

CITIZEN PETITION

Standard of Identity for Olive Oil and Olive-Pomace Oil

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TABLE OF CONTENTS

Introduction..... 1

A. Action Requested ..... 2

B. Statement of Grounds..... 2

    1. The Need for an Olive Oil and Olive-Pomace Oil Standard of Identity ..... 2

        a. An SOI Will “Empower Consumers to Make Better and More Informed Decisions About Their Diets and Health” ..... 3

        b. An SOI Will Promote Honesty and Fair Dealing, Which Is Critical to Meeting Consumers’ Expectations When They Choose to Purchase Olive Oil ..... 8

    2. The U.S. Standard of Identity for Olive Oil Should Be Based on the Codex Standard..... 8

        a. Interest Group Consultations under 21 CFR §130.6(c) ..... 9

        b. Support for Proposed Deviations Pursuant to 21 CFR § 130.6(b)(1)..... 10

    3. FDA Should Consider an Alternative Horizontal Approach for an Olive Oil and Olive-Pomace Oils Standard of Identity..... 29

C. Environmental Impact ..... 30

D. Economic Impact ..... 30

E. Certification..... 30

Table of Appendices ..... 31

## Citizen Petition

The North American Olive Oil Association (“NAOOA”) (hereafter, “Petitioner”), a marketing association founded in 1989 whose members’ olive oil sales comprise a majority of all of the olive oil sold in the United States, submits this petition pursuant to 21 CFR §10.30, requesting the Commissioner of Food and Drugs, U.S. Food and Drug Administration (“FDA”), promulgate a standard of identity (“SOI”) for olive oils and olive-pomace oils pursuant to 21 CFR § 130.6 and section 401 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 341).

### **INTRODUCTION**

Olive oil is produced in the U.S., traded internationally, consumed by Americans as both as a packaged food and as a food ingredient, and widely-touted for its potential health benefits. Despite this, there currently is no nationally-mandated standard to define olive oil and its various categories and grades.

Over 40 years ago, FDA solicited public comment on the adoption of a standard of identity for olive oils and olive-pomace oils (the “1979 ANPRM”),<sup>1</sup> based on the Codex Alimentarius Commission’s (“CAC’s”) international standard.<sup>2</sup> Although the majority of comments FDA received were in favor of establishing a U.S. standard, the agency concluded there was “not sufficient need” to warrant a U.S. standard, citing a lack of data.<sup>3</sup> However, FDA noted its willingness to consider development of a U.S. standard in the future.<sup>4</sup>

Since FDA’s decision, olive oil consumption in the U.S. has grown appreciably. Potential health benefits have been a driving factor in the growth of olive oil consumption in the U.S. and globally. Annual U.S. imports of olive oils in 1980 were 28,000 metric tons; by 2019, they had grown to 356,000 metric tons.<sup>5</sup> Today, the U.S. ranks second in the world after the E.U. in total olive oil consumption.<sup>6</sup> The U.S. also has a burgeoning olive oil industry with an estimated 48,000 acres of trees planted for production as of 2019, with producers, the vast majority of

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<sup>1</sup> 44 FR 10742, Feb. 23, 1979.

<sup>2</sup> At that time, the CAC had all but completed work on what would become the Codex Standard for Olive Oils and Olive Pomace Oils (CODEX STAN 33-1981, adopted 1981; revised 1989, 2015, and 2017; amended 2009 and 2013 (formerly CAC/RS 33-1970)) (hereinafter, the “Codex Standard”), a copy of which is included as Appendix 2. “Olive-pomace oil” was in the past more commonly referred to as “olive residue oil.” Today the World Trade Organization (“WTO”) relies on collaboration with the CAC to ensure international food safety standards through the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (“SPS Agreement”). The WTO SPS Agreement names the CAC directly as the relevant standard-setting organization for food safety.

<sup>3</sup> 47 FR 42123, Sept 24, 1982.

<sup>4</sup> Id.

<sup>5</sup> Index Mundi, United States Olive Oil Imports by Year, <https://www.indexmundi.com/agriculture/?country=us&commodity=olive-oil&graph=imports> (last visited May 19, 2020) (data source noted as United States Department of Agriculture).

<sup>6</sup> International Olive Oil Council, Olive Oils (Nov. 2019), <https://www.internationaloliveoil.org/wp-content/uploads/2020/04/HO-W901-29-11-2019-C.pdf>.

whom are in California, ranging in size from boutique firms to agriculture businesses that produce thousands of gallons of olive oil that is distributed throughout the country.<sup>7</sup>

Additionally, FDA recently identified modernization of its standards of identity as an agency action item, with particular priority given to potential standards of identity with public health value.<sup>8</sup> Given this strategic policy goal, olive oil's health benefits, and significant and growing consumer consumption and production over the past 40 years, Petitioner respectfully submits that the time is ripe for FDA to adopt a standard of identity for olive oils and olive-pomace oils.<sup>9</sup>

Petitioner also respectfully submits that in adopting an olive oil standard, FDA should consider Petitioner's proposal as described herein for a horizontal approach that would facilitate future updates to the standard. This is because international olive oil standards for purity and quality are regularly updated as science and technology improve. To the extent a U.S. olive oil standard cannot be easily updated, American consumers will be deprived of the protections such updates would afford on fraud detection, for instance, and could be an impediment to international trade. Petitioner's proposal in this regard is in keeping with topics discussed at the public meeting entitled Horizontal Approaches to Food Standards of Identity Modernization that FDA hosted on September 27, 2019.<sup>10</sup>

#### *A. Action Requested*

In accordance with section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §341) and 21 C.F.R. § 130.6(b)(1), Petitioner requests that the Commissioner review for adoption a proposed U.S. standard of identity for olive oil and olive-pomace oils as set forth in Appendix 1, which is based upon the Codex Standard as set forth in Appendix 2, with specified deviations explained in this petition.

#### *B. Statement of Grounds*

##### **1. The Need for an Olive Oil and Olive-Pomace Oil Standard of Identity.**

Olive oil has become a staple of many American kitchens, an important domestic agricultural product, and a product consumers value for its potential health benefits. An olive oil standard of identity ("SOI") is needed for many reasons, principal among which are: promotion of honesty and fair dealing in the interest of consumers, empowering consumers to make informed choices

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<sup>7</sup> <http://www.aopaa.org/assets/uploads/pdfs/Challenges-and-Opportunities.pdf>. Domestic production, which has recently amounted to as much as 15,000 metric tons, typically accounts for approximately 5% of domestic consumption, with the balance being imported olive oil.

<sup>8</sup> FDA, Healthy Innovation, Safer Families: FDA's 2018 Strategic Policy Roadmap (Jan. 2018), <https://www.fda.gov/media/110587/download>.

<sup>9</sup> Prior to the instant petition, the Petitioner filed two citizen petitions seeking to have the Commissioner regulate olive oil and olive-pomace oil. The first petition was submitted in 1990, the year after the NAOOA was formed. A copy of that petition is included as Appendix 3. Petitioner subsequently withdrew that petition and filed a new one in 2012, a copy of which is included as Appendix 3a. On September 30, 2019, the Petitioner withdrew the 2012 petition (a copy of the withdrawal is included as Appendix 3b) in preparation for and to facilitate the filing of the instant petition.

<sup>10</sup> 84 FR 45497 (Aug 29, 2019) (FDA-2018-N-2381). A representative of NAOOA attended this meeting and submitted written comments relating to its plan to submit a petition for an olive oil SOI.

for their health, and assuring consumers their expectations will be met when they choose to purchase olive oil.

As detailed further below, these reasons for an SOI are supported and affirmed by the results of a recent consumer survey (the “NAOOA Consumer Study”), commissioned by Petitioner and conducted by an outside research firm.<sup>11</sup> This 2020 NAOOA Consumer Study consisted of a nationally representative sample of 1,500 adult consumers around the United States that do at least half the shopping for their household.

American consumers deserve science-based mandatory olive oil standards to empower them with knowledge they need to make informed choices for their health, and facilitate enforcement to protect all consumers from fraud, and promote a vibrant, competitive and fair-dealing industry.

- a. An SOI Will “Empower Consumers to Make Better and More Informed Decisions About Their Diets and Health.”<sup>12</sup>

An SOI will serve the interest of consumers who may decide to choose olive oil for their health in three ways.<sup>13</sup> First, it will help educate consumers about the differences among olive oil product grades. This is critical because the health benefits vary among the grades due to the presence of different types and levels of bioactive constituents such as phenolic compounds and antioxidants. Second, having a clear federal definition of the olive oil grades will enable consumers to discern the value differentials among uniformly labeled olive oil products that they may find on their supermarket shelves. Third, an SOI will also facilitate industry self-regulation and enforcement of the standards to protect the interests of consumers—including victims of actual and perceived fraud.

- i. Consumer Research Shows Consumers Believe Olive Oil Has Health Benefits.

Olive oil is widely considered a healthy food by both experts and consumers.<sup>14</sup> The potential health benefits relate to coronary heart disease as well as other critical chronic diseases affecting the American population.<sup>15</sup> As part of the NAOOA Consumer Study, respondents were shown a

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<sup>11</sup> A copy of the NAOOA Consumer Study is included as Appendix 7.

<sup>12</sup> See FDA Roadmap, note 8 supra.

<sup>13</sup> Petitioner restricts its discussion of health benefits to olive oil as opposed to olive-pomace oil, which is not generally sold at retail, and specifically for which there is much less health research available.

<sup>14</sup> In a 2016 survey of 672 nutritionists by the Morning Consult, 96% said that they consider olive oil “healthy.” Similarly, 88% of 2000 American consumers said that olive oil was “healthy”. NY Times, Is Sushi ‘Healthy’? What About Granola? Where Americans and Nutritionists Disagree (July 5, 2016), <https://nyti.ms/2jUmdOG>; Morning Consulting, National Tracking Poll (June 22, 2016), [https://intel.morningconsult.com/public/mc/160600\\_topline\\_NYT\\_v2\\_AP.pdf](https://intel.morningconsult.com/public/mc/160600_topline_NYT_v2_AP.pdf); Morning Consult, National Tracking Poll (May 19, 2016), [https://intel.morningconsult.com/public/mc/160506\\_topline\\_NYT\\_v3\\_KD.pdf](https://intel.morningconsult.com/public/mc/160506_topline_NYT_v3_KD.pdf).

<sup>15</sup> See, e.g., White Paper prepared by Tassos C. Kyriakides, Ph.D, Yale School of Public Health, January 13, 2020 (“Yale University White Paper”), and submitted in response to the U.S. Trade Representative’s Notice of Hearing and Request for Public Comments: Enforcement of U.S. WTO Rights in Large Civil Aircraft Dispute, published on April 12, 2019, 84 Fed. Reg. 15028, pursuant to Sections 301 et seq. of the Trade Act of 1974, included as Appendix 6. See also the summary of olive oil’s health benefits in “Why Extra Virgin Olive Oil is The Healthiest Fat on Earth,” <https://www.healthline.com/nutrition/extra-virgin-olive-oil>.

list of fourteen cooking oils, and asked to indicate which oils they considered healthy (if any). Results show that of the common cooking oils listed, the most consumers consider extra virgin olive oil to be healthy (58%), with olive oil coming in second (43%).<sup>16</sup>

ii. U.S. Health Policy Reinforces Consumer’s Perceptions About Olive Oil’s Potential Health Benefits.

