



NORTH AMERICAN OLIVE OIL ASSOCIATION

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UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Citizen Petition to:

Margaret A. Hamburg, M.D.,
Commissioner of Food and Drugs

Docket No.

For Review of **Standard of Identity for Olive Oil and Olive-Pomace Oil**, Pursuant to 21 CFR
130

Submitted by:

North American Olive Oil Association
July 9, 2012



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Division of Dockets Management
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I. Introduction / Statement of Grounds

After six years of research and review, the Agricultural Marketing Service (“AMS”) U.S. Department of Agriculture (“USDA”) put revised U.S. Standards for Grades of Olive Oil and Olive-Pomace Oil into effect in October 2010. Petitioners are requesting the U.S. Food and Drug Administration (“FDA”) consider the USDA’s due diligence as a basis to enhance and reaffirm the FDA’s prior comments on the standard of identity for olive oil and olive-pomace oil. *See* 47 Fed. Reg. 42123-01 (Sept. 4, 1982).

Food standards are intended to promote honesty and fair dealing in the interest of consumers. While olive oil is produced in the U.S., traded internationally, and consumed both as a packaged food and as a food ingredient, there currently is no nationally mandated standard to ensure the identity for olive oil in U.S. law. Considering the unique health benefits associated with olive oil, it is especially important to establish a consistent federally-recognized standard so that consumers can be assured of the authenticity of olive oils purchased in the U.S. In fact, in 2004 the FDA approved a Qualified Health Claim for olive oil (docket no. 2003Q-0559), and the industry needs a uniform path to enforcement to ensure fair dealing within the marketplace and protection of consumer interests. An enhanced standard of identity, especially one that includes a compositional standard and analytic testing to ensure compliance, would provide such a path.

As olive oil is a truly global commodity, with more than 98% of the olive oil consumed in the U.S. being imported from other countries, it is important to note that globally-accepted standards for olive oil exist. The World Trade Organization (“WTO”) relies on collaboration with the Codex Alimentarius Commission (“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. Furthermore, in regards to olive oil, the Codex Standard (CODEX STAN 33-1981) is based primarily on the International Olive Council (“IOC”) trade standard (COIT. 15/NC No 3/Rev. 5). As the science and production of olive oil evolve, these standards are adapted. The Codex standard for olive oils was originally adopted in 1981, and was revised in 1989 and 2003, and was amended in 2009. The IOC standard, first defined in 1959, was most recently updated in November 2010. Representatives from the U.S. participate in both organizations - directly within the CAC in the development of international standards; and within the IOC as a signatory association for quality monitoring and an observer member in other



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matters. The FDA, too, has favorably commented on CAC, noting that “an imported food which complies with the requirements of the Codex standard may move freely in interstate commerce in this country.” 47 Fed. Reg. at 42123.

In addition to proven global acceptance, USDA’s recent work on the olive oil standards shows significant support from the industry for the acceptance of a standard in the U.S. and further demonstrates the IOC trade standard is the most encompassing standard related to the olive oil industry. The original AMS petition requested the “U.S. grade standards be revised to make them consistent with the IOC standards for olive and olive-pomace oil.” In response to its first published notice in the November 8, 2004, Federal Register (69 FR 64713), AMS received 30 comments in response to determining interest in revising the U.S. grade standards. With only one exception, all of the comments received agreed that the U.S. grade standards should be revised.

AMS then developed proposed grade standards and published a notice in the June 2, 2008, Federal Register (73 FR 31426). At the conclusion of this comment period, AMS had received 26 comments from the U.S., Australia, Argentina, New Zealand, Portugal, Spain, and Tunisia that represented producers, consumers, trade associations, government agencies and representatives. Again, with only one exception, all of the comments were in support of the proposed U.S. grade standards.

Ultimately, AMS’ published notice in the April 28, 2010 Federal Register (75 FR 22363) noted that after addressing questions and recommendations received during the comment period, the resulting U.S. grade standards “include the same requirements as the IOC standard except for the limits for linolenic acid and campesterol. The revised grade standards provide for slightly larger limits for both of these components to account for domestic variation from the IOC limits.”

As noted in the FDA’s recently released *Global Engagement* report, changes in international trade have created a truly global marketplace. For U.S. consumers, this is especially true in the case of olive oil. More than 98% of the olive oil sold in the U.S. today is imported. At the same time, the domestic olive oil industry has doubled in size in just a few short years. Considering the challenges of harmonizing global standards and fair trade, there is no food more appropriate than olive oil to set an example of FDA’s ability to engage globally.

Petitioners respectfully submit that a food’s *statement of identity* is the first place a consumer goes for product information. With a plethora of oil and fat options, if a consumer intends to purchase heart-healthy olive oil, there should be confidence, implicit in the food name, that the product is not a blend of oils or a less-healthy oil masquerading as olive oil. Petitioners strongly believe in order for consumers to take advantage of a heart-healthy diet, the term “Olive Oil” as used on a product label must mean olive oil. Consumers and industry alike will accrue the benefits of the internationally-based standard being adopted into U.S. law, with the identity and composition of olive oil preserved in a market of many less-healthy edible oils and fats.



