



February 16, 2023

Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, Maryland 20852

Submitted electronically at [www.regulations.gov](http://www.regulations.gov)

RE: Docket No. FDA-2016-D-2335 for "Food Labeling: Nutrient Content Claims; Definition of Term 'Healthy.'"

Dear Sirs and Madams:

Thank you for the opportunity to submit public comments regarding the nutrient content claim definition of the term "healthy."

### **Background**

The Institute of Shortening and Edible Oils (ISEO) submits these comments on behalf of U.S. refiners who produce 95 percent of domestic edible fats and oils from the following commodities: U.S. grown soybean, U.S. grown corn, U.S. grown cottonseed, U.S. grown canola, U.S. grown sunflower, U.S. grown safflower, U.S. grown rice bran, U.S. produced lard, tallow, and wheat germ, as well as imported commodities such as: olive, palm, palm kernel, coconut, canola and sunflower used for a wide variety of edible applications, which include baking, frying, spray oils, spreads, margarine and other food uses to provide nutrition and functionality. Fats and oils are also used in animal feeds as a source of energy and essential fatty acids.

Human and animal diets have always contained fats and oils, which are naturally present in many foods, such as meats, dairy products, poultry, fish, and nuts. Today our industry builds on this by providing fats and oils, as processed products, which make significant and important positive contributions by:

- **Contributing Essential Nutrients:** Fats and oils are recognized as essential nutrients in both human and animal diets. Nutritionally, they are concentrated sources of energy (9 Kcal/gram); provide essential fatty acids, which are the building blocks for the hormones needed to regulate bodily systems; and are a carrier for the fat soluble vitamins A, D, E, and K.
- **Enhancing the Eating Experience:** Fats and oils enhance the foods we eat by providing texture and mouth feel, imparting flavor, and contributing to the feeling of satiety after eating.
- **Providing Key Functionality:** Fats and oils provide important functionality in the preparation of many food products. They act as tenderizing and release agents, facilitate aeration, carry flavors and colors, and provide a heating medium for food preparation.

ISEO appreciates that the Dietary Guidelines for Americans 2020-2025 (DGA) acknowledged the importance of oils and essential fatty acids; however, ISEO recommends avoiding overly simplistic



solutions that favor one edible oil over another, as this can create consumer confusion and result in unintended consequences. Edible oils have different nutritional profiles, amounts of essential nutrients, functionality and uses, market prices, and environmental and sustainability impacts. There is room for all edible oils in the market and in most diets based on individual health needs, wellness goals, tastes, and preferences.

### **ISEO Comments on FDA's proposed "healthy" definition**

#### **ISEO supports FDA finalizing the "healthy" definition to include oils, but also believes that FDA should acknowledge the benefits of the category**

Fats and oils are an important part of human diets, providing naturally occurring essential nutrients and key functionality. We were pleased to see the FDA acknowledge our important role in the diet and align its proposed definition of "healthy" with the DGA, which promotes predominantly monounsaturated and polyunsaturated fats, emphasizing oils, such as 100% canola, corn, olive, soybean, and sunflower. Moreover, we acknowledge the proposal would also allow oil-based spreads, such as tub margarine, when its fat content comes solely from oils and where the product's overall saturated fat content is no more than 20% of total fat, and the product contains 0% of the daily value (DV) for added sugars and no more than 5% DV for sodium. Finally, we appreciate that oil-based dressings containing at least 30% oil, which is consistent with the oil content in the standard of identity for salad dressings, would also qualify.

While we understand FDA chose to limit oils with less than or equal to 20% saturated fat of total fat, it is important to acknowledge that the benefits of edible oils and the reasons that consumers choose them as part of healthy balanced diets lie beyond fat standards. These factors include unique nutritional profiles, significant amounts of essential nutrients, functionality and use considerations. Therefore, it is important that FDA clarify that fats and oils that do not meet the "healthy" definition are not "unhealthy" and acknowledge the benefits of all fats and edible oils which can be a part of a healthy balanced diet. ISEO encourages FDA to educate consumers on how food products, whether "healthy" or not, play a role in a healthy balanced diet.