U.S. health policy also plays a role in the consumers’ understanding that olive oil is healthy. In 2004, in response to a petition from the NAOOA, FDA approved a qualified health claim for olive oil:

Limited and not conclusive scientific evidence suggests that eating about 2 tablespoons (23 grams) of olive oil daily may reduce the risk of coronary heart disease due to the monounsaturated fat in olive oil. To achieve this possible benefit, olive oil is to replace a similar amount of saturated fat and not increase the total number of calories you eat in a day. One serving of this product contains [x] grams of olive oil.<sup>17</sup>

Similarly, the 2015-2020 Dietary Guidelines for Americans recommended Americans adopt one of three healthy dietary eating patterns, including the “Healthy Mediterranean-Style Eating Pattern.”<sup>18</sup> Olive oil is considered the cornerstone of the Mediterranean diet.<sup>19</sup>

iii. Potential Health Benefits Drive Purchases of Olive Oil.

Not only do Americans recognize olive oil to be healthy, but that is the primary reason they buy it. In 2018, the NAOOA and the American Olive Oil Producers Association (“AOOPA”) jointly commissioned Rose Partners LLC to conduct a National Attitude and Usage Study (“Attitude and Usage Study”) interviewing 2,000 respondents in the U.S. From this study, Rose Partners concluded: “‘Health’ is a primary purchase motivator for olive oil consumers.”<sup>20</sup>

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<sup>16</sup> NAOOA Consumer Study, Appendix 7 at 30.

<sup>17</sup> FDA docket no. 2003Q-0559. <http://wayback.archive-it.org/7993/20171114183732/https://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm072963.htm>. Another qualified health claim that relates to oleic acid (and thus also applies to olive oil) was adopted in 2018 (FDA docket no. 2017-Q-0807). <https://www.fda.gov/media/118199/download>.

<sup>18</sup> [https://health.gov/sites/default/files/2019-09/2015-2020\\_Dietary\\_Guidelines.pdf](https://health.gov/sites/default/files/2019-09/2015-2020_Dietary_Guidelines.pdf) at pp. 16-36.

<sup>19</sup> Key Ingredients of the Mediterranean Diet — The Nutritious Sum of Delicious Parts, Carrie Dennett, MPH, RDN, CD, Today's Dietitian, quoting Antonia Trichopoulou, MD, PhD, president of the Hellenic Health Foundation and director of the World Health Organization Collaborating Center for Nutrition at the University of Athens (Greece) School of Medicine, (“Olive oil is essential in defining the Mediterranean diet... You cannot consume vegetables and legumes in the quantity in which they are consumed in the Mediterranean diet unless they are cooked in olive oil.”) <https://www.todaysdietitian.com/newarchives/0516p28.shtml>.

<sup>20</sup> A copy of the Attitude and Usage Study is included as Appendix 4. All respondents reported conducting at least half of the shopping and half of the cooking for their household and having purchased olive oil in the prior six months. It is worth noting here that AOOPA and Deoleo, S.A. submitted a petition for an olive oil standard of identity in November 2019 (FDA-2019-P-5191-0014) (the “AOOPA/Deoleo Petition”), which in many respects aligns with the proposed standard in this petition. The AOOPA/Deoleo Petition, however, did not address olive oil’s potential health benefits as a reason an SOI is needed, and thus did not cite the Attitude and Usage Study. Petitioner believes such data may be critical to the success of an SOI petition; FDA declined to adopt an olive oil SOI in 1982

iv. When It Comes to Potential Health Benefits, Not All Olive Oils are Equal.

The consumer's choice, however, is not just whether to buy olive oil, but also what kind of olive oil. Some grades of olive oils have more potential health benefits than others. As set out in Petitioner's proposed SOI, there are two basic categories of olive oil: virgin and refined. The FDA qualified claims for cardiovascular health are applicable to both categories. This is because each of those claims relates to the fatty acid profile of olive oils that does not vary by category or grade. However, much of the current research on the potential health benefits of olive oils for other chronic diseases points to an additional factor: the content of bioactive constituents including antioxidants and polyphenols unique to virgin olive oils.<sup>21</sup> These constituents, however, are largely destroyed in the refining process. For this reason, it is critically important that olive oil grades be uniformly defined and that proper disclosure of grades contained in a product be provided on the label to inform consumers making choices for their health.

v. Americans Are Confused About Olive Oil Types and Quality and this Discourages Consumers from Consuming More Olive Oil.

The results of the NAOOA Consumer Study clearly show a general lack of understanding about the different categories and grades of olive oils:<sup>22</sup>

- Between one-fourth and one-third of respondents did not believe or were not sure that olive oil actually came from olives.
- Close to 60% of respondents stated that they either did not know or were not sure what the words "virgin" or "refined" means with respect to cooking oils.<sup>23</sup>
- Large percentages of respondents are confused by extra virgin olive oil labels: 55% believe the term "extra virgin" indicates that the oil is "more virgin" than products labeled as "virgin olive oil;" 64% believe or are not sure the word "extra" has any meaning other than as a marketing term; and 41% did not know if "extra virgin" on a label indicated that the oil was one of the top quality oils available.
- With respect to products labeled as "olive oil," only 36% knew that the product was a mixture of refined olive oil and virgin olive oil.

The 2018 Attitude and Usage Study referenced above also found that consumers' lack of knowledge impacts their behavior when it comes to deciding whether to purchase olive oil. In response to the question seeking reasons consumers do not buy more olive oil, 24% (after answers were netted) attributed the cause to confusion over olive oil types, quality and brands.

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citing a lack a lack of data supporting the need for one, see note 3 supra, and has more recently communicated the importance of such data to petitioners. Petitioner offers this discussion on why olive oil's potential health benefits support the need for an SOI, and cites the Attitude and Usage Study, in a collaborative spirit, recognizing it should support both petitions.

<sup>21</sup> See e.g., Yale University White Paper, at p. 3 (Appendix 6); Garcia-Gonzalez D, Aparicio-Ruiz R, Aparicio R (2009) Olive oil. In: Moreau RA, Kamal-Eldin A (eds) Gourmet and health-promoting specialty oils. AOCS Press, Urbana, pp 33-72.

<sup>22</sup> See Appendix 7 at slides ## 34-37.

<sup>23</sup> Accounting for the content of written explanations of the words "virgin" and "refined" provided by respondents, the actual percentage may be higher.

To the extent an SOI will create a single uniform standard defining olive oil and olive-pomace oils, this will alleviate confusion about types and quality, and it will give more consumers confidence to make choices for their health among the various olive oil products.

vi. An SOI Will Protect Concerned Consumers from Fraud.

The Attitude and Usage Study also supports finding that consumer confusion about olive oil goes beyond the ability to discern quality differences or potential health benefits among olive oil grades. Among the types of information respondents in the Attitude and Usage Study said they want about olive oil included “certifications” (22%) and “source/country of origin” (27%).<sup>24</sup> This desire for information is reinforced by additional evidence that many consumers perceive that the olive oil market is rife with fraud.

The traffic statistics from Petitioner’s website, AboutOliveOil.org, confirm this. The NAOOA website has approximately 230 separate webpages. Since 2015, of the over 1.8 million visits to Petitioner’s website, over 800,000 visits were to the page that concerns the AboutOliveOil Quality Seal certification program. (The next closest ranking page has had only 37,000 visits.) . This suggests consumer concern regarding olive oil quality and the desirability of a nationally-enforceable standard. Submissions to NAOOA’s social media page reflect similar consternation, with 32% of all consumer comments since 2016 related to concerns about “fake olive oil.”<sup>25</sup>

That consumers are worried about olive oil fraud is further borne out by other data from search engines:<sup>26</sup>

- Since September 2016, the phrase “fake olive oil” was searched approximately 1.4 million times on Google.com, or an average of approximately 402,500 per year.
- According to SEM Rush, 152,000 additional searches are performed per month on variations on the keyword “fake olive oil” (including “olive oil not pure” and “counterfeit olive oil”).
- There are approximately 14,900,000 web pages indexed by Google on the topic of “fake olive oil,” including 50,200 videos listed on YouTube related to the keyword “fake olive oil.”

vii. An SOI Will Empower Industry and Government Agencies to Combat Fraud—and Foster Trust in Olive Oil Products.

A peer-reviewed journal article authored by FDA scientists highlights the motivations for olive oil fraud:

Extra virgin olive oil (EVOO) is highly regarded for its nutritive value and potential health benefits. These oils sell at a premium for their desirable organoleptic properties and rich concentration of bioactive constituents. However, the discrepancy in pricing

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<sup>24</sup> Attitude and Usage Study, Appendix 4 at slide #31.

<sup>25</sup> See Letter from Agile Pixel Studio, which manages Petitioner’s social media channels, Appendix 8.

<sup>26</sup> Id.

between EVOO and other commodity oils has rendered this product *a primary target for fraudulent activities, namely economic adulteration and deliberate mislabeling*. [Emphasis added.]<sup>27</sup>

At least with respect to the retail market, the extent of actual fraud appears to be relatively low.<sup>28</sup> Nevertheless, there can be no doubt that lack of confidence in olive oil legitimacy harms American consumers seeking to make choices for their health.

The NAOOA, as the country's largest trade association, has made industry self-enforcement a priority. Over the past decades, the NAOOA has randomly sampled and tested against international standards thousands of olive oils from supermarket shelves.<sup>29</sup> Where the NAOOA has found oils to be non-compliant, the lack of a national standard makes it more difficult to hold bad actors accountable. When in 2013, the NAOOA sued to stop a serious mislabeling problem, it had to file its lawsuit in New York, which is one of the few states that has a standard for olive oil and olive pomace oils.<sup>30</sup> Because so few states have standards, and those that do are not consistent, an enforceable national standard will give industry the tools it needs to step-up self-enforcement to protect consumers from being victimized.

Consumers who choose not to buy olive oil because of the perception of fraud are victims themselves. As noted in the Attitude and Usage Study, many consumers cite concerns about quality as a reason they don't purchase more olive oil. This is confirmed by the findings that awareness of the existence of cases of olive fraud—even if emanating from one country—cause consumers to devalue olive oil as a category:

If consumers exposed to information about food fraud incidents come to distrust product labeling, their valuation of these products is likely to decrease, which may mean that higher quality products will not be able to compete in the market if producers are unable to effectively signal that quality to consumers.<sup>31</sup>

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<sup>27</sup>[https://www.researchgate.net/publication/286479191\\_Authenticity\\_Assessment\\_of\\_Extra\\_Virgin\\_Olive\\_Oil\\_Evaluation\\_of\\_Desmethylsterols\\_and\\_Triterpene\\_Dialcohols](https://www.researchgate.net/publication/286479191_Authenticity_Assessment_of_Extra_Virgin_Olive_Oil_Evaluation_of_Desmethylsterols_and_Triterpene_Dialcohols) (the "FDA EVOO Study").

<sup>28</sup> The FDA EVOO Study cited in note 27 supra focused on one type of potential fraud—adulteration of extra virgin olive oil with other oils. After randomly sampling and testing 88 bottles labeled extra virgin olive oil from Washington D.C. area stores and online vendors, the authors found the risk of this type of fraud to be low: "Overall, a low occurrence rate of adulteration (<5 %) was found for market samples of EVOO based on purity criteria for total sterol content, desmethylsterol composition, and content of triterpene dialcohols, as specified in the US Standards for grades of olive oil and olive pomace oils." As discussed further in this petition, the cited US Standards as promulgated by the United States Department of Agriculture are voluntary and not mandatory. See United States Department of Agriculture, United States Standards for Grades of Olive Oil and Olive-Pomace Oil (Oct. 25, 2010) at § 52.1539 and § 52.1540 (the "USDA Standard").

