulteration. It is important to note that the CDFA standard includes the most recent and modern analytical testing methodologies for freshness (i.e., DAGs and PPPs) reflected in the proposed standards.

In 2017 and 2018, the Olive Oil Commission of California ("OOCC"), a government entity of the state of California administered by the CDFA, conducted two studies assessing the quality of California olive oil in a retail environment at least one year after harvest.[22] The purpose of these studies was to quantify the impact of the CDFA standard on quality for consumers at retail. California producers subject to the CDFA standard showed that 90% and 74% of samples tested met CDFA requirements for extra virgin olive oil in 2017 and 2018, respectively, as compared with only 18% and 50% of producers not subject to the CDFA standard.[23] These results indicate that producers required to meet the mandatory standard had in fact effectively improved the quality of the products offered to consumers.

Since the implementation of the CDFA standard for olive oil administered by the Olive Oil Commission of California, California olive oil tested at the time of production has shown a steady improvement in two critical areas: First, the percentage of the total crop that meets the requirements for extra virgin olive oil under the CDFA standard has increased, indicating that producers have been successful in implementing good practices to improve quality.[24] Second, yearly evaluations of quality testing performed by the University of California, Davis have shown improved compliance in handler reported verification of grades.[25] Increasing compliance in handler reported grades for lots is consistent with the testing performed by CDFA inspection personnel. Grade verification has improved from 85% in the 2014-2015 harvest to 100% compliance in the 2016-2017 harvest.[26] These results demonstrated the ability of OOCC participants to provide and maintain the high quality of California olive on retail shelves for consumers under the newly enacted CDFA standards.

2.3.5 European Union Standard

The European Union ("EU") Commission Regulation, EEC No. 2568/91, as amended by Commission Implementing Regulation 2019/1604, is similar to the IOC standards for olive oil and is enforced in all EU countries.[27]

2.4 Proposed Olive Oil and Olive-Pomace Oil Standards 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 definitions, grades, and parameters are largely similar to those implemented in California with great success. The reasoning behind the proposed standards, and how they differ from the Codex standard, are discussed below.

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[21] CDFA, Grade and labeling Standards for Olive Oil, Refined-Olive Oil and Olive-Pomace Oil, effective Sept. 26, 2014, *available at* https://www.cdfa.ca.gov/mkt/mkt/pdf/CA_Olive_Oil_Standards.pdf.
[22] Appendix 2, Section 8.
[23] Impact Report July 2014-June 2019, Olive Oil Commission of California, available at http://www.oliveoilcommission.org/wp-content/uploads/2019/01/Impact-Report-2018.pdf.
[24] Appendix 2, Section 8.
[25] *Id.*
[26] *Id.*
[27] EEC 2568/91, *On the characteristics of olive oil and olive-residue oil and on the relevant methods of analysis*, as amended by Commission Implementing Regulation (EU) 2019/1604.
[27] See Appendix 1, §§ 170.3-170.5 (Definitions).

2.4.1 Categories and Grades of Olive Oil and Olive-Pomace Oil

The proposed standards contain three categories of olive oil products: olive oil, olive-pomace oil, and mixtures of olive oil or olive-pomace oil with vegetable or seed oils.[28] The olive oil category contains five grades: extra virgin olive oil, virgin olive oil, olive oil, refined olive oil, and lampante oil. The olive-pomace oil category contains three grades: olive pomace oil, refined olive-pomace oil, and crude olive-pomace oil. Each category and grade is defined based on requirements for ingredients, extraction methods, free acidity levels, degrees of fruitiness, median defects, and other characteristics. These standards and grades permit the measurement of levels of quality and value, providing a consistent basis for domestic and international trade and promoting marketplace efficiency.

These categories and grades build upon other standards from around the world such as CDFA, Codex, IOC, and EU with slight variations in terminology directed at U.S. consumers. As seen in the 2015-2019 data described in Appendix 2, half of sampled products labeled as extra virgin olive oil failed one or more of seven international criteria for the category, indicating major inconsistencies across products sold.[29] Such inconsistencies result in consumers being unable to predict or identify what products they are buying and consuming. In contrast to the Codex standard, the proposed grades include "lampante olive oil" and "crude olive-pomace oil." These terms appropriately and transparently describe products that do not meet higher quality grade criteria and are commonly used throughout the industry. The "ordinary olive oil" category used in the Codex standard is also eliminated, as this category added to consumer confusion and mistrust because its distinction from "olive oil" was unclear.[30] The new addition of a category for mixtures of olive oils and olive-pomace oils with vegetable and seed oils will directly address the problem of adulteration and require appropriate categorization of these products.