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II. Action Requested

This petition requests action by the commissioner to enhance its standard of identity for olive oil and olive-pomace oils based on the October 2010 U.S. Standards for Grades of Olive Oil and Olive-Pomace Oil, pursuant to 401 of the Federal Food Drug and Cosmetic Act. Copies of the U.S. Standard, the IOC Standard from which the U.S. Standard was modeled and the nearly identical Codex Standard are attached hereto as Exhibit “A,” Exhibit “B” and Exhibit “C” respectively. Petitioners request the commissioner to publish this petition in the Federal Register as a proposal.

III. Reasons for Deviations

Petitioners herein were actively involved in the process with AMS related to revising the grade standards. As such, petitioners support the resulting standard as defined and implemented in October 2010, with one exception to analysis used to demonstrate proof of identity. In the USDA standard, several tests for authenticity are listed in a secondary table (Table II) to be used only as confirmatory tests. The NAOOA’s experience in more than 20 years through the IOC’s Quality Monitoring Agreement suggests products being sold as olive oil in the U.S. may pass all the Table I tests but still fail on several of the Table II criteria. Specifically, past lab reports have shown that olive-pomace oil might be labeled as olive oil or even extra virgin olive oil and pass all of the Table I tests. However, if the tests in Table II are carried out, the mislabeling is easily identified. For this reason, the standard of identity should include all criteria outlined in both Table I and Table II of the USDA standard. Finally, in consideration of the overwhelmingly global nature of the olive oil trade, petitioners request any future adjustments to the standard of identity be consistent with international standards, as this would indicate acceptance by the global community representing the vast majority of olive oil production.

IV. Statement of How the Proposed Standard Conforms to General Principles Outlined in Proposed Rules to 21 CFR Part 130.5; 70 F.R.29234 (May 20, 2005)

The first proposed general principle for agency consideration in the adoption of a food standard is consideration of whether the requested standard promotes honesty and fair dealing in the interest of consumers.

With the growing interest in the health benefits of monounsaturated-rich diets (i.e. the “Mediterranean” diet), and demonstrated benefits for lowering serum cholesterol without lowering HDL cholesterol and with a variety of edible oils and blends being introduced into the market, consumer understanding of the meaning of the term “Olive Oil” is likely to erode. Thus, a consistent identity statement for “Olive Oil” is timely and sorely needed in the United States. The standard will preserve the food name of “Olive Oil” for the traditional food and clearly



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encourage and aid consumers in making a healthy eating choice in a category of foods that can contribute to CHD risk.

As research related to the health benefits of olive oil evolves, it is clear that even within the category of olive oil the health benefits vary based on the grade, i.e. Extra Virgin, Olive Oil and Olive-Pomace Oil. In order to protect consumers selecting a specific grade of olive oil not just for flavor or cooking style but for diet or health-related reasons, a complete standard including comprehensive testing methods for grade authenticity is necessary.

Petitioners submit the proposed enhanced standard will promote honesty and fair dealing not only in the interest of consumers but in the interest of the olive oil industry as well. A compositional standard for olive oil will serve as a tool to help regulators combat the economic adulteration of olive oil and misbranding of olive oil pretenders.

With olive oil costing more than most cooking oils, including canola and soy oils, the economic incentive to cheat and substitute cheaper oils for olive oil is evident. Additionally, olive pomace oil has significantly less value than olive oil or extra virgin olive oil, further providing an opportunity for mislabeling and fraudulent economic gain within the industry. The FDA has previously recognized that “[s]olvent-extracted olive oil is lower in quality than pressed olive oils” 47 Fed. Reg. at 42123. An enhanced U.S. olive oil standard of identity would aid enforcement and industry compliance with FDA regulations, the Food Drug and Cosmetic Act and the Fair Packaging and Labeling Act. The resultant reduced economic adulteration and misleading labeling will benefit both consumers and producers.

The proposed standard is expected to promote honesty and fair dealing within the food trade in general, where olive oil is used as an ingredient in other foods.

In addition, as required by 21 C.F.R. 130.5(c) we commit to substantiate any information in this petition by evidence in a public hearing, if such a hearing becomes necessary.

V. Statement of Meetings with Other Interest Groups

In formulating this petition, the Petitioners and other interest groups have conducted the following meetings, where the need for this action was either discussed or the petition itself discussed.

- **North American Olive Oil Association, Annual Meeting, June 15, 2012, Washington, D.C.**



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VI. Environmental Impact

Petitioners claim categorical exclusion from environmental assessment and environmental impact statement requirements because the action requested is of the type excluded pursuant to 21 C.F.R. §25.32(a).

VII. 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 petition which are unfavorable to the petition.

Respectfully submitted on behalf of members of the North American Olive Oil Association,

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