<sup>29</sup> From these controls, NAOOA estimates that the incidence of non-compliant oils found, adjusted for market share, is consistent with the findings of the FDA EVOO Study (i.e., less than 5%).

<sup>30</sup> <https://www.oliveoiltimes.com/business/north-america/north-american-olive-oil-association-sues-capatriti/32695>; see 1 CRR-NY 269.1; N.Y. Agric. & Mkts. Law § 204-a.

<sup>31</sup> Meerza SIA, Gustafson CR. Does prior knowledge of food fraud affect consumer behavior? Evidence from an incentivized economic experiment. PLoS One. 2019 Dec 3;14(12):e0225113. doi: 10.1371/journal.pone.0225113. PMID: 31794556; PMCID: PMC6890166 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6890166/#pone.0225113.ref007>.

To the extent the lack of standards contributes to the decision by many consumers to devalue olive oil and not purchase it at all, it harms those consumers by depriving them of potential healthy outcomes, and the consequential increase in health care costs.<sup>32</sup>

- b. An SOI Will Promote Honesty and Fair Dealing, Which Is Critical to Meeting Consumers' Expectations When They Choose to Purchase Olive Oil.

For the reasons stated in the prior section, an SOI will promote honesty and fair dealing in a product that is prized for its potential health benefits, and thus exposes consumers to the risks of bad actors looking to take unfair advantage of a largely unregulated industry. An SOI will empower consumers with knowledge to make informed choices for their health among different grades of olive oil and empower industry to combat fraud and ensure the integrity of olive oil for U.S. consumers.

## 2. The U.S. Standard of Identity for Olive Oil Should Be Based on the Codex Standard

FDA has suggested that a proposal for a new SOI should reflect “[h]armonization with existing international food standards to the extent feasible,”<sup>33</sup> and that where there is a standard for a food adopted by the Codex Alimentarius, that standard should be the base against which a proposed new SOI is considered:

*If a food standard presented in a petition is different from the requirements in a Codex standard for the same food, we are proposing that the petition should specify the reasons for these differences.* This principle is consistent with FDA’s existing regulation, 21 CFR 130.6, which states that food standards adopted by the Codex Alimentarius Commission will be reviewed by FDA, and either will be accepted (with or without change) or will not be accepted. This regulation also states that petitioners who petition FDA for a new or amended food standard based on the relevant Codex food standard shall specify any deviations in the requested standard from those in the Codex standard and the reasons for any such deviations.<sup>34</sup>

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<sup>32</sup> Following the release of the 2015-2020 Dietary Guidelines, the well-regarded scientific consulting firm Exponent did a study to determine just how effective adopting the recommended dietary patterns would be, and concluded that if Americans could increase their adherence to the Mediterranean diet by just 20%, it could save the U.S. economy approximately \$21–26 billion annually in health-related costs for chronic diseases including breast, colorectal and prostate cancer, coronary heart disease, stroke, type-2 diabetes, hip fractures and Alzheimer’s disease.

<https://www.oliveoiltimes.com/olive-oil-health-news/mediterranean-diet-could-save-u-s-economy-billions/63593>

<sup>33</sup> 70 FR 29214, 29235 (May 20, 2005) (the “2005 NPRM”). In the 2005 NPRM, FDA, in conjunction with the Food Safety and Inspection Service of the U.S. Department of Agriculture (“USDA”), proposed a general set of principles for the agencies to use in evaluating proposed and existing food standards. Recently, FDA has reopened the comment period on the 2005 NPRM. 85 FR 10107 (Feb. 21, 2020), and then extended it once again, 85 FR 21795 (April 20, 2020). For the extended comment period, FDA seeks specific comment only on FDA-specific aspects of the 2005 NPRM, including the full set of thirteen principles with which a proposed new standard of identity should be consistent. 85 FR at 10109. Harmonization with international standards is the seventh principle, and the 2005 NPRM explained the rationale behind it: “With the rising trend in globalization and increased accessibility of U.S. goods to other nations’ markets, efforts to harmonize U.S. food standards with international food standards will facilitate international trade and foster competition. These efforts may also result in lowered costs and the increased diversity of the food supply, which in turn would benefit consumers.” 70 FR at 29223.

<sup>34</sup> 70 FR at 29223 (emphasis added).

In promulgating regulations establishing the process for considering a new SOI for a food product already regulated by Codex, FDA recognized that given the active supporting role played by the U.S. in the CAC, “[t]he United States is obligated to review [established Codex] standards for possible adoption.” 37 FR 21102 (Oct. 5, 1972). The FDA regulation adopted a year later, 21 CFR §130.6 provided three ways for the U.S. to meet this obligation: (1) filing of a citizen petition stating grounds for the petition as well as reasons for any proposed deviations from the Codex standard; (2) publication by FDA on its own initiative to adopt the standard, along with reasons for any proposed deviations from the Codex; or (3) publication by FDA of the standard for review and informal content as a prelude to deciding whether to adopt or terminate consideration of such a standard.<sup>35</sup> As noted above, FDA initiated the 1979 ANPRM under 21 CFR § 130.6(b)(3) but cited the lack of data supporting a need for establishing an SOI for olive oils and olive-pomace oils in the U.S. at that time.<sup>36</sup>

Petitioner believes that the time has come for an olive oil SOI and accordingly, the instant petition requests the Commissioner adopt the Codex Standard as an SOI with deviations Petitioner maintains are necessary to protect American consumers in accordance with 21 CFR §130.6(b)(1).

a. Interest Group Consultations under 21 CFR §130.6(c)

As part of the review process of a Codex standard, 21 CFR § 130.6(c) encourages petitioners to consult with other interest groups prior to filing a petition. Petitioner has had discussions concerning a renewed effort to establish an olive oil SOI with many different companies and interest groups.

Since early 2016, Petitioner has discussed with NAOOA members the proposed filing of a new SOI petition, including at seven association-wide meetings, in newsletters and memos, and at many meetings of the NAOOA Quality Control Committee. During that period, NAOOA members have accounted for between an estimated 60% and 75% of all olive oil sold in the United States.

Petitioner has also reached out to industry and interest groups beyond NAOOA members. Between 2018 and 2019, Petitioner engaged in joint meetings and discussions with AOOPA, including joint communication with FDA regarding the need for a SOI. Based on these discussions, and as confirmed by the AOOPA/Deoleo Petition, there is substantial alignment between the standard of identity positions of these entities.

In addition to AOOPA, Petitioner has also discussed the need for an SOI and/or sought input on specific issues connected with the SOI with other industry groups both in the United States (including leaders of the California Olive Oil Council and the Extra Virgin Alliance) and abroad,

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<sup>35</sup> 21 CFR § 130.6(b)(1)-(3).

<sup>36</sup> See note 3, supra.

including representatives of the International Olive Council,<sup>37</sup> as well as representatives and/or members of industry associations in other countries, including Associazione Italiana dell'Industria Olearia (Italy), Asociación Española de la Industria y el Comercio Exportador del Aceite de Oliva (Spain), Aegean Exporters Association (Turkey), Office Nationale de l'Huile (Tunisia), and Syndesmos Ellinikon Viomichanion Typopoiiseos Elaioladou (Greece), Morocco Foodex (Morocco) and Casa do Azeite (Portugal)—countries whose combined annual production accounts for over 80% of worldwide production of olive oils.

Beyond industry, since July 2018, Petitioner also engaged with representatives of the consumer interest organization, Center for Science in the Public Interest (“CSPI”), concerning the proposed effort to establish an SOI for olive oil; although CSPI representatives expressed support for the general idea of an olive oil SOI that would protect consumers, they declined an invitation to provide specific input or comment on the proposal.

b. Support for Proposed Deviations Pursuant to 21 CFR § 130.6(b)(1).

Petitioner’s proposed SOI, contained in Appendix 1, includes certain deviations to the Codex Standard in accordance with the 21 CFR 130.6(b)(1). These deviations are proposed with the consensus of NAOOA members, together representing a substantial proportion of the market, for reasons including: (1) to raise the bar on the Codex Standard and improve quality levels and better guard against fraud in the U.S.; (2) to improve the way products are labeled to protect consumers, conforming with consumer research and customary norms within the U.S. market; (3) to more logically classify the different categories and grades of olive oils to promote clarity and understanding by American consumers as well as industry; and (4) to update the Codex Standard with the latest research.

In considering these deviations, it is important to understand how the Codex Standard relates to the other important international trade standard established by the International Olive Council (“IOC”). The IOC standard serves as the basis for the original Codex Standard and many other national olive oil standards.<sup>38</sup> As the IOC notes on its website, “[t]he IOC and Codex Alimentarius have always worked together to harmonise standards for trade and food. This goal materialised in June and July 2003 when the IOC adopted the revision of the trade standard and the Codex Alimentarius Commission adopted the revision of the food standard at its 26<sup>th</sup> session in Rome, Italy.”<sup>39</sup> The IOC serves as an observer to the Codex Committee on Fats and Oils (“CCFO”) with respect to the Codex Standard.

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<sup>37</sup> The International Olive Council (“IOC”) is a quasi-governmental organization chartered by the United Nations, among whose principle tasks is the establishment of standards of trade for olive oils and olive-pomace oils. Members of the IOC are countries that produce and/or consume olive oils (and olives).

<sup>38</sup> The latest IOC Standard (COI/T. 15/NC No 3/Rev. 4, November 2019) is included as Appendix 5. National standards based on the IOC standard regulate 95% of the world’s olive oil production. The United States Department of Agriculture (“USDA”) Standards for Grades of Olive Oil was revised in 2010 following a petition from the California Olive Oil Council, and is based largely on the IOC standards in effect at that time except for three principal differences: elimination of the grade “ordinary virgin olive oil,” and different limits on the content of the fatty acid linolenic acid, and the sterol campesterol (as some domestically produced olive oil was found to be naturally outside the limits for these components). 75 FR 22363 (April 28, 2010). USDA Standard at §52.1539 and §52.1540.

<sup>39</sup> <https://www.internationaloliveoil.org/60-years-of-standardisation/>.

There are key differences, however, between the IOC and the Codex. The IOC Session of the Council of members takes place twice a year. Accordingly, the consideration of new standards, methods and/ or revisions of existing ones can be done every year, if required. By contrast, the meetings of the Codex CCFO takes place every two years, the most recent being held in 2019. As a result, the Codex Standard often lags behind the latest updates and revisions made to the IOC standard. Also, there are producer nations that are part of the CAC that are not members of the IOC.<sup>40</sup>

Another important difference between the IOC and Codex is that the IOC maintains two technical groups of experts (one on chemistry, the other on sensory analysis) actively working not only to discuss olive oil and olive-pomace oil standards and methods, but also to directly carry out experimental work to check methods, highlighting, if any, both advantages and drawbacks, with the final goal to propose a method for validation. Validation, too, is carried out within these expert groups and if results are positive, the method is proposed for adoption that will be in the agenda of the next Session of the Council of Members. The CCFO does not have this capability; it does not directly organize or conduct experiments but instead must request other bodies to study selected problems and organize working groups (most of them are electronic working groups) that are chaired by experts from different countries. Thus, change can sometimes come slowly to the Codex Standard.