Our members are concerned the "healthy" definition could be used as standard criteria for foods to qualify under government initiatives, including the Supplemental Nutrition Assistance Program (SNAP), Special Supplemental Program for Women, Infant, and Children (WIC), and more. Therefore, it is important that FDA acknowledge the benefits of all fats and edible oils, including, but not limited to: soybean oil, corn oil, cottonseed oil, canola oil, sunflower oil, safflower oil, rice bran oil, lard, tallow, wheat germ oil, palm oil, coconut oil, and fully hydrogenated oils. Disregarding the benefits of edible oils could result in at risk populations lacking essential fatty acids in their diets.

As elaborated on in page one in the background section of this comment, fats and oils are an important part of both human and animal diets, providing naturally occurring essential nutrients and key functionality.



### **FDA should allow use of the term “healthy fats”**

Given that many oils can now be considered “healthy” if they meet the proposed criteria, ISEO members request that FDA recognize that it is appropriate to refer to oils that qualify as healthy as “healthy fats.”

### **FDA should confirm “healthy” applies only to those terms expressly and currently defined as synonyms for a “healthy” nutrient content claim and acknowledge qualified health claims (QHCs) as useful tools to encourage healthier dietary patterns**

FDA should confirm “healthy” applies only to those terms expressly and currently defined as synonyms for a “healthy” nutrient content claim (e.g., “healthier”) and does not apply to other labeling claims, such as QHCs.

As proposed, non-dairy spreads only meet the proposed definition of “healthy” if their total fat is comprised of  $\leq 20\%$  saturated fat. However, a 2017 QHC on soybean oil and coronary heart disease risk-reduction (“the QHC”) requires soybean oil-based spreads to comply with the disqualifying nutrient levels of 21 CFR 101.14(a)(4),<sup>1</sup> which limits saturated fat to  $\leq 4\text{g}$  per RACC, not based on its proportion to total fat. Neither the QHC nor the proposed rule prohibits spreads from containing tropical oils, such as palm oil, which are higher in saturated fat but necessary to achieve the functionality and texture consumers expect in non-dairy butter alternatives. This means some lower-fat spreads would be simultaneously qualified for the QHC, but prohibited from using the term “healthy”.

We would like to provide an example that illustrates this paradox:

A soybean oil-based spread with 40-45% fat<sup>2</sup> that qualifies for the QHC contains, per 14g RACC:

- 6.3g total fat
- 5g soybean oil – required to qualify for the QHC – which contributes 0.75g saturates<sup>3</sup>
- The remaining 1.3g may be palm oil, which would contribute 0.64g saturates<sup>4</sup>

This results in a saturated fat content that meets the conditions of the QHC ( $\leq 4\text{g}$  per RACC) yet makes up 22% of total fat, exceeding the 20% maximum under the proposed definition of “healthy”.

Without clarification from FDA, it is unclear whether this formula could continue to bear the QHC for which it otherwise qualifies, or if it would become misbranded under the rule. The latter outcome would contradict the proposed rule itself, which encourages the consumption of non-dairy spreads as sources of healthier unsaturated fats, even noting that “use of spreads made with vegetable oils can help shift intake away from other fats high in saturated fat.”

Careful consideration should also be given when lumping saturated fatty acids under the general term “saturates.” This is important, given that all saturates do not behave the same from a physiological perspective.



The proposed rule also states that FDA is seeking “comment on whether nuts with relatively higher amounts of saturated fat should be eligible for the ‘healthy’ claim”, acknowledging the multiple QHCs pertaining to nut consumption and reduced disease risk.

Failure to address paradoxes such as these will create confusion among consumers and possibly discourage them from consuming products that otherwise fulfill the public health goals of the proposed rule. Additionally, it will unintentionally set up food manufacturers for failure and non-compliance.

ISEO requests FDA confirm “healthy” applies only to those terms expressly and currently defined as synonyms for a “healthy” nutrient content claim (e.g., “healthier”) and does not apply to other labeling claims, such as QHCs.