For greater transparency, the virgin olive oil grade is also included within this standard. This is intended to address the critical issue of misrepresentation of grades by requiring products currently sold as "extra virgin olive oil," but which do not meet the parameters for that grade, to be sold under labels reflecting the appropriate grade as defined in Appendix 1. This will empower consumers to make informed purchasing decisions.

The definitions include additional detail beyond that contained in other standards with transparent terminology to promote honest and fair dealing in the interest of U.S. consumers. This is of critical importance in the grade of extra virgin olive oil. The proposed categories and grades align closely with those implemented in California.[31]

2.4.2 Revised Free Acidity Levels as an Indicator of Quality

The proposed standards reduce the maximum free acidity levels under the Codex standard for the grades of extra virgin olive oil, olive oil, and olive-pomace oil. These levels are reduced from a maximum free acidity of 0.8, 1.0, and 1.0 gram per 100 grams (measured as oleic acid) in each grade, respectively, to a maximum of 0.5 gram for each grade.[32] Free acidity values provide key information in determining quality levels for olive oil, including indications of the condition of the fruit harvested, how the fruit was handled prior to processing, and the length of time from

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[28] *See* Appendix 1, §§ 170.3 - 170.7.
[29] *See* Appendix 2, § 3.
[30] 75 Fed. Reg. 22363, 22364 and 22367 (Apr. 28, 2010).
[31] California Dep't of Food & Agriculture, Grade and Labeling Standards for Olive Oil, Refined-Olive Oil and Olive-Pomace Oil, eff. Sept. 26, 2014, available at https://www.cdfa.ca.gov/mkt/mkt/pdf/CA_Olive_Oil_Standards.pdf.
[32] *See* Appendix 1, §§ 170.3 - 170.7.

harvest to milling.[33] Generally, higher quality grades of olive oil contain lower levels of free fatty acids (FFAs).[34]

The reduced maximum free acidity levels for extra virgin olive oil, olive oil, and olive-pomace oil will more accurately match the quality and purity of each grade. For example, the current Codex standard maximum of 0.8 for extra virgin olive oil is widely recognized as potentially encompassing far lower quality olive oils. Indeed, studies of California oils have shown that, as the result of quality controls, virtually all oils contained less than 0.225 percent FFA levels, well below the Codex standard of 0.8 percent for the extra virgin olive oil grade.[35] Reducing the maximum levels of FFAs, combined with the factors discussed below, will ensure that consumers can differentiate between varying grades and quality levels of olive oil products.

The results in table 8 of Appendix 1 were obtained from the analyses of 4,790 extra virgin olive oil samples and all samples showed a limit for FFA, K232 and PV under 0.5, 2.40, and 15, respectively. Therefore, the proposed standards address the need for more restrictive parameters than those set forth in other standards.

2.4.3 Revised Fatty Acids and Sterols Ranges to Reflect Broader Olive Tree Growing Conditions and Varieties

The proposed regulations reflect the expanding geographic and climatic range of olive tree growing conditions and varieties across the world. Specifically, they revise the parameters for certain fatty acids and sterols to more appropriately encompass quality olive oils grown outside of Europe and the Mediterranean, in the U.S., Australia, and other new olive oil producing countries.

The proposed changes are based on a number of comprehensive studies of olive oils from new geographic olive oil producing regions, including more than 2,300 samples from a wide range of olive tree growing conditions and varieties within a four-year period.[36] These studies demonstrated that the concentrations of sterols such as campesterol and stigmasterol, are affected by the latitude and altitude of olive tree orchards, which in turn affects the climate in which the olives grow and therefore the nature of the chemical pathways in which these components are synthesized within the olives as they grow and mature.[37] They also showed that by increasing the permissible levels of total sterols, campesterol, and stigmasterol, the new standards would include quality olive oil from new geographic olive oil producing regions without any detrimental effect on overall quality levels.

