



Cédric Langhi, Ph.D.
Nutraveris
6 rue de la gare
22 000 Saint Brieuc
FRANCE

Re: GRAS Notice No. GRN 001267

Dear Dr. Langhi:

The Food and Drug Administration (FDA, we) completed our evaluation of GRN 001267. We received the notice you submitted on behalf of Shankar Nutricon (Shankar) on April 9, 2025 and filed it on July 7, 2025. Shankar submitted amendments to the notice on September 12, 2025, October 10, 2025, October 15, 2025, December 29, 2025, February 5, 2026, and February 9, 2026, providing additional information and clarifications regarding the intended uses, specifications, dietary exposure, manufacturing process, and analytical methods.

The subject of the notice is sunflower lecithin for use as an emulsifier, surfactant, dispersing agent, and a dietary source of choline and fatty acids in various foods at the maximum use levels as specified in Table 1, excluding use in infant formula and products under the jurisdiction of the United States Department of Agriculture. The notice informs us of Shankar's view that these uses of sunflower lecithin are GRAS through scientific procedures.

Table 1. Intended food uses and maximum use levels for sunflower lecithin.

Food Category	Food Uses	Maximum Use Level (mg/kg)
Milk and Milk Products	Milk (whole, reduced fat, low fat, nonfat), flavored milk (whole, reduced fat, low fat, nonfat), dairy drinks, milk shakes	55,000
Dairy Products	Cheese	650
Dairy Products	Cottage/ricotta cheese	1,000
Dairy Products	Ice cream, frozen dairy desserts	1,500
Dairy Product Analogs	Plant based milk	55,000

Food Category	Food Uses	Maximum Use Level (mg/kg)
Fats and Oils	Margarine	4,000
Condiments and Sauces	Dips, gravies, sauces	7,500
Grain Products	Pasta, noodles, cooked grains	15,000
Baked Goods	Yeast breads, biscuits, muffins, quick breads, pancakes, waffles, French toast	20,000
Soups	Soups, broth-based	5,000
Snack Foods	Potato chips, tortilla/corn/other chips, popcorn, pretzels/snack mix, cereal bars	17,500
Confectionery	Candy containing chocolate	3,300
Confectionery	Candy not containing chocolate	30,000
Prepared Foods	Peanut butter and jelly sandwiches	4,000

Our use of the term “sunflower lecithin” in this letter is not our recommendation of this term as an appropriate common or usual name for declaring the substance in accordance with FDA’s labeling requirements. Under 21 CFR 101.4, each ingredient must be declared by its common or usual name. In addition, 21 CFR 102.5 outlines general principles to use when establishing common or usual names for non-standardized foods. Issues associated with labeling and the common or usual name of a food ingredient are under the purview of the Office of Nutrition and Food Labeling (ONFL) in the Nutrition Center of Excellence (NCE). The Office of Pre-Market Additive Safety (OPMAS) did not consult with ONFL regarding the appropriate common or usual name for “sunflower lecithin”.

Shankar provides information on the identity and composition of sunflower lecithin. Shankar describes sunflower lecithin as a complex mixture of primarily acetone-insoluble phospholipids with varying amounts of triglycerides, glycolipids, fatty acids, and carbohydrates. Shankar states that the identity and composition of the sunflower lecithin, including the phospholipid and fatty acid profiles, are similar to currently used lecithin from other sources. Shankar states that sunflower lecithin may be produced in liquid, powder, and granule forms. Shankar describes sunflower lecithin as a golden yellow to brown viscous liquid, a light yellow to cream fine powder, and a light yellow to cream granule.

Shankar describes the manufacturing process for sunflower lecithin. The seeds of sunflower (*Helianthus annus* L.) are cleaned and dried, cracked, dehulled, crushed, and

then sent through an expander. The first extraction step combines the seed cake with food grade hexane in the extractor. After filtration and solvent evaporation, the crude sunflower oil is obtained. The crude oil is then subjected to a degumming process during which water-hydratable phosphatides (gums) precipitate. Shankar states that water, phospholipids and glycolipids, some triglycerides, carbohydrates, traces of sterols, free fatty acids, and carotenoids are present in the gum fraction. Shankar states that after an evaporation step, crude sunflower lecithin is produced. The crude sunflower lecithin undergoes purification and standardization yielding liquid sunflower lecithin. The liquid sunflower lecithin can be further processed and de-oiled with acetone and dried to produce the powder form of sunflower lecithin. The powder can then be agglomerated by physical pressure in a granulator and dried to form granular sunflower lecithin. Shankar states that sunflower lecithin is manufactured according to current good manufacturing practices (cGMPs) and that all raw materials are food grade and approved for use in food in the United States.

Shankar provides specifications for sunflower lecithin that include phosphatidylcholine (> 13 % for the liquid form, 18-24 % for the powder and granule form), acetone-insoluble matter (> 60 % for the liquid form, > 97 % for the powder and granule form), hexane-insoluble matter (< 0.3 %), toluene-insoluble matter (< 0.3 %), acid value (< 35 mg KOH/g), peroxide value (< 10 milliequivalents (mEq) O₂/kg for the liquid form, < 5 mEq O₂/kg for the powder and granule form), moisture (< 1.5 %), lead, arsenic, cadmium, mercury (≤ 0.1 mg/kg each), ethanol (< 10 mg/kg), acetone (< 25 mg/kg), and hexane (< 1 mg/kg), and limits on microorganisms, including *Salmonella* serovars (absent in 375 g) and *Escherichia coli* (absent in 1 g). Shankar provides the results from the analyses of three non-consecutive batches for each form of sunflower lecithin to demonstrate that each form meets the specifications. Based on the results of the stability study, Shankar states that sunflower lecithin in the liquid and powder form is stable for two years at 25 °C.