Finally, the Codex Alimentarius is concerned with foods for human consumption. For this reason, it does not have a standard for oils that are intended for further manufacturing (such as lampante virgin olive oil) or oils considered not fit for human consumption (such as solvent-extracted crude olive-pomace oil). By contrast, the IOC is concerned with all oil products derived from the olive, including lampante virgin olive oil and crude olive-pomace oil, and thus has established standards for all.

i. Deviations from Codex Standard Section 1

The Codex Standard concerns only food products “presented in a state for human consumption.” Petitioner proposes deleting that phrase.<sup>41</sup> The SOI should be broad enough to cover all oils

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<sup>40</sup> The U.S. is not a member of the IOC, but representatives from the U.S. participate in both the IOC and the CAC. The U.S. participated in the most recent Codex Committee on Fats and Oil (“CCFO”). U.S. Delegate to the CCFO for the most recent session was Dr. Paul South, Division of Plant Products and Beverages, Center for Food Safety and Applied Nutrition, Office of Food Safety, FDA. A copy of the CCFO Proposed Draft Revision to the Standard for Olive Oils and Olive Pomace Oils (CXS 33-1981) prepared by the Electronic Working Group) (November 2018) is attached as Appendix 2b. Representatives of U.S.-based entities have participated in various IOC activities in recent years, including as a signatory member of its association for quality monitoring (NAOOA), as an observer member in other matters (USDA), and as a participant at chemistry standards meetings (COOC).

<sup>41</sup> Petitioner is including as Appendix 2c a red-lined version of the Codex Standard showing the changes that are being proposed sections by section. The proposed SOI included as Appendix 1 incorporates these changes, but in an order and format conforming to FDA’s existing standard of identity regulations, which is very different from the Codex Standard, making a document-to-document comparison impossible.

derived from the olive fruit that are traded or potentially traded in the U.S., including oils that are intended for further manufacturing. (This is in accordance with the eleventh of FDA’s proposed general principles (the “Proposed Principles”) for establishing a food standard, suggesting that such foods be included in developed standards and not reserved for separate standards).<sup>42</sup> As a result, throughout the proposed SOI, Petitioner adds references to crude olive-pomace oil and lampante virgin olive oil.<sup>43</sup>

ii. Deviations from Codex Standard Section 2

The Codex Standard describes three categories of food: “olive oil,” “virgin olive oils,” and “olive-pomace oils.” However, virgin olive oils are a subcategory of “olive oil” and are thus more logically defined in a different section, so Petitioner proposes deleting the definition of virgin olive oils and moving it to a different section. Petitioner believes this change is in accordance with the second and third of the Proposed Principles in clearly describing the basic nature and stressing the “essential characteristics” of olive oils. For the same reasons, Petitioner proposes adding language to the description of “olive-pomace oil” to define “olive-pomace,” clarifying the relationship of olive oil to olive-pomace oil.

iii. Deviations from Codex Standard Section 3

Petitioner, with the consensus of NAOOA’s members, proposes several changes to this section, which lays out the classifications of the different categories and grades of olive oils and olive-pomace oils to minimize redundancy and confusion. First, the section is divided into two, one each for olive oils and olive-pomace oils.

*A. Definition of Categories and Grades for Olive Oils--* Within the olive oil classification, Petitioner proposes changes to the Codex Standard to clarify that there are two categories of olive oils: virgin olive oil and refined olive oil. The definition of virgin olive oil from the Codex Standard Section 2 is thus moved here. Further, the virgin olive oil category is divided into three grades: extra virgin, virgin and lampante.

Regarding the virgin olive oil grades, Petitioner proposes to modify the extra grade from the Codex Standard to lower the limit of free acidity to 0.50% from the 0.8% provided in the Codex (as well as in the IOC standard). This change, proposed with consensus of Petitioner’s members, will provide an additional assurance of quality to American consumers.<sup>44</sup>

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<sup>42</sup> 85 FR at 10109.

<sup>43</sup> The AOOPA/Deoleo Petition also includes these grades.

<sup>44</sup> The AOOPA/Deoleo Petition also proposes reducing the limit, but Petitioner proposes extending the limit an extra decimal place, supported by the latest IOC methodology proposed in Deviations from Codex Standard Section 8 below. It is worth noting that the CCFO Draft Revisions to the Codex Standard indicates a consensus was reached to use the additional decimal place as well. See Appendix 2a.

Another deviation from the Codex with respect to virgin olive oils is the addition of the grade “lampante,” which as noted above does not exist in the Codex Standard. As a traded commodity, Petitioner believes it should be part of the SOI. Moreover, Petitioner finds it important for clarity that the lampante virgin olive oil grade be included since the SOI includes the category “refined olive oil” which is made from lampante; it is difficult to define the refined products without reference to the source materials from which they are produced. However, to protect American consumers from low quality products, Petitioner believes it should be expressly stated that lampante virgin olive oil “may not be sold for retail or mixed with other oils unless it is refined.”

Petitioner also proposes deletion of the grade “ordinary virgin olive oil” that is included in the Codex Standard.<sup>45</sup> This grade was adopted by IOC and Codex several years ago, intended as the minimum category of virgin olive oil suitable for direct sale to consumers. Petitioner proposes to delete this category in order to simplify the standard, avoid unnecessary classification problems (in accordance with the eighth of the Proposed Principles) and improve the quality of olive oil that can be offered to consumers in the U.S. market.

With respect to “refined olive oil,” Petitioner extends the limit of free acidity an extra decimal place, consistent with the latest IOC methodology for determining free acidity proposed in Deviations to Codex Standard Section 8 below and clarifies that refined olive oil may be produced from lampante virgin or other virgin olive oils.

Petitioner also proposes deletion of the grade “olive oil” in the Codex standard.<sup>46</sup> In the Codex, the mixture of two grades of olive oil, refined olive oil and virgin olive oils, is defined to be a different “grade,” which is called “olive oil.” The IOC standard similarly defines the mixture of refined olive oil and virgin olive oils as a grade, but recently amended the name for this grade from “olive oil” to “olive oil composed of refined olive oil and virgin olive oils,” in an effort to improve clarity and transparency. In the latest meeting of the CCFO, a consensus was reached to follow the revision made to the IOC standard.<sup>47</sup> Petitioner agrees with the CCFO and IOC’s objective of improving clarity, but disagrees with the means of accomplishing it.

Creating an 11-words-long product name would be both commercially awkward and confusing to American consumers. Petitioner proposes instead deleting the “grade” altogether and addressing the need for more clarity to American consumers through labeling requirements, including the use of an ingredient statement if the name of the food does not indicate the grades

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<sup>45</sup> Accordingly, deletion of the grade requires deletion of the quality and purity standards related to the grade throughout the Codex Standard as well. The AOOPA/Deoleo Petition also proposes deletion of this grade.

<sup>46</sup> “Olive oil” is traditionally defined to be a blend of a refined (usually, higher amount) olive oil and one of the edible virgin oils; it is a product that is appreciated by consumers of many countries who choose to consume olive oil, but do not appreciate bitter and pungent characteristics of the more flavorful virgin olive oils. Similarly, “olive-pomace oil” is traditionally defined to be a blend of refined olive-pomace oil and virgin olive oils. As discussed below, Petitioner proposes deletion of the Codex Standard grade “olive-pomace oil” as well.

<sup>47</sup> See Appendix 2a at ¶ 35.

and categories in the product (as will be discussed in Deviations from Codex Standard Section 7 below). Indeed, a blend of different categories or grades is more akin to a recipe than a grade, particularly where there are no parameters in terms of proportions or qualities.<sup>48</sup> Indeed, the new name for this “grade” that has been adopted by IOC and is being adopted by Codex itself constitutes a definition, and is in effect a statement of ingredients.

Deletion of the grade is in accordance with several of the Proposed Principles: it focuses on the basic nature of the food because whether it is virgin olive oil, refined olive oil, or some combination thereof, it is in essence “olive oil” (second and twelfth); it simplifies the standard and eliminates an unnecessary grade (eighth); it allows for variations in the physical attributes of the food (ninth); is consistent with general regulatory provisions applicable to cooking oils and common usage (tenth); and does not require manufacturers to name the ingredients in the product name as opposed to an ingredient statement (thirteenth). While this is a deviation from Codex and other international standards, it will have little if any impact on trade. Products currently traded as “olive oil” grade (meaning a mixture of refined and virgin olive oils) can still be called “olive oil” (but the product will need to have an ingredient statement identifying the component oils as provided in Deviations from Codex Standard Section 7 below). Similarly, consumers will not see any change in the labeling of the food name on their supermarket shelves.<sup>49</sup>

In addition, deletion of the grade has another advantage which is in accordance with the sixth of the Proposed Principles. By allowing manufacturers to rely on the general term “olive oil” as the name for all grades and categories of olive oils and their mixtures (as opposed to restricting it to the mixture of refined olive oil and virgin olive oils), it will provide them with more commercial flexibility. For instance, a product that is 100% virgin grade virgin olive oil, or even 100% refined olive oil, could be marketed as “olive oil”—provided the details about categories or grades are stated in the ingredient statement.<sup>50</sup>

*B. Definition of Categories for Olive-Pomace Oils.*—Within the olive-pomace classification, Petitioner proposes adding to the Codex Standard the category “crude olive-pomace oil,” not fit for human consumption, as distinct from “refined olive-pomace oil.” As with the proposed addition of the “lampante virgin olive oil” grade, this change is due to the fact that the Codex Standard does not cover products unless they are intended for human consumption. As with the addition of the lampante virgin olive oil grade, adding crude olive-pomace is in accordance with the eleventh of the Proposed Principles. “Crude olive-pomace oil” is the food from which “refined olive-pomace oil” is created. The proposed definition tracks the definition from the IOC standard.

With respect to “refined olive-pomace oil,” Petitioner extends the limit of free acidity an extra decimal place, consistent with the latest IOC methodology for determining free acidity proposed

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<sup>48</sup> To report the exact concentration of each component of the blend is not possible to be controlled: markers of the presence of virgin oils could be polyphenols, however of the natural variability of composition of olive oils makes their concentration widespread within a large range, so that their amount in the blend, too, will vary widely depending on the characteristics of the virgin oil used in the blend.

<sup>49</sup> As will be explained further in this petition, this change is also supported by findings of the NAOOA Consumer Study.

<sup>50</sup> By contrast, in the E.U., it is forbidden to sell 100% refined olive oil at retail.

in Deviations from Codex Standard Section 8 below and clarifies that refined olive oil may be produced from crude olive-pomace oil.

Petitioner also proposes the deletion of the grade “olive-pomace oil,” which Codex defined as a mixture of refined olive-pomace oil and virgin olive oils. This change is proposed for the same reasons Petitioner proposes deletion of the grade “olive oil” as explained above. Labeling of olive-pomace oil will be addressed in Deviations from Codex Standard Section 7 below in a manner consistent with how the mixture of refined olive oil and virgin olive oil is treated,<sup>51</sup> but this change will not have an impact on consumers since olive-pomace oil is not widely sold at retail.

C. *Purity and Quality Standards.*--Petitioner proposes to modify the Codex Standard for numerous parameters of olive oils and olive-pomace oils used to establish purity and quality in conformity with the IOC standard.<sup>52</sup>

1.) Change to definition of organoleptic standards for categories and grades of olive oils

Petitioner has proposed changing the Codex Standard for organoleptic characteristics to add an additional decimal place to the medians for extra virgin olive oil, to delete the parameters for the deleted grade ordinary virgin olive oil, and to add the category of lampante virgin olive oil (and add the footnote related to the lampante virgin olive oil grade). The additional decimal place for the organoleptic medians is supported by the IOC’s latest revisions.