The need for adjustments to fatty acid and sterol levels is demonstrated in correlation studies of olive oils from the warm valleys of Northwest Argentina, which suggest that temperature during the oil synthesis period could be the main environmental factor affecting fatty acid composition of virgin olive oils. In this region, negative relationships between oleic acid concentrations at final harvest and seasonal mean temperatures during oil synthesis have been found for the commercial virgin olive oil "cv Arbequina."[38] When the dynamics of fatty acid accumulation were modeled as a function of thermal time, oils from "cv Arbequina" showed a significant reduction in oleic acid content with thermal time (approximately 0.8% per 100° Cd),

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[33] Appendix 2, § 9.
[34] USITC Investigation 332-537, at 1-5.
[35] USITC Investigation 332-537, at 5-13.
[36] Appendix 2, §§ 4-5.
[37] *Id.* at 5-6.
[38] Rondanini et al., *Contrasting patterns of fatty acid composition and oil accumulation during fruit growth in several olive varieties and locations in a non-Mediterranean region.* 52:B European Journal of Agronomy, 237-246 (January 2014), *available at* https://www.researchgate.net/publication/259144652_Contrasting_patterns_of_fatty_acid_composition_and_oil_accumulation_during_fruit_growth_in_several_olive_varieties_and_locations_in_a_non-Mediterranean_region.

resulting in concentrations of less than 50% at final harvest, which coincided with a thermal time of about 3,500° Cd.[39]

Similar to Argentina, the wide variations in Australian olive crop growing climates sometimes result in oils with chemical attributes being more variable than those observed in oils produced in Mediterranean countries.[40] Comparable impacts have been observed in growing regions across the U.S.[41]

2.4.4 New Chemical Tests of PPPs and DAGs to Identify Degraded and Rancid Oils

The proposed regulations include chemical testing parameters for pyropheophytins (PPPs) and 1,2-diacylglycerol (DAGs). These tests are included as quality parameters in the mandatory CDFA standard, as well as the Australian standard, and have resulted in demonstrated improvements in the quality of olive oil products for consumers at retail. The tests serve as strong indicators of degradation through age or poor storage conditions, lower quality oils, and oil produced from deteriorated fruit.[42] As seen in the 2016 study by Guillaume and Ravetti, the levels of these chemicals are strongly correlated with age and help to predict olive oil shelf life. The addition of these chemical tests have long been supported by petitioners and by researchers at the Olive Center within the University of California, Davis.[43]

It has been argued previously that the PPP and DAG tests are inconsistent or inaccurate because these levels vary over time.[44] However, the precise purpose of these tests is to accurately and predictably reflect the stage and progression of degradation of the olive oils. The presence of PPPs has been proven to serve as a reliable indicator of freshness.[45] Christian Gertz from the German Society for Fat Science (DGF) has released studies showing that a low content of 1.20 DAGs is indicative of poor quality oils and that further decreases during storage depend among other factors including initial FFA levels.[46]

The inclusion of these tests in Australia and California has been correlated with improved quality of olive oil products sold by retailers.[47] In the U.S., these chemical tests will similarly help ensure that degraded, adulterated, and rancid olive oils do not reach consumers.

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[39] *Id*.

[40] Mailer et al., *The natural chemistry of Australian extra virgin olive oil*, (Jan. 2007), *available at* https://www.agrifutures.com.au/product/the-natural-chemistry-of-australian-extra-virgin-olive-oil-english-version/. *See also* Ayton et al. *Quality and oxidative stability of Australian olive oil according to harvest date and irrigation*, 14:2 Journal of Food Lipids 135-156, (June 2007), *available at* https://onlinelibrary.wiley.com/doi/abs/10.1111/j.1745-4522.2007.00076.x.

[41] Appendix 5.

[42] USITC Investigation 332-537, at 3-10 (citing Devarenne, *Olive oil analysis discussed at American Oil Chemists' Society annual meeting*, Olive Oil Times (May 7, 2012)).

[43] USITC Investigation 332-537, at 3-11, D-16 ("Olive Center researchers state that the DAGs and PPPs levels in olive oil are directly related to the age of the olives used to produce it, so the results of testing their levels are very closely related to the age and the freshness of the oil and correlate best with sensory characteristics.").