Shankar discusses the estimated dietary exposure to sunflower lecithin and incorporates information presented in GRN 000533¹, GRN 000682², and GRN 000939³. Shankar estimated the dietary exposure to sunflower lecithin from the intended uses to be 7,879 mg/person(p)/d (159.59 mg/kg body weight (bw)/d) at the mean and 21,322 mg/p/d (398.26 mg/kg bw/d) at the 90th percentile for the U.S. population aged 2 years and older using food consumption data from the 2021-2023 National Health and Nutrition Examination Survey (NHANES), Shankar notes that under 21 CFR 184.1400, lecithin derived from soy, safflower, or corn oils is used in food without limitation other than cGMP. Shankar states that the intended uses of sunflower lecithin will be substitutional for current uses of other lecithins, and therefore, will not increase the current

¹ The subject of GRN 000533 is canola-derived lecithin/lysolecithin. We evaluated this notice and responded in a letter dated March 20, 2015, stating that we had no questions at the time regarding the notifier's GRAS conclusion.

² The subject of GRN 000682 is canola lecithin. We evaluated this notice and responded in a letter dated July 7, 2017, stating that we had no questions at the time regarding the notifier's GRAS conclusion.

³ The subject of GRN 000939 is sunflower lecithin. We evaluated this notice and responded in a letter dated March 3, 2021 stating that we had no questions at this time regarding the notifier's GRAS conclusion.

cumulative dietary exposure to lecithin.

Shankar states that the identity and composition of the sunflower lecithin, including the phospholipid and fatty acid profiles, is comparable to other lecithins, including sunflower lecithin considered in GRN 000939, as well as canola lecithin considered in GRN 000533, and GRN 000682. Shankar also states that lecithin derived from sunflower is expected to have the same biochemistry, absorption, metabolism, and fate in the human body as other plant-derived lecithins, including those that have been determined to be safe for human consumption. Shankar conducted a literature search through September 2025 and did not identify any information that would contradict its GRAS conclusion.

Shankar references published toxicological studies demonstrating the safety profile of lecithin and related phospholipids. Shankar discusses acute, repeated dose, and reproductive and developmental toxicity studies that showed no signs of treatment-related adverse effects. Lecithin and related compounds are non-mutagenic and non-genotoxic. Shankar also discusses several published human clinical trials on lecithin and related phospholipids and notes that there were no treatment related effects.

Based on the totality of information discussed in the notice, Shankar concludes that sunflower lecithin is GRAS under the conditions of its intended use.

Standards of Identity

In the notice, Shankar states its intention to use sunflower lecithin in several food categories, including foods for which standards of identity exist, located in Title 21 of the Code of Federal Regulations. We note that an ingredient that is lawfully added to food products may be used in a standardized food only if it is permitted by the applicable standard of identity.

Potential Labeling Issues

Under section 403(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), a food is misbranded if its labeling is false or misleading in any way. Section 403(r) of the FD&C Act lays out the statutory framework for labeling claims characterizing a nutrient level in a food or the relationship of a nutrient to a disease or health-related condition (also referred to as nutrient content claims and health claims). If products containing sunflower lecithin bear any nutrient content or health claims on the label or in labeling, such claims are subject to the applicable requirements and are under the purview of ONFL in NCE. OPMAS did not consult with ONFL on this issue or evaluate any information in terms of labeling claims. Questions related to food labeling should be directed to ONFL.

Potential Requirement for a Color Additive Petition

There is no GRAS provision for color additives. In the notice, Shankar notes that sunflower lecithin ranges from yellow to brown in color. As such, the use of sunflower

lecithin in food products may constitute a color additive use under section 201(t)(1) of the FD&C Act and FDA's implementing regulations in 21 CFR Part 70. Under section 201(t)(1) and 21 CFR 70.3(f), a color additive is a material that is a dye, pigment, or other substance made by a synthetic process or similar artifice, or is extracted, isolated, or otherwise derived from a vegetable, animal, mineral, or other source. Under 21 CFR 70.3(g), a material that otherwise meets the definition of a color additive can be exempt from that definition if it is used (or is intended to be used) solely for a purpose or purposes other than coloring.

Our response to GRN 001267 is not an approval for use as a color additive nor is it a finding of the Secretary of the Department of Health and Human Services within the meaning of section 721(b)(4) of the FD&C Act. Questions about color additives should be directed to the Division of Food Ingredients in OPMAS.

Section 301(ll) of the FD&C Act

Section 301(ll) of the FD&C Act prohibits the introduction or delivery for introduction into interstate commerce of any food that contains a drug approved under section 505 of the FD&C Act, a biological product licensed under section 351 of the Public Health Service Act, or a drug or a biological product for which substantial clinical investigations have been instituted and their existence made public, unless one of the exemptions in section 301(ll)(1)-(4) applies. In our evaluation of Shankar's notice concluding that sunflower lecithin is GRAS under its intended conditions of use, we did not consider whether section 301(ll) or any of its exemptions apply to foods containing sunflower lecithin. Accordingly, our response should not be construed to be a statement that foods containing sunflower lecithin, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll).

Conclusions

Based on the information that Shankar provided, as well as other information available to FDA, we have no questions at this time regarding Shankar's conclusion that sunflower lecithin is GRAS under its intended conditions of use. This letter is not an affirmation that sunflower lecithin is GRAS under 21 CFR 170.35. Unless noted above, our review did not address other provisions of the FD&C Act. Food ingredient manufacturers and food producers are responsible for ensuring that marketed products are safe and compliant with all applicable legal and regulatory requirements.

In accordance with 21 CFR 170.275(b)(2), the text of this letter responding to GRN 001267 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J. Carlson -S

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