2.) Changes to definition of fatty acid compositions for olive oils and olive - pomace oils

Petitioner proposes modifying the Codex Standard by adding parameters (according to the IOC standard) for lampante virgin olive oil and crude olive-pomace oil. Petitioner proposes changing the topic headings for the grades “olive oil” and “olive-pomace oil” (grades removed under the

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<sup>51</sup> The consumer research on the labeling of “olive oil” (the mixture of refined and virgin) did not address the labeling of “olive-pomace oil” since that is a product that is not widely available in retail markets around the United States and would have only led to confusion. Petitioner proposes that the labeling of the mixture of refined olive-pomace oil and virgin olive oils be consistent with the labeling of olive oil mixtures since the products are identical except for whether the refined oil is either olive or olive-pomace. As with the deletion of the “olive oil” grade from the Codex Standard, references to the grade “olive-pomace oil” in the Codex Standard will also be deleted except in connection to standards needed to protect quality for products which constitute blends of refined olive-pomace oils and virgin olive oils. In those cases, Petitioner proposes maintaining the quality and purity standards developed for these products but refer to the standards as being applicable to “mixtures of refined olive-pomace and virgin olive oils.”

<sup>52</sup> To improve clarity, Petitioner also proposes to deviate from the formatting of the Codex Standard to create a new section specifically addressing purity, quality and organoleptic standards, including an introductory paragraph to the standards and introducing a symbol to identify quality parameters considered dynamic (which has relevance in connection with proposed changes discussed in Deviations from Codex Standard Section 7 below). In addition, Petitioner proposes deleting from the Codex Standard parameters that would have applied to “ordinary virgin” grade of olive oil, and has clarified that where the Codex Standard referred to parameters for the “olive oil” grade, these parameters apply to mixtures of refined olive oils and virgin olive oils, and that the parameters for the “olive-pomace oil” grade apply to mixtures of refined olive-pomace oil and virgin olive oils.

proposed SOI) to describe instead the mixtures of olive oils and/or olive pomace oils. Further, to correspond with the methodology to determine these parameters described in Deviations from Codex Standard Section 8, Petitioner has added an additional decimal place to the parameters where appropriate.<sup>53</sup>

In addition to those broad changes to the Codex Standard, Petitioner proposes specific changes to the parameters for individual fatty acids, which standards are useful in detecting adulteration, in accordance with IOC standards, as follows:

*a.) Myristic Acid C14:0.*--The C14:0 limit established for olive oils and olive-pomace oils in the Codex Standard is  $\leq 0.05\%$ . However, since May 2013, the limit adopted for this parameter was decreased to 0.03% in the IOC trade standard (accompanied by the expression of the limits for the rest of the fatty acids to two decimal places). This decrease was proposed and framed by the expert chemists of the IOC in order to improve detections of adulterations of olive oils and olive pomace oils. A ring test was organized to fix a definitive limit. As a result, the previous limit enabled the detection of certain types of oil (palm, high oleic, etc.) but only when they were added singly. If more than one extraneous oil was added, the limit was not effective. For this reason, the limit for myristic acid was reduced to 0.03% as a measure to detect admixtures of palm oil. Data supporting this change is included as Appendices 9 and 9a.

*b.) Heptadecanoic Acid C17:0.*-- An increase of the limits from 0.3% to 0.40% was adopted by the IOC in the revision COI/T.15/NC No 3/Rev. 11 of July 2016. Chemists determined that raising the limit and adopting two decimal places for heptadecanoic acid did not increase the risk of adulteration. Data supporting this change is included as Appendices 9 and 9a.

*c.) Heptadecanoic Acid C17:1.*--The increase of the limits from 0.3% to 0.60% was adopted by IOC in the revision COI/T.15/NC No 3/Rev. 11 of July 2016. Chemists determined that raising the limit and adopting two decimal places for heptadecanoic acid did not increase the risk of adulteration. Data supporting this change is included as Appendices 9 and 9a.

*d.) Linoleic Acid C18:2.*--This limit was updated by the IOC in the revision COI/T.15/NC No 3/Rev. 8 of February 2015 to become between 2.50 and 21.00%. Chemists proposed decreasing the lower limit for linoleic acid from 3.50 to 2.50% to allow early olive

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<sup>53</sup> The main differences for fatty acids composition between IOC and the Codex Standard concern: the use of two decimal figures in the IOC standard, which derives from the adoption of the “Global method” (formerly) and nowadays of the “Method for the coherence of TAG composition with the fatty acid composition,” which algorithm works with two decimal figures; and differences for concentration of critical fatty acids (i.e., those that can be used to identify adulteration, namely myristic (C14:0), linolenic (C18:3), arachidic (C20:0), gadoleic (C20:1), behenic (C22:0), and lignoceric (C24:0)) and non-critical fatty acids (e.g., palmitic acid and oleic acid.). Within the critical fatty acids, identical limits for C14:0, C20:1, C22:1 and C24:0 exists, while a difference exists for C20:0, but the most important one is for C18:3, which is important as marker of the presence of soybean oil. Within the non-critical fatty acids, the C16:0 minimum percentage had been proposed to be reduced to 7.0% within Codex, but no consensus was reached for a perceived lack of scientific data. The minimum percentage for C18:1 is also being considered for a reduction in Codex, but no consensus has yet been reached. It must be stressed that the oleic acid content has been considered an important component of the positive role played by olive oils in the “Mediterranean diet.” In 2018, FDA approved a qualified health claim for cooking oils with high content of oleic acid in connection with coronary diseases. See note 17 supra.

harvesting since the linoleic acid content increases with the olive maturation. Data supporting this change is included as Appendices 9 and 9a.

*e.) Linolenic Acid C18:3.*--The establishment of this limit by the IOC at 1.00% was to detect the presence of high-linolenic oils, primarily soybean oil, rapeseed oil, mustard seed oil and linseed oil. The IOC organized two studies on these parameters and reports are available in the IOC executive secretariat. Further studies are ongoing and have been sent to all countries including USA. The executive secretariat fixed the 31th January 2020 as a deadline for sending results. Responding to this request, Australia has sent results. Data supporting this change is included as Appendix 10.

*f.) Eicosanoic Acids C20:0.*--This increase from 0.4% to 0.50% was adopted by IOC in the revision COI/T.15/NC No 3/Rev. 11 of July 2016 following the problems raised in the content of these fatty acids, and by adopting the limits to two decimal places. Data supporting this change is included as Appendix 9a.

### 3.) Definition of sterol and triterpene dialcohol composition for olive oils and olive-pomace oils.

Petitioner proposes to modify the Codex Standards for sterol composition in conformance with the latest revisions to the IOC standards, specifically with respect to the use of a series of parameter-dependent decisions for Delta-7-Stigmastenol, and to adopt the inclusion of parameters for lampante virgin olive oils as well as crude olive-pomace and refined olive-pomace oils.

The IOC has determined that these series of parameter-dependent decisions are necessary find the appropriate balance between being able to detect fraud and respecting natural sterols variations that may occur in different parts of the world.<sup>54</sup> The IOC's series of parameter-dependent decisions with respect to campesterol was adopted in the 100th session (in the format of a decision-tree) and included in the revision COI/T.15/NC No 3/Rev. 7 of May 2013, and subsequently adopted in the Codex Standard.<sup>55</sup> The study supporting this revision was carried out from 2009 to 2012 and it was performed on several oils produced from different varieties and different countries during different harvest seasons. Experts proposed a number of decision trees as the solution to the high campesterol level observed in several oils. They commented that campesterol largely depended on climatic conditions and olive variety. Accordingly, additional determinations were needed to guarantee the authenticity of oils with anomalous campesterol

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<sup>54</sup> In the FDA EVOO Study, cited in note 28 supra, the authors appeared to affirm the utility of using decision trees for these components in order to distinguish between authentic oils and adulterated oils: "Findings from the present study highlight the variability in desmethylsterol compositions of EVOO grown around the world and emphasize the importance of using multiple chemical tests for assessing authenticity due to the diverse compositions of such products."

<sup>55</sup> See Appendices 11 and 11a. Codex previously adopted the decision tree regarding campesterol. The importance of this sterol in detecting fraud is due to its high concentration in seed oils, not depending on genetic improvement (e.g. canola oil contains very high amounts of campesterol). The decisional trees were developed on the basis of scientific knowledge, but also on the basis of an high number of samples that through several years were analyzed by IOC recognized laboratories; samples were sent on voluntary basis by several countries claiming for oils not fitting standards (e.g. Spain, Syria, Greece, Argentina), while some other countries claiming natural variations never sent samples.

levels. Such oils tend to have a high linolenic and palmitic acid content, which causes greater deviation in delta ECN42. It was decided to fix a stigmasterol limit of  $\leq 1.4\%$  considering that it would be a very useful parameter since seed oils with a high campesterol content also have a high stigmasterol content, and also to include the index apparent  $\beta$ -sitosterol/(campesterol + delta-7-stigmastenol) because it's an effective parameter for fraud detection purposes in the event of high delta 7-stigmastenol values in extra virgin and virgin olive oils. In addition, the experts agreed that it would be necessary to include delta ECN42 in the delta-7-stigmastenol because it is a sensitive parameter for detecting mixtures with soybean oil.

Campesterol, however, is not the only sterol subject to variations by geographic origin. After a long study of the off-standard olive pomace oils and crude and refined olive pomace oils, the experts agreed to include the existing decision tree for delta-7-stigmastenol for these categories to allow for geographic variations, but not diminish the ability to detect adulteration with high oleic sunflower and safflower oils.<sup>56</sup> In addition, the IOC chemists also decided to apply the decision tree for lampante virgin olive oils presenting off-limit levels of delta-7-stigmastenol. The study was based on a wide range of data and calculations done by experts. This decision was adopted in the 110th session of November 2019 and included in the trade standard COI/T.15/NC No 3/Rev. 14. In fact, this parameter is effective in the detection of fraud in terms of mixture of olive oils with sunflower oils and putting 0.8% as a maximum limit would guarantee the best performance.

4.) Definition of value of total sterols for olive oils and olive-pomace oils.

Petitioner's proposed deviations from the Codex Standard parameters for minimum value for sterols are to conform to other proposed changes made to the categories and grades of oils discussed above, including the addition of lampante virgin olive oil grade and crude olive-pomace oil category.

5.) Definition of erythrodiol and uvaol content for olive oils and olive-pomace oils.

Petitioner's proposed deviations from the Codex Standard parameters for maximum erythrodiol and uvaol content are to conform to other proposed changes made to the categories and grades of oils discussed above, including the addition of lampante virgin olive oil grade, and the addition of parameters for olive-pomace oils, including crude olive-pomace oil category, which are laid out in the IOC standard.

6.) Definition of wax content for olive oils and olive-pomace oils.

Petitioner proposes to modify the Codex Standard for wax composition (C42+C44+C46) for virgin olive oils, as distinct from other oils (C40+C42+C44+C46) in order to conform the SOI to

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<sup>56</sup> See Appendices 11b and 11c. Delta-7-stigmastenol is an important marker for the presence of high oleic safflower or high oleic sunflower.

the standards in the IOC as supported by the latest research, and for the inclusion of the lampante virgin olive oil grade and crude olive-pomace oil category.

Waxes are important markers to discriminate between oils extracted by mechanical means and by solvents (which are potential adulterants). The wax content limit was updated in the revision COI/T.15/NC No 3/Rev. 7 of May 2013. This decision was owing to the results found by chemists which agreed to lower the limit from 250 mg/kg to 150 mg/kg and to consider the sum of C42 to C46 instead of C40 to C46. This decision was taken due to the problems found with the chromatographic separation since most of the laboratories did not manage to separate phytol-behenate from C40. Higher wax levels were observed at C44 and C46 in some oils with high contents of C40 waxes and phytol close to C42. Usually, C46 was not found in good quality oils or only at very small levels. Besides, this modification was performed to solve the problem of the high content of C40 found in olive oils from some countries of the southern hemisphere. After lengthy study, a consensus was reached on proposing a limit of 150 mg/kg for the virgin and extra virgin categories. Codex in 2019 reached a consensus to amend its standard according to this research. Data supporting this change is included as Appendices 12, 12a and 12b.