[44] USITC Investigation 332-537, at D-12.

[45] Aparicio-Ruiz et al., *Predicting extra virgin olive oil freshness during storage by fluorescence spectroscopy*, 68:4 Journal of Fats and Oils (2017), *available at* https://pdfs.semanticscholar.org/9145/eaf21c454f8973726defcfa513293b35c684.pdf.

[46] Gertz, *Rapid assessment of quality parameters in olive oil using FTNIR and conventional standard methods*, Proceedings of the European Commission, Workshop of Olive Oil Authentication 55-70 (June 2013), *available at* https://ec.europa.eu/agriculture/sites/agriculture/files/events/2013/olive-oil-workshop/proceedings_en.pdf.

[47] *See* Appendix 2, § 8.

2.4.5 Additional Quality Parameters to Determine Oxidation, Freshness and Fruitiness

In addition to the revised free acidity levels discussed above, the proposed standards would include further quality parameters that indicate oxidation, freshness, and fruitiness of olive oil and olive-pomace oil. These quality parameters include ranges of peroxide values and absorbency in ultraviolet (K232), which are used to measure oxidation and detect rancid or adulterated oils.[48] Additionally, the median of fruitiness for extra virgin olive oil, determined through sensory analyses, is broadened to permit any level above zero. These changes are essential to reflect the advancements made in agronomy, harvest techniques, olive oil processing, storage and handling, and analytical technologies.

These additional quality parameters are reflective of technological advancements in testing methodologies and provide more accurate analyses of olive oil quality.[49]

2.4.6 Substantiation of "Best if Used By" Date

The proposed regulations further allow producers an opportunity to provide evidence to substantiate the "Best if Used By" date in the label, in the event that a product fails quality parameters after the time of bottling.

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

An economic impact analysis has not been requested from petitioners at this time.

[48] Appendix 2, § 9.
[49] *Id.*

5. Certification

The undersigned certifies, that, to the best of the undersigned's 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 64 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.*

Appendix 1: Proposed Regulations

Part 170. Olive Oils and Olive-Pomace Oils
Subpart A. General Provisions

170.1 Scope

This Part applies to all products sold in the U.S. labelled as olive oil, olive-pomace oil, or products that are mixtures of olive oils and olive-pomace oils with other types of oils. This Part further:

(a) defines the grades of olive oils and olive-pomace oils;
(b) specifies purity and quality parameters for each grade;
(c) establishes the requirements for labelling and packaging; and
(d) lists acceptable methods of analysis.

170.2 Objective

The purpose of this Part is to:

(a) ensure the quality, purity and authenticity of olive oil produced and bottled locally and or imported into the U.S.;
(b) promote honesty and fair dealing in the interest of consumers concerning the quality, authenticity and labelling of olive oil grades, refined olive oils, and olive-pomace oils as well as mixtures of olive oil with other types of oils; and
(c) provide the producers, handlers, buyers and consumers of olive oil products with reliable and trustworthy information concerning the quality, purity and grade of the product.

Subpart B. Definitions

170.3 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 physical refining. This term does not include oils obtained by re-esterification processes or using solvents, nor does it include any mixture of olive oil with other types of oils.

170.4 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 or other physical Treatments. This term does not include oils obtained by re-esterification processes, nor does it include any mixture of olive-pomace oil with other types of oils, with the exception of olive oils.

170.5 Mixture of Vegetable Oil and Olive Oil (Mixed Oil)

A mixture of vegetable oil and olive oil or mixed oil is any product that includes one or more edible vegetable or seed oils in addition to olive oil or olive-pomace oil.

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

170.6 Olive Oil Grades

170.6.1. Extra Virgin Olive oil

Extra virgin olive oil is a superior category of olive oil obtained directly from olives and solely by mechanical means, having a maximum free acidity of 0.5 g per 100g measured as oleic acid, a degree of fruitiness higher than 1, a median of defects equal to 0, and the other characteristics which correspond to the limits fixed for this grade in this Part. Extra virgin olive oil can be made up of a blend of extra virgin olive oils of different olive varieties. The term “Blend” can only be utilized in products regulated under this Part when referring to extra virgin olive oil; this is a limiting rule.