#### **FDA should clarify how the food group equivalents are calculated and determined**

FDA should provide additional guidance related to the food group equivalent requirements. While we appreciate that the proposal relies on definitions of food group equivalents outlined in the “Healthy U.S.-Style Dietary Pattern” in Table A3-2 of the DGA, this does not appear to be an exhaustive list and, therefore, we suggest that FDA provide additional clarity on what counts as a food group equivalent for each category.

#### **FDA should limit the definition to the term “healthy” only**

ISEO recognizes this regulation covers all derivatives of the word “healthy” and that FDA is seeking comments on if there are other synonymous terms they should consider as it finalizes this rulemaking. Our concern is that it would limit members' ability to guide consumers towards better-for-you options. We recommend the Agency limit its work to “healthy” rather than make it challenging to understand what terms or phrases may be considered synonymous.

#### **FDA should provide additional clarifications on recordkeeping requirements**

FDA should provide additional clarifications regarding the rule’s recordkeeping requirements. For example, FDA should clarify that records kept to verify the food group contributions are limited in nature and need only include the specific information regarding the food group component information. The records do not need to include confidential and trade secret information, such as the complete product recipe or formulation, but instead would be limited to the specific information regarding the food group component contribution. Relatedly, we agree with FDA’s statements that manufacturers should be permitted to demonstrate compliance using the records they best believe meet the requirements and are not required to produce any specific form or document. Such an approach is similar to FDA’s recordkeeping system for nutrition labeling of added sugars and other nutrients for which no analytical test method exists.

#### **FDA should respond to member questions**

ISEO members have the following questions and ask that these be clarified and addressed as the Agency finalizes the “healthy” definition:



- Will the “healthy” definition have any impact on comparative nutrient content claims? For example, if a food contains too much saturated fat to bear the “healthy” claim, could it still say it has “x% less saturated fat” than a comparison food? Or would that be considered an implied “healthier” claim?
- Has any attempt been made to align the “healthy” definition with private certifications, for example American Heart Association's "Heart Check" program?
- How has FDA determined that this measure will effectively accomplish the stated goal? What evidence/research was used?

**FDA should state that the term “healthy” may continue to be used on food sold lawfully and shipped in interstate commerce until the compliance date**

In its final rule FDA should state that the term “healthy” may continue to be used consistent with the existing regulation, and products bearing the term “healthy” may continue to be lawfully sold and shipped in interstate commerce under the Federal Food, Drug, and Cosmetic Act until the compliance date.

**FDA should articulate its vision on labeling generally**

Finally, ISEO members would appreciate clarity from the Agency on how the definition fits into the broader food regulatory landscape. We understand that FDA has begun to conduct research on a symbol that industry may voluntarily use to label food products that meet the proposed “healthy” definition on a separate but related track. The proposed definition and the ongoing icon research came out nearly to the day of release of the Biden Administration’s National Strategy on Hunger, Nutrition, and Health, calling for front-of-package labeling. ISEO requests better articulation of the Agency’s vision and research for how these labels work together to help consumers maintain healthy dietary practices that are consistent with the DGA.

**Closing**

Thank you for the opportunity to submit public comments and for your continued commitment to seeking stakeholder input. ISEO looks forward to partaking in this process and stands ready to be a resource to you.

Sincerely,

*Kailee Tkacz Buller*

Kailee Tkacz Buller  
President & CEO  
Institute of Shortening and Edible Oils  
1310 L Street, Suite 375, Washington, DC 20005  
contactus@iseo.org  
www.iseo.org



## References

1 CFR - Code of Federal Regulations Title 21:

[https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=101.14#.-:text=\(4\)%20Disqualifying%20nutrient%20levels](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=101.14#.-:text=(4)%20Disqualifying%20nutrient%20levels)

2 USDA Food Data Central <https://fdc.nal.usda.gov/fdc-app.html#/food-details/173589/nutrients>

3 USDA Food Data Central: <https://fdc.nal.usda.gov/fdc-app.html#/food-details/171411/nutrients>

4 USDA Food Data Central: <https://fdc.nal.usda.gov/fdc-app.html#/food-details/171015/nutrients>