7.) Definition of difference between the actual and theoretical ECN 42 triglyceride content for olive oils and olive-pomace oils.

Petitioner's deviations from the Codex Standard for maximum difference between actual and theoretical ECN 42 triglyceride content are to conform to other proposed changes made to the categories and grades of oils discussed above, and to add the extra decimal place in accordance with the adopted methodology. In addition, Petitioner proposes to change the way the difference between the actual and theoretical ECN42 triglyceride content is expressed in the Codex Standard to conform to that used in the IOC standard. The IOC standard uses the absolute value of the difference since the intent is to measure the difference between two values. This is to avoid a negative value which has no scientific interpretation. If, for example, the actual difference was -0.4 it is  $< 0.2$ , which would incorrectly render the oil as satisfying the standard. However, under application of the absolute value criterion i.e.  $|0.4|$ , the oil would not satisfy the IOC standard since the absolute value of  $|0.4|$  is greater than  $|0.2|$ .

8.) Definition of stigmastadienes content for olive oils and olive-pomace oils.

Petitioner proposes to modify the Codex Standard for stigmastadiene composition for virgin olive oils in order to conform the SOI to the standards in the IOC as supported latest research, and to add the lampante virgin olive oil grade.

Up until 2013, the stigmastadiene limits were 0.10 and 0.50 mg/kg for edible virgin olive oils and lampante virgin olive oil, respectively. Since May 2013, IOC chemists have framed a proposal to change the limit of the stigmastadiene to 0.05 and 0.50 mg/kg, respectively for virgin olive oils (not including lampante), and lampante virgin olive oil and to adopt these changes on the revision COI/T.15/NC No 3/Rev. 7.

Indeed, in view of the laboratory data obtained after ring tests, the experts considered it wise to lower the stigmastadiene limit to 0.05 mg/kg for virgin olive oils excluding lampante given that the limit existing in previous versions did not afford sufficient guarantees to protect the

authenticity of extra virgin olive oil. The reduction of the limit is intended to help clean up the market and to detect the presence of refined oils. Data supporting this change is included as Appendix 13.

9.) Addition of definition of 2-glyceryl monopalmitate content for olive oils and olive-pomace oils.

Petitioner proposes to modify the Codex Standard for purity and quality to add 2-glyceryl palmitate composition in order to conform the SOI to the standards in the IOC as supported by the latest research. The 2 glyceryl-monopalmitate limits were adopted in the revision COI/T.15/NC no. 3/Rev. 2 of November 2006 for edible virgin olive oils and olive oil, non-edible virgin olive oils and refined olive oils, olive pomace oil and for crude and refined olive pomace oils.

The results obtained by IOC experts on applying the method for the determination of the percentage of palmitic acid at the 2-position in oils of different geographical origin had provided confirmation of the reliability of applying the relative content for detecting esterified oil. They found that the previous palmitic acid content at the 2-position of authentic olive oil was always lower than the theoretical content. Hence, the difference between the two contents would enable detection of esterified oil when the oil had a low palmitic acid content. The experts agreed that it was important for the limits to be narrow in order to guarantee the validity of the method and for the statistical data to be included. Indeed, they proposed applying one limit for oils with a palmitic content  $> 14.00\%$  and other limits for oils with values  $\leq 14.00\%$ . Consequently, the chemists agreed to put forward a concrete proposal to the Committee on Olive Oil Chemistry and Standards Setting with a view to revising the trade standard and the Codex Alimentarius standard by replacing the limits for palmitic acid + stearic acid at the 2-position and the ISO standard applied, which was not considered to be sufficiently precise. The method was validated within an international ring test carried out involving chemists from the E.U. and the IOC. Data supporting this change is included as Appendix 14.

10.) Definition of peroxide value for olive oils and olive-pomace oils.

Petitioner proposes to modify the peroxide value limits of the Codex Standard to conform to the changes in the grades and categories explained in Deviations to Codex Standard Sections 2 and 3 above, and in conformance with IOC standards, including the addition of the extra decimal place consistent with the established methodology as proposed in Deviations to Codex Standard Section 8 below. Petitioner also indicates peroxide value to be a highly dynamic quality parameter.<sup>57</sup>

11.) Definition of absorbency in ultra-violet K270.

Petitioner proposes to modify the Codex Standard for absorbency of ultra-violet K270 to conform the SOI to the standards in the IOC as supported latest research, and to conform to changes in the grades and categories explained in Deviations to Codex Standard Sections 2 and 3

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<sup>57</sup> As indicated in note 52 supra, the designation of certain parameters as “highly dynamic” (i.e., susceptible to changes from improper storage that can occur after bottling) such as for peroxide relates to labeling provision in Deviations to Codex Standard Section 7.

above. K270 limit was updated in the revision COI/T.15/NC No 3/Rev. 11 of July 2016. IOC chemists decided to raise the K270 limit from 1.10 to 1.25 for refined olive oil according to several studies and samples analyzed. Data supporting this change is included as Appendices 15 and 15a. In addition, Petitioners propose to indicate the K270 standard as a highly dynamic quality parameter.

12.) Addition of definition of fatty acid ethyl esters for extra virgin olive oil.

Petitioner proposes to modify the Codex Standard to add fatty acid ethyl esters as a quality parameter for virgin olive oils in order to conform the SOI to the standards in the IOC as supported by research over the past ten years. Data supporting this change is included as Appendices 16, 16a, 16b, 16c, 16d and 16e.<sup>58</sup>

13.) Definition of absorbency in ultra-violet K232 for olive oils and olive-pomace oils.

Petitioner proposes to modify the Codex Standard to add a mandatory absorbency of ultra-violet K232 standard. Both IOC and Codex include a UV absorption K232 standard, but it is not mandatory for either standard. Codex describes the significance of this standard (and some other described quality and composition factors as “supplementary information to the essential composition and quality factors of the standard. *A product, which meets the essential quality and composition factor but does not meet these supplementary factors, may still conform to the standard.*” (Emphasis added.) Furthermore, in the case of K232, the footnote no. 4 says, “The country of retail sale may require compliance with these limits when the oil is made available to the end consumer.” By contrast, in the case of IOC standard, the footnote to table of quality criteria says, “The determination is solely for application by commercial partners on an optional basis.”

Petitioner, after consultation within the industry, believes that to better assure the quality of oils to American consumers, the absorbency of ultra-violet K232 should be made mandatory, recognizing however that it is among others a highly dynamic quality control parameter.<sup>59</sup>

14.) Addition of definition of moisture and volatile matter for olive oils and olive-pomace oils.

As with ultra-violet K232, moisture and volatile matter is not a mandatory standard within the Codex (but it is in the IOC standard). Petitioner proposes to modify the Codex Standard to include the IOC standard for this parameter to better assure quality to American consumers.

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<sup>58</sup> The CCFO considered but did not reach a consensus to add fatty acid ethyl esters to the Codex Standard in its latest meeting. See Appendix 2a at ¶ 55. This parameter is included in the AOOPA/Deoleo Petition.

<sup>59</sup> The AOOPA/Deoleo Petition similarly adds mandatory parameters for K232, as well as the parameters discussed in the following subsections regarding moisture, volatile matter and impurities, but proposes a modification to the K232 standard that Petitioner has concluded is not supported by industry nor scientific consensus and could result in an unjustifiable trade barrier.

15.) Addition of definition of insoluble impurities for olive oils and olive-pomace oils.

As with moisture and volatile matter, insoluble impurities is not a mandatory standard within the Codex Standard, but is in the IOC standard. Petitioner proposes to modify the Codex Standard to include the IOC standard for this parameter to better assure quality to American consumers.

16.) Addition of definition of flash point for crude olive-pomace oils.

Petitioner proposes to modify the Codex Standard, which does not include crude olive-pomace oil, to adopt the IOC standard for flash point for crude olive-pomace oil.

iv. Deviations from Codex Standard Section 4

Petitioner does not propose any substantive changes to the content of Codex Section 4 except for the deletion of references to the grades “olive oil” and “olive-pomace oil.”

v. Deviations from Codex Standard Section 5

Petitioner proposes to delete references to other Codex standards, as general FDA regulations applicable to foods will apply instead.

Also, in the Codex Standard, limits on trace metals iron and copper are not mandatory. Petitioner proposes to modify the mandatory Codex section on halogenated solvents contaminants to add these trace metals. In addition, Petitioner proposes to add limits for arsenic and lead following the IOC standard to better ensure the safety of the products subject to this standard.

vi. Deviations from Codex Standard Section 6

Petitioner proposes to delete this section with its references to other Codex standards, as general FDA regulations applicable to foods will apply instead.

vii. Deviations from Codex Standard Section 7

Codex Section 7 deals with labeling. Petitioner proposes extensive deviations to this part of the Codex Standard, in part to incorporate changes required by the changes to the categories and grades described in Deviations to Codex Standard Sections 2 and 3 above, to recognize that blends of olive oils and olive-pomace oils with other cooking oils are regularly sold in the U.S., both in foodservice and retail, and to incorporate the findings of consumer research.

*A. Changes to Name of Food for Olive Oils and Olive-Pomace Oils.--*

Petitioner proposes to modify the Codex Standard by deleting the reference to the Codex General Standard for the Labelling of Prepackaged Foods, as general FDA regulations concerning food labeling will control instead. In addition, Petitioner proposes other additional provisions to

inform and protect consumers, as well as to promote clarity and certainty to facilitate compliance by manufacturers.

1.) Possible names of food for olive oils and olive-pomace oils.

As a general matter, Petitioner proposes replacing the Codex Standard's reference in Section 7 to its definitions of categories and grades with a more specific requirement: the name of the food shall either disclose the categories and/or grades in the product or include an ingredient statement that does. This general requirement applies to both olive oils and olive-pomace oils, except that olive-pomace oils have the additional stricture that a product called "olive-pomace oil" may contain only refined olive-pomace oil and/or olive oils.

Having proposed the deletion of the grade of "olive oil" (which the Codex Standard defined as a mixture of refined olive oil and virgin olive oil), Petitioner proposes that such products could continue to be labeled with the food name "olive oil" but with an ingredient statement in which the producer must indicate the grades of oil in the product in order of predominance by volume.<sup>60</sup>

FDA regulations regularly inform consumers about the contents of a product in two ways: either by the use of a commonly-used or defined product name, or through an ingredient statement. Where a product name does not provide a sufficiently clear indication as to what the ingredients are, an ingredient statement provides needed information.

Petitioner, with the consensus of its members, maintains that because the term "olive oil" by itself does not indicate the component oils, it is appropriate to require an ingredient statement that does so. To support this petition, Petitioner conducted consumer research to test consumer awareness of olive oil definitions, and to gauge reactions to the different ways a product commonly known as "olive oil"—a mixture of refined olive oil and virgin olive oils—might be labeled.<sup>61</sup> As an initial question, respondents were asked to what extent they thought it was important that a bottle of olive oil identify the grade or grades of olive oil that are in the bottle, and an overwhelming 77% said it was either very or extremely important, and another 17% said it was "somewhat" important. This, in addition to the finding noted above that only 36% knew that the product was a mixture of refined olive oil and virgin olive, confirms the need to improve transparency to consumers about the oil in an "olive oil" bottle.