170.6.2. Virgin Olive oil

Virgin olive oil is the oil obtained directly from olives and solely by mechanical means, having a maximum free acidity of 2g per 100g measured as oleic acid, fruitiness greater than 0, a median of defects equal to or less than 2.5, and the other characteristics which correspond to the limits fixed for this grade in this Part.

170.6.3. Olive Oil

Olive oil is composed of refined olive oils and extra virgin or virgin olive oils, having a free acidity content of not more than 0.5g per 100g measured as oleic acid, a median of defects equal to or less than 2.5, and other characteristics that correspond to those fixed for this grade in this Part. The addition of alpha-tocoferol is permitted. These products shall have a declaration on the front of the product stating "Composed of refined olive oil and extra virgin (or virgin) olive oil."

170.6.4. Refined Olive oil

Refined olive oil is an oil obtained from olive oil which 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 this category in this Part. Refined olive oil is an 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, nor does it include any mixture with other types of oils.

170.6.5. Lampante Olive Oil

Lampante olive oil is olive oil that has a free acidity of more than 2.0g per 100g measured as oleic acid and a median of defects greater than 2.5 and meets the characteristics which correspond to those fixed for this category in this Part. Lampante olive oil is not fit for human consumption without further processing and is intended to be used for refining or for technical use.

170.7 Olive-Pomace Oil Grades

170.7.1. Olive-Pomace Oil

Olive-pomace oil 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 category in this Part.

170.7.2. Refined Olive-Pomace Oil

Refined olive-pomace oil is 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 category in this Part.

170.7.3. Crude Olive-Pomace Oil

Crude olive-pomace oil is olive-pomace oil that does not meet the requirements for refined olive-pomace oil but that meets the purity requirements for this category. 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

170.8 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.

170.9 Quality parameters

The different grades of olive oil or olive-pomace oil must comply with the limits presented in Table 5.

TABLE 1

GENERIC CHEMICAL COMPOSITION PARAMETERS - PURITY

		Extra virgin olive oil	Virgin olive oil	Olive oil, composed of refined olive oil and extra virgin or virgin olive oil	Refined olive oil	Lampante olive oil	Olive pomace oil, composed of refined olive pomace oil and extra virgin or virgin olive 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	N/A	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	≤250	≤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 (%)		≤1.0	≤1.0	≤1.0	≤1.1	≤1.1	≤1.2	≤1.4	≤1.4

NOTE:

1. 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%.
2. 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)

Myristic acid (C14:0)	≤0.03
Palmitic acid (C16:0)	7.5–20.0
Palmitoleic acid (C16:1)	0.3–3.5
Heptadecanoic acid (C17:0)	≤0.4
Heptadecenoic acid (C17:1)	≤0.6
Stearic acid (C18:0)	0.5–5.0
Oleic acid (C18:1)	53.0–85.0
Linoleic acid (C18:2)	2.5–22.0
Linolenic acid (C18:3)	≤1.5
Arachidic acid (C20:0)	≤0.6
Gadoleic acid (eicosenoic) (C20:1)	≤0.5
Behenic acid (C22:0)	≤0.2 (See Note)
Lignoceric acid (C24:0)	≤0.2

NOTE: ≤0.3 for olive-pomace oils

TABLE 3

STEROL AND TRITERPENE DIALCOHOLS COMPOSITION - PURITY (EXPRESSED AS % OF TOTAL STEROLS)

Cholesterol	≤0.5
Brassicasterol	≤0.1
Campesterol	≤4.8
Stigmasterol	≤1.9
Delta-7-stigmastenol	≤0.5
Apparent Beta-sitosterol	≥92.5
Erythrodiol + Uvaol (Olive oils)	≤4.5
Erythrodiol + Uvaol (Olive-pomace oils)	>4.5

