



February 17, 2023

Ignacio Silva
President and CEO
Deoleo
C/ Marie Curie, 7, 4a planta.
Rivas Vaciamadrid 28521
Madrid, Spain

Re: Docket No. FDA-2022-P-1457

Dear Mr. Silva:

Thank you for your citizen petition dated July 5, 2022, under Docket No. FDA-2022-P-1457, requesting that the Food and Drug Administration (FDA or we) establish a standard of identity for olive oil and olive-pomace oil. FDA may establish and amend standards of identity when doing so would promote honesty and fair dealing in the interest of consumers (21 U.S.C. 341). While reviewing the petition, we identified a few questions and would like additional information to better understand issues raised in your petition.

Specifically, the petition states that a federal standard would “facilitate enforcement to protect all consumers from fraud” (Petition at page 1). However, the petition does not discuss the types and prevalence of fraud that you (the petitioners) are most concerned with, which could potentially impact U.S. consumers. Please provide information on how these products are fraudulent (such as, what types of products they are diluted with, and the evidence needed to support these claims).

The petition proposes a standard that contains five tables of parameters and twenty-one methods of analysis (Appendix 1, petition at page 5). Please provide support on the effectiveness of these methods of analysis and the parameters in detecting these different types of fraud of concern. Also, is there a minimum set of methods and parameters that could be used to determine the identity of olive oil and olive-pomace oil products?

In Appendix 3, petition at page 1 of the petition, you acknowledge that you were not able to reach consensus on parameters “which concern variation in the chemistry of olive oils and olive-pomace oils that fall outside the authenticity parameters in the proposed standard of identity.” We understand that many important parameters are affected by the natural variation in olive oil chemistry. However, could you please suggest a set of parameters that are not as affected by the natural variation in olive oil chemistry but would still be able to detect fraud?

We find it helpful to have scientific evidence to support any requests to establish a standard of identity. Therefore, to complete our review of your petition, we request that you submit additional scientific studies and data, scientific literature from peer-reviewed journals, and any other scientific evidence in response to our questions above. We note that one of the exhibits (Exhibit AD-7, consisting of 12 un-numbered pages) is not in English. If you would like us to consider the information, please submit an English translation. You can submit any additional information as well as the requested information for the petition to Docket No.

FDA-2022-P-1457. We would be happy to set up a call to further discuss our questions, and if you have any questions, please let us know.

Sincerely,

Claudine Kavanaugh, PhD, MPH, RD
Director
Office of Nutrition
and Food Labeling
Center for Food Safety
and Applied Nutrition