Next, the NAOOA Consumer Study leveraged feedback from the respondents to determine how best to identify the ingredients in a product that is simply labeled "olive oil." Three options were proposed in the NAOOA Consumer Study: two that involved traditional ingredient statements, and one that would require stating the ingredients in the product name, such as "Olive Oil Comprised of Refined Olive-Oil and Virgin Olive Oil" (which is effectively the solution adopted by the IOC standard, and approved by the CCFO for the Codex Standard). The difference

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<sup>60</sup> The rationale for the changes to the name of food for "olive oil" applies also to "olive-pomace oil," including the requirement of an ingredient statement. Therefore, these are treated similarly in the SOI but will not be separately discussed.

<sup>61</sup> The NAOOA Consumer Study (included as Appendix 7) solicited responses from March 4 to March 17, 2020 from a nationally representative sample of 1,500 respondents around the United States who were at least 18 years old and do at least half the shopping for their household; of the group, 60% were women and 40% were men. Olive-pomace oils are generally not sold at retail and thus the study only focused on olive oil.

between the two ingredient statement options was that on one, the ingredient statement was added on the principal display panel (“PDP”), and in the other, on the information panel (here, the back label).<sup>62</sup>

The totality of the results of the NAOOA Consumer Study support the adoption of an ingredient statement for the labeling of products called “olive oil” instead of the product name option. All options performed well individually in terms of acceptability and but almost three-fifths of respondents preferred options that included an ingredient statement (PDP or information panel).<sup>63</sup>

Between the two ingredient statement options, Petitioner submits that two key factors support the use of a standard ingredient requirement that would allow the manufacturer to choose placement on either the PDP or information panel, as opposed to a mandatory PDP ingredient statement.<sup>64</sup> First, according to the NAOOA Consumer Study, the number one reason respondents said they chose the back label ingredient statement as their first choice was that it was more consistent with how other products are labeled.<sup>65</sup> Indeed, consistency with and incorporation of regulations pertaining to other food standards, including those applicable to a commodity group (here, cooking oils), which is in keeping with the eighth and tenth of the Proposed Principles.

Second, consumer research shows the choice of whether to include the ingredient statement on the PDP or on the information panel could have important marketing implications, and possibly result in increasing consumer confusion, and therefore should be left up to the manufacturer. The key issue here is that the ingredient statement will be required to disclose if the product contains “refined olive oil.” The NAOOA Consumer Study indicates that consumers have a general lack of understanding of the term “refined.” Indeed, over three-fifths of the NAOOA Consumer Study respondents acknowledged they either did not know, or were unsure of, the meaning of “refined” when it comes to cooking oils.<sup>66</sup> Indeed, among those who responded that they understood what

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<sup>62</sup> See NAOOA Consumer Study at slide #16 (Appendix 7). Petitioner included two “ingredient statement” options because the AOOA/Deoleo Petition proposed requiring what amounts to a PDP ingredient statement for its grade “olive oil” olive oil, which would preclude the option of an information panel ingredient statement.

<sup>63</sup> Respondents were exposed to the three label options in two steps. First, groups of five hundred were randomly shown only one of the three labels and asked questions about them. All three options performed well (although on some measures some of the options performed better than one or both of the others). Specifically, at least 63% percent found each option “acceptable” and “consistent” with how other products are labeled, indicating substantial support for any of the three options. NAOOA Consumer Study at slide 17. As a second step, each of the groups was shown all three labels, and was asked for a ranking (and other reactions). When asked to compare the three options side by side, almost three-fifths preferred options that included ingredient statements (PDP or information panel) compared to the product name option. (When considered individually, however, the consumers found equally “most appropriate” the PDP ingredient statement the product name options.) See NAOOA Consumer Study at slide #24.

<sup>64</sup> Although the PDP ingredient statement scored higher than the back label ingredient statement in the three-option ranking, the NAOOA Consumer Study did not ask consumers to weigh the PDP ingredient statement versus the information panel ingredient statement, and it is not possible to conjecture which they might have preferred if the product name option was not in the mix.

<sup>65</sup> See NAOOA Consumer Study slide #25.

<sup>66</sup> NAOOA Consumer Study, slide #32. Respondents were clearly also confused about which cooking oils on the market are refined. Only 22% believed that soybean oil is a refined cooking oil; by contrast, 33% believed that extra virgin olive is refined and over two-thirds believed or were unsure if extra virgin olive oil has been refined. NAOOA Consumer Study, slides ## 29 and 35. Similarly, three-fifths of respondents acknowledged they either do not know

“refined” means, it is clear that many in fact did not, as they used words such as the following to explain the meaning: “healthy,” “good,” “filtered,” “purify,” “virgin,” “pure,” “natural,” “better,” “quality” and “best.” Thus, inclusion of the term “refined” is likely to result in some increased confusion among those consumers who are unfamiliar with its meaning.

The NAOOA Consumer Study also supports a finding that use of the word “refined” could negatively impact the decision of a significant number of consumers whether to purchase a cooking oil: 29% said it is likely they would not purchase an oil that they knew was “refined,” and another 34% said they were not sure if they would.<sup>67</sup>

Cooking oil is not a luxury item, but a necessary kitchen staple. If a consumer is confused by the use of the term “refined” that they do not understand, or if they are discouraged from purchasing a bottle of olive oil because it includes the term “refined,” the reality is that they will likely end up purchasing an alternative that is 100% refined such as vegetable, canola or corn oils, but does not disclose that fact.<sup>68</sup> This not only risks pushing consumers to unwittingly choosing an oil that may be less healthy for them, but it puts olive oil and olive-pomace oil manufacturers at a competitive disadvantage to competitor manufacturers of other cooking oils.

In conclusion, the fact that disclosing the presence of refined oil is not required across the commodity group argues against requiring olive oil ingredients on the PDP.<sup>69</sup> Following standard FDA regulations that allow ingredient statements on either the PDP or the information panel would allow manufacturers to assess how best to balance the conveyance of important information regarding the ingredients in an olive oil product with the risk of confusing or even misleading consumers.

## 2.) Consistent characterizations of categories and grades.

Petitioner seeks to modify the Codex Standard by clarifying that any characterization of the categories and grades of olive oils and olive-pomace oils on labels or otherwise must only be done in reference to the quality and purity requirements including organoleptic standards of the SOI expressly including the specified methodologies in order to facilitate compliance by manufacturers and avoid uncertainty (in accordance with the fifth of the Proposed Principles).

Petitioner further seeks to modify the Codex Standard to address concerns about the highly dynamic nature of certain quality parameters. Certain of the quality parameters included in the SOI are highly dynamic and susceptible to change depending on exposure to ambient conditions of storage. Thus, a product that may be in compliance with the labeled grade and category at

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or are unsure of the meaning of the word “virgin” with respect to cooking oils (and comments show that many who believe they do know actually do not. NAOOA Consumer Study, slide #31. As a further indication of the general lack of understanding about olive oils in particular, over one-fourth of respondents do not believe or are unsure if “extra virgin olive oil” is made from olives, and three-tenths don’t believe or are unsure if “olive oil” is made from olives. NAOOA Consumer Study, slides ## 35-37.

<sup>67</sup> NAOOA Consumer Study, slide #33.

<sup>68</sup> According to industry statistics, corn oil, vegetable oil and canola, all of which are refined, comprise 66% by volume of cooking oil sales.

<sup>69</sup> Petitioner thus proposes a separate regulation defining the requirements for ingredient statements applicable to oils subject to this SOI, as will be discussed below.

bottling may through no fault of the manufacturer become non-compliant with the stated grade on the label if the product is not handled properly by downstream distributors or retailers. To provide some measure of protection to manufacturers, Petitioner has proposed to add a safe harbor provision.<sup>70</sup> Under this provision, a product for which a quality parameter designated as “highly dynamic” tests out of the specification will still be considered to be labeled in compliance with the SOI if the product satisfies all non-dynamic quality parameters and purity parameters, and if the product contains a best-before-date for which the manufacture can demonstrate support with reasonable technical support.<sup>71</sup>

Absent such protection, manufacturers could potentially be liable for selling a mislabeled product if it was labeled appropriately when it left their custody and control. Such a safe harbor does not put consumers at risk, as there is no danger associated with the degraded product, nor would it leave the consumer without a remedy. As with any product they may have purchased that has degraded before its time, they would be entitled to a replacement or a refund.

### 3.) Adoption of Rules for Names of Foods Consistent of Blends of Olive Oils and Olive-Pomace Oils with other Edible Oils.

The Codex Standard does not address the prevalent sale of products consisting of blends of olive oils and olive-pomace oils with other edible oils (hereafter, collectively referred to as “olive oil blends.”) While olive oil blend products are not common in all parts of the world (and in fact are illegal in some European countries), in the U.S. such products are commonly found in retail and especially in food service. Although there is currently no U.S. standard of identity for olive oils or olive-pomace oils, there is an FDA regulation for the naming of products which consist of olive oil blends.<sup>72</sup>

Therefore, Petitioner proposes modifying the Codex Standard to include a regulation based on 21 CFR §102.37.<sup>73</sup> From NAOOA’s efforts to protect consumers from potentially misleading labeling, it is imperative that section §102.37 be made stronger to address the many olive oil blend products with potentially misleading labels that imply that the product is 100% extra virgin olive oil when it is in fact a blend.<sup>74</sup> Petitioner believes it is necessary to do more to protect the consumers from misrepresentation on olive oil blend products, given the difference that may exist in the relative value of the component oils (e.g. extra virgin olive oil vs. soybean oil or sunflower oil). A more robust regulation on labeling such blends will help assure, in accordance with the first four of the Proposed Principles, that an olive oil blend is not labeled in a dishonest

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<sup>70</sup> Petitioner models this provision on a similar provision in the AOOPA/Deoleo Petition. In that petition, the “safe harbor” only applies to “freshness” quality parameters they have been proposed in their standard because of the highly dynamic nature of those parameters. A safe harbor provision that makes sense for one set of highly dynamic quality provisions makes sense for other highly dynamic parameters as well.

<sup>71</sup> A best-before date is not required by the proposed standard but would be necessary for a manufacturer to take advantage of the safe harbor provision. Determination of best-before-dates, however, is not an exact science, and may depend on many different factors, including cultivar varieties and growing areas, as well as timing and methods of harvesting and milling. For illustrative examples of different methods currently in use, see Appendices 17 and 17a.

<sup>72</sup> See 21 CFR § 102.37.

<sup>73</sup> The Petitioner’s intention is that the new provision in the SOI would replace § 102.37.

<sup>74</sup> See, e.g., photos of actual labels included in Appendix 18 (also included are screenshots of comments from Amazon.com customer reviews on one of the products).

way, misrepresenting the essential character of the food, misleading consumers to believe that it will have the same benefits of, for instance, 100% extra virgin olive oil, or otherwise appearing to have greater value than it does.

4.) Adoption of ingredient statement rules.

In accordance with the changes to the name of food labeling as provided above, Petitioner is proposing modifying the Codex Standard to include a rule governing the use of ingredient statements for olive oils and olive-pomace oils in order to provide consumers with the transparency that they deserve and desire when it comes to choosing an olive oil that meets their expectations.

5.) Additional labeling statements.

Petitioner believes it is necessary modify the Codex Standard to restrict certain label statements and terms in order to prevent confusion, meet consumer expectations, and not allow manufacturers to mislead consumers into thinking a product is of better or greater quality than it is in accordance with a number of the Proposed Principles.

a.) Misleading terms.