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, composed of refined olive oil and extra virgin or virgin olive oil	Crude olive-pomace oil	Refined olive pomace oil	Olive pomace oil, composed of refined olive pomace and extra virgin or virgin olive oil
Free fatty acid content (FFA) (% m/m):		≤0.5	≤2.0	>2.0	≤0.3	≤0.5	N/A	≤0.3	≤0.5
Peroxide value (PV) (meq O_2/kg oil)		≤15.0	≤20.0	>20.0	≤5.0	≤15.0	N/A	≤5.0	≤15.0
Absorbency in ultraviolet	K_{232}	≤2.40	≤2.60	>2.60	N/A	N/A	N/A	N/A	N/A
	K_{270}	≤0.22	≤0.25	>0.25	≤1.10	≤0.90	N/A	≤2.00	≤1.70
	Delta K	≤/0.01/	≤/0.01/	>/0.01/	≤/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) (%)		≤17	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	≤2.5	≤2.5	N/A	≤2.5	≤2.5
	Median of fruitiness (MeF)	>1.0	>0.0	N/A	N/A	>0.0	N/A	N/A	>0.0

*These criteria are not required to be concurrent for lampante olive oil, one is sufficient.

Subpart E. Definitions of Related Terms

170.10 Definitions of Related Terms

For the purpose of this Part the following definitions apply.

170.10.1. Absorbency in Ultraviolet (UV)

Spectrophotometric test which examines the oil and measures the absorption under ultraviolet light. These absorptions are expressed as K (extinction coefficient) for the specified wavelength. The wave regions examined are 232 nanometers (nm) to calculate K232,270 nm to calculate K270, and 264-274 to calculate delta K (ΔK).

170.10.2. Apparent β-sitosterol

The sum of the concentrations of β-sitosterol, Δ-5avenasterol, Δ-5,23-stigmastadienol, Δ-5,24-stigmastadienol, clerosterol, and sitostanol.

170.10.3. Aroma

A volatilized chemical compound that is perceived by olfaction.

170.10.4. Cold Pressed and Cold Extracted

The term "cold pressed" shall be utilised only for extra virgin olive oil and virgin olive oil obtained by pressing crushed olives with a mechanical, hydraulic, or centrifugal presses at a temperature that does not lead to significant thermal alterations. The term "cold extracted" shall be utilised only for extra virgin olive oil and virgin olive oils obtained by separating the oil by any mechanical or other physical means at a temperature that does not lead to significant thermal alterations.

170.10.5. Desmethylsterol Composition

A test used to indicate the origin and purity of the oil, reported as Total Sterols and the individual phyto-sterols as percentages of total sterols indicated in Table 3.

170.10.6. Diacylglycerol (DAG)

A glyceride consisting of two fatty acids chains covalently bonded to a glycerol molecule through ester linkages. In mechanically extracted olive oils, DAGs are present in a range of 1% to 3% and they are found as 1,2- and 1,3- isomers.

170.10.7. Equivalent Carbon Number 42 (ECN 42)

The determination of the difference between the actual Equivalent Carbon Number triacylglycerol content of the oil molecules determined by High Performance Liquid Chromatography (HPLC) and the theoretical amount of ECN 42 triacylglycerol using fatty acid composition.

170.10.8. Erythrodiol and Uvaol

Two triterpene dialcohol components found in olive oil and olive-pomace oil. The levels of these components differentiate oils that were physically extracted from oils that were produced by solvent extraction.

170.10.9. Fatty Acid Ethyl Esters

Analysis applicable to products declared as extra virgin olive oil that may indicate adulteration with oil of lower quality than extra virgin olive oil due to fermentative degradation.

170.10.10. First extraction.

First mechanical process to separate the oil from olive paste by centrifugation, decantation, or pressing. This does not include the second mechanical extraction or solvent extraction used to chemically separate the oil remaining in the pomace.

170.10.11. Flavor

The sensory impression of oil determined mainly by the senses of taste and smell. Refers to the typical flavor of olive oil produced from olives and the degree of positive or negative attributes as determined by the method in Section 170.11.10.

170.10.12. Free fatty acid content and free acidity

Expressed as a percentage by weight of grams per 100 grams, as oleic acid. The free fatty acid is a measure of the quality of the oil, and reflects the care taken in producing the oil and the quality of the incoming fruit.

170.10.13. Initial Glyceridic Structure

The pattern of mono-, di-, and triglycerides present in olive oils or crude olive-pomace oils as extracted prior to any refining process.

170.10.14. Median of Defects (Md)

A calculation of the median score of the negative flavor and aroma attributes of the oil according to the method in Section 170.11.10 or an equivalent method. This calculation includes but is not limited to measurements of the following defects:

(a) **Fusty.** A flavor defect attributable to poor storage conditions usually promoting the bacterial growth of the *Clostridium* and *Pseudomonas* genera.
(b) **Muddy-sediment.** A flavor defect caused by the storage of olives in contact with oil sediment for long periods of time giving the oil a putrid flavor and aroma. The resulting oil has a moldy aroma.
(c) **Musty and Earthy.** A flavor defect occurring when low temperatures and high humidity promote mold growth, mainly of the *Aspergillus* and *Penicilium* genera.
(d) **Rancid.** A flavor defect caused by the oxidation of the oil and subsequent formation of aldehydes during the production process or during storage, giving the oil an oxidized flavor and aroma.
(e) **Winey-vinegary.** A flavor defect caused by the storage condition of the olives that causes aerobic fermentation by the growth of yeasts that produce ethanol, acetic acid, and ethyl acetate.

170.10.15. Median of Fruity (Mf)

A calculation of the median score of the intensity of the positive fruity characteristics of the oil according to the method in Section 170.11.10 or an equivalent method.

170.10.16. Monopalmitate (2-Glyceryl) Content Determination

A test used to determine if an oil has been re-esterified by synthetic means or by the addition of animal fat.

170.10.17. Organoleptic Analysis

An analysis based on flavor and aroma characteristics as measured in accordance with Section 170.11.

170.10.18. Peroxide value

A measure of the oxidation of oil expressed as milliequivalents of active oxygen per kilogram of oil.

170.10.19. Pyropheophytin

A degradation product of Chlorophyll a that results from the thermal or age-related degradation of the oil.

170.10.20. Refining

A process by which oil undergoes treatment, including but not limited to processes involving heat (typically stripping steam) or chemicals (typically caustic soda or sodium carbonate) in combination

with heat. Soft column refining, also sometimes known as deodorization, is a type of refining using lower temperatures and high vacuum.

170.10.21. Shelf Life
A date on the container that signifies the end of the period during which the intact package of oil, if stored in accordance with stated storage conditions, will retain any specified qualities for which express or implied claims have been made. Mandatory terminology shall state "Best if Used By" in accordance with FDA regulations and guidance.

170.10.22. Sterols
A subgroup of steroids with a hydroxyl group at the 3-position of the A-ring. Sterols comprise one of many minor constituents of oils that are characteristic indicators of purity or impurity.

170.10.23. Stigmastadienes
Stigmastadienes are byproducts produced by the dehydration of β-sitosterol during refining, which are not present in significant quantities in virgin olive oil. The bleaching process is the main refining step that causes the formation of stigmastadienes.

170.10.24. Trans fatty acids
A group of compounds consisting of all geometrical isomers of monounsaturated and polyunsaturated fatty acids having one or more non-conjugated carbon-carbon double bond in the trans configuration interrupted by at least one methylene group. As they are not present in extra virgin, virgin or crude (lampante) olive oil, their presence indicates that processing such as deodorization or de-coloring of the product has taken place.

170.10.25. Triglyceride
A major component of oil comprised of an ester of three fatty acids and glycerol, also known as triacylglycerol.

170.10.26. Wax content
A minor component of olive oil that is found in the skin of the olive fruit.

Subpart F. Methods of Analysis
170.11 Methods of Analysis

170.11.1. General
The following methods shall be used to determine the characteristics of the olive oil, refined olive oils, and olive-pomace oils. At all times the most recently published version of the listed method or their equivalent alternatives shall be used.

170.11.2. 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.

170.11.3. Determination of trans fatty acid content
According to AOCS Ch 2a-94 (Rev. 2002) or ISO 15304 or COI/T.20/Doc.17.Rev.1.

170.11.4. Determination of the sterol composition and total sterol content
Sterol composition and total sterol content shall be determined in accordance with ISO 12228 or COI/T.20/Doc.10.Rev.1 or AOCS Ch 6-91.

170.11.5. Determination of the content of erythrodiol + uvaol
Erythrodiol + uvaol content shall be determined in accordance with IUPAC no. 2.431; capillary columns are recommended or IOC/T.20/Doc. 30.

170.11.6. Determination of wax content and alkyl esters

According to COI/T.20/Doc. No 28/Rev.2, "Determination of the content of waxes, fatty acid methyl esters and fatty acid ethyl esters by capillary gas chromatography".