Petitioner proposes that any use of the word “light” to describe an olive oil must clearly indicate that it refers to taste and/or color and be excluded from the statement of identity itself. As the NAOOA Consumer Study showed, a significant number of respondents believe that the term “light” or “extra light” on an olive oil label indicates the oil is lower in calories or fat when that is not the case.<sup>75</sup>

In addition, the NAOOA Consumer Study showed that a significant number of respondents believe that the term “pure” when used on an olive oil label indicates that the oil has not been refined and/or contains the best quality of olive oil.<sup>76</sup> To ensure such consumers are not confused, Petitioner proposes that the term “pure” may only be used to describe extra virgin olive oil, which by definition has not been refined and which is the highest grade.

Although the NAOOA Consumer Study revealed some confusion among consumers regarding the meaning of the term “extra” in connection with “extra virgin olive oil,” a significant number of respondents (59%) stated that they believed use of the term indicated the oil was of “top quality.”<sup>77</sup> Petitioners therefore propose that the term “extra” may not be used on an olive oil label except as part of the grade “extra virgin olive oil.”

b.) Lot and Optional Best-if-Used-By Date.

While a mandatory best-if-used-by date would protect olive oil consumers from products that may purport to be better quality than in fact they are, Petitioner recognizes that FDA discourages

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<sup>75</sup> NAOOA Consumer Study, slide #39.

<sup>76</sup> Id. at slide #41.

<sup>77</sup> Id. at slide #35.

mandatory best-before-dates. Therefore, Petitioner proposes modifying the Codex Standard to state that if a best-if-used-by date is used, it may be no more than two years from bottling, which is consistent with the recommendation made in the IOC standard.

c.) Provenance and Varietals.

Again, to protect consumers from labeling that might incorrectly suggest the product has a greater or better value than it does, Petitioner proposes to modify the Codex Standard by including rules for the use of designations of provenance and varietals. From the results of the Attitude and Usage Study, it is clear that consumers have strong perceptions—with or without justification—that oils from certain geographic regions are better than others.<sup>78</sup> Therefore, it is important that rules be provided to avoid deception, and to make it easy for manufacturers to comply with the regulations.<sup>79</sup>

6.) Labeling of Non-retail containers.

Petitioner does not propose and substantive changes to this provision from the Codex Standard.

viii. Deviations from Codex Standard Section 8

Petitioner proposes to modify the Codex Standard’s list of approved methodologies for analysis and sampling to conform to the lasted methodologies adopted by the IOC, many of which have yet to be updated in the Codex Standard.

**3. FDA Should Consider an Alternative Horizontal Approach for an Olive Oil and Olive-Pomace Oils Standard of Identity.**

At the end of September 2019, FDA held a Public Meeting on Horizontal Approaches to Food Standards of Identity Modernization. FDA recognizes the need to find ways to update standard of identity regulations more easily than the agency’s existing workload and limited budget—and complicated regulatory framework—allow.

Cognizant of the concerns that prompted the public meeting, Petitioner offers an alternative approach to a standard of identity for olive oil and olive-pomace oil to facilitate future updates to standards and methodologies. As noted above, the most influential standard setting entity in the world is the IOC, which meets regularly to study and to refine standards necessary to improve, promote and control quality for a product that has been historically susceptible to fraud, and for which regional variations in existing standards continue to become important as olive orchards are planted in new growing regions around the world. The CCFO also meets regularly to consider updates to the Codex Standard. As noted above, many of the deviations proposed by the

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<sup>78</sup> Among consumers who expressed an opinion, 55% said Italy produced the best olive oil, and the next highest was California (18%). The AOOPA/Deoleo Petition also includes a similar provision.

<sup>79</sup> Although Petitioner is not aware of any research that indicates consumers’ relative value perceptions of different varietals that may be used to make olive oils, Petitioner has also included a regulation involving designations of varietals modeled after a similar provision in the AOOPA/Deoleo Petition.

Petitioner to the Codex Standard are essentially recent updates to the IOC standard that would likely eventually be added to the Codex Standard as well.

One example of a potential need for a horizontal approach concerns the possible future inclusion of standards for pyropheophytins (PPPs) and 1,2-diacylglycerol (DAGs) content. Petitioner recognizes that these standards may have significance in improving the control of quality among virgin olive oils, particularly in the calculation of best-before dates. The California Department of Food and Agriculture includes standards for these chemicals as part of that state's quality standards for olive oils, and the AOOPA/Deoleo Petition proposes adopting those standards. But neither the CAC nor IOC have to this point reached a consensus to adopt such standards. In fact, the inclusion of PPP and DAGs was proposed at the recent CCFO meetings but it was determined that it "required further discussion and or clarification," and therefore, the further collection of data and information.<sup>80</sup> The PPP and DAGs parameters may ultimately achieve sufficient scientific consensus to be added to the Codex Standard and the IOC standard; adopting a horizontal approach such as proposed by Petitioner would facilitate future scientifically-backed updates to the SOI to include these or other provisions that might improve protection for American consumers.

Petitioner suggests therefore that in its review of the Codex Standard, FDA consider omitting the quality and purity parameters, as revised, from Codex Standard Section 3 (which Petitioner has put in § 167.10(d)-(e) of the proposed SOI) and the approved methodologies for analysis and sampling as revised from Codex Standard Section 8 (which Petitioner has put in § 167.5 in the proposed SOI), and permit Petitioner to file a separate petition with United States Department of Agriculture ("USDA") to adopt these standards as revisions to the USDA Standard. Codex Standard Sections 3 and 8 (as modified in the proposed SOI) are subject to fairly frequent review and potentially important updates, and these provisions could replace the USDA's outdated voluntary standards for olive oils and olive-pomace oils. Future updates to these provisions would be more easily accomplished through USDA, and it would enable USDA to continue its own monitoring programs concerning olive oils using the most up-to-date standards.

Petitioner had an initial conversation with USDA representatives Robin Chilton, Chief, Standardization Branch, Fruit and Vegetable Program and Lindsay Mitchell, Standardization Specialist, Specialty Crops Inspection Division, concerning this proposed approach to regulating olive oil and olive-pomace oils on February 26, 2020. USDA representatives expressed no opinion on the proposal but stated that there is precedent for the regulation of certain food products by both FDA and USDA, such as with maple syrup, and that they were open to exploring this concept for olive oil and olive-pomace oils.

Should FDA agree to pursue this alternative, Petitioner proposes deleting § 167.5 and § 167.10(d)-(e) from the proposed SOI, and replacing § 167.10(d) with the following:

§ 167.10(d) Quality and Purity Standards. Olive oils and olive-pomace oils shall meet the quality and purity standards, and appropriate methods of analysis, published within the United States Standards for Grades of Olive Oil and Olive-Pomace Oil, maintained by USDA/AMS/Fruit and Vegetable Programs.

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<sup>80</sup> See Appendix 2a at ¶ 55(b)(ii).

*C. Environmental Impact*

Petitioner claims a categorical exclusion from environmental assessment/environmental impact analyses pursuant to 21 C.F.R. § 25.32(a).

*D. Economic Impact*

A statement of economic impact will be provided to the extent requested by the Commissioner.

*E. Certification*

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Respectfully Submitted,

North American Olive Oil Association



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## TABLE OF APPENDICES

<b>Appendix 1</b>	<b>Proposed Olive Oil Standard of Identity Regulation</b>
<b>Appendix 2</b>	<b>Codex Standard</b>
<b>Appendix 2a</b>	<b>CAC Report July 2019</b>
<b>Appendix 2b</b>	<b>CCFO Proposed Revisions to Codex Standard November 2018</b>
<b>Appendix 2c</b>	<b>Codex Standard Redline</b>
<b>Appendix 3</b>	<b>NAOOA Olive Oil Standard Petition (1990)</b>
<b>Appendix 3a</b>	<b>NAOOA Olive Oil Standard Petition (2012)</b>
<b>Appendix 3b</b>	<b>NAOOA Withdrawal of 2012 Petition</b>
<b>Appendix 4</b>	<b>Attitude and Usage Study 2018</b>
<b>Appendix 5</b>	<b>IOC Standard November 2019</b>
<b>Appendix 6</b>	<b>Yale Public Health Statement</b>
<b>Appendix 7</b>	<b>NAOOA Consumer Study March 2020</b>
<b>Appendix 8</b>	<b>Agile Pixel Studio Letter</b>
<b>Appendix 9</b>	<b>IOC Report April 2016 Heptadecanoic, Heptadecenoic, Eicosanoic Acids Content</b>

<b>Appendix 9a</b>	<b>IOC Report April 2016 Revision of Heptadecanoic, Heptadecenoic and Eicosanoic Acids Limits</b>
<b>Appendix 10</b>	<b>IOC Report Oct 2006 Linolenic Acid Limit</b>
<b>Appendix 11</b>	<b>IOC Report April 2016 General Data Campesterol Complete</b>
<b>Appendix 11a</b>	<b>IOC Report Oct 2011-Study Delta-7-Stigmastenol +Campesterol</b>
<b>Appendix 11b</b>	<b>IOC Report Oct 2019-<math>\Delta</math>7-Stigmastenol Decision Tree in Refined OO</b>
<b>Appendix 11c</b>	<b>IOC Study Delta-7-Stigmastenol</b>
<b>Appendix 12</b>	<b>IOC Report Oct 2012 Reduction of Wax Limit Annex 7</b>
<b>Appendix 12a</b>	<b>IOC Report Oct 2012 Wax Content of EVOO from Argentina</b>
<b>Appendix 12b</b>	<b>IOC Report Oct 2012 Annex 2 Alkyl Esters, Waxes and Stigmastadiene</b>
<b>Appendix 13</b>	<b>IOC Report Oct 2012 Reduction of Stigmastadiene Limit Annex 6</b>
<b>Appendix 14</b>	<b>IOC Report May 2006 2-Glyceryl-Monopalmitate</b>
<b>Appendix 15</b>	<b>IOC Oct 2015 K270 and Decision Tree Proposals</b>
<b>Appendix 15a</b>	<b>IOC Report 2016 – General Data Presentation K270</b>
<b>Appendix 16</b>	<b>Fatty Acid methyl and ethyl esters as well as wax esters for evaluating the quality of olive oils, Biederman et al., Eur Food Res Tech 2008</b>
<b>Appendix 16a</b>	<b>Ethyl esters versus fermentative organoleptic defects in virgin olive oil Di Serio et al. Food Chem 2017</b>

<b>Appendix 16b</b>	<b>Review of Scientific papers on FAEEs</b>
<b>Appendix 16c</b>	<b>IOC Report: Detection of Admixures of Deodorized OO with EVOO April 2008</b>
<b>Appendix 16d</b>	<b>Fatty acid ethyl esters (FAEE) in extra virgin olive oil: A case study of a quality parameter, Gomez-Coca et al LWT Food Sci Tech 2016</b>
<b>Appendix 16e</b>	<b>Determination of Esters of Fatty Acids with Low Molecular Weight Alcohols in Olive Oils, Perez Camino et al FFAE JAFC 2002</b>
<b>Appendix 17</b>	<b>Shelf life of extra-virgin olive oils: First efforts toward a prediction model, Di Serio et al., J Food Process Preserv 2018</b>
<b>Appendix 17a</b>	<b>Shelf Life of Extra Virgin Olive Oil and Its Prediction Models Li et al, Journal of Food Quality 2018</b>
<b>Appendix 18</b>	<b>Olive Oil Blend Labels and Amazon.com Comments</b>