170.11.7. Determination of the stigmastadiene content

According to COI/T.20/Doc. No 11/Rev.3, "Determination of stigmastadienes in vegetable oils", or COI/T.20/Doc. no. 16/Rev.1, "Determination of sterenes in refined vegetable oils", or ISO 15788-1 or AOCS Cd 26-96.

170.11.8. Determination of the content of 2-glyceryl monopalmitate

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

170.11.9. 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.Rev.3.

170.11.10. Determination of organoleptic characteristics

Organoleptic characteristics shall be determined in accordance with COI/T.20/Doc. 15.Rev.2.

170.11.11. Determination of free fatty acid content

Free fatty acid content shall be determined in accordance with ISO 660 or AOCS Ca 5a-40.

170.11.12. Determination of the peroxide value

Peroxide value shall be determined in accordance with AOCS Cd 8b-90 or ISO 3960.

170.11.13. 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. Rev.2.

170.11.14. Determination of moisture and volatile matter

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

170.11.15. Determination of insoluble impurities in light petroleum

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

170.11.16. Determination of trace metals

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

170.11.17. Determination of alpha-tocopherol

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

170.11.18. Determination of pyropheophytins

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

170.11.19. Determination of 1,2-Diacylglycerol content.

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

Subpart G. Labelling

170.12 Substantiation of "Best if Used By" Date

If a producer fails any freshness quality parameter, the producer shall have the opportunity to provide evidence to substantiate the "Best if Used By" date applied to the product in question. If

the product in question is shown to be in compliance with all other quality parameters and has a "Best if Used By" date supported by technical evidence, the producer will not be subject to FDA enforcement action.

170.13 Mandatory Labelling

170.13.1. General

In addition to the requirements set out herein, sellers of olive oils, refined-olive oils and olive-pomace oils shall comply with the requirements of 21 C.F.R Subchapters A, B, D, E, F, G, Part 101.

170.13.2. Product Name

The mandatory labeling on each container shall indicate the specific grade of the product in accordance with Sections 170.6 and 170.7. Indications of grades must not mislead the purchaser as to the characteristics of the oil contained therein by attributing to it characteristics that it does not possess.

The designation of grades shall be prominent and clearly legible in the principal display panel of the label. The following are the only grade designations permitted:

1. Extra Virgin Olive Oil
2. Virgin Olive Oil
3. Olive Oil
4. Refined Olive Oil
5. Refined Olive-Pomace Oil
6. Refined Olive-Pomace Oil
7. Mixed Oil

170.13.3. Designation of Region

If reference is made to a specific region in the labelling of the product, then at least 85% of the oil (by weight) must be from olives grown in that region.

170.13.4. Varietal Names

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

170.13.5. Harvest Date

The harvest date shall be indicated as Harvest Month(s) and Year, or Harvest Year. The earliest harvest month or year of the oil in the package shall be used.

170.13.6. Lot Identification

All bottles and packaging shall indicate lot allocation with full traceability.

170.13.7. Shelf Life

Shelf life of the oil in compliance with its labelled grade shall be expressed as "Best if Used by [Month Year]", *e.g.* "Best if Used by November 2020."

170.13.8. First Cold Pressing/ Cold Extracted

If the terms "first cold pressing" or "first cold extracted", or similar terms, are used in the labelling of the product, the product must meet the definitions for these terms in with Sections 170.10.4 and 170.10.10.

170.13.9. Mixed Oil

For any mixed oil, when the presence of olive oils is referenced in the labelling, outside of the list of ingredients, by words, images or graphic representations, the following statement shall appear: "Mixture of vegetable oils (or the specific names of the vegetable oils concerned) and olive oil", directly followed by the percentage of olive oil (and/or olive-pomace oil) in the mixture. The presence of olive oil (and/or olive-pomace oil) may only be referenced by images or graphics on the labelling of a mixed oil when it accounts for more than 50% of the mixture.

170.13.10. Prohibited Grade Terminology Use

Any product that is labelled with "Extra Virgin Olive Oil" or terminology that implies that the product is extra virgin olive oil must conform to the standard of identity definition of that grade. The use of "Extra" in the primary product name is prohibited except when used to describe extra virgin olive oil.