



Mr. Donald F. Schmitt M.P.H.
ToxStrategies, Inc.
23501 Cinco Ranch Blvd.
Suite B226
Katy, TX 77494

Re: GRAS Notice No. GRN 001098

Dear Mr. Schmitt:

The Food and Drug Administration (FDA, we) completed our evaluation of GRN 001098. We received the notice that you submitted on behalf of Tate & Lyle, PLC (Tate & Lyle) on August 18, 2022 and filed it on December 7, 2022. Tate & Lyle submitted an amendment to the notice on April 5, 2023, providing clarifications on specifications, use levels, publications supporting safety, and allergenicity.

The subject of the notice is chickpea protein concentrate for use as a source of protein at a maximum level of 30% by weight in pasta, snack foods, and sugar-free, gluten-free, and high-fiber bakery products; at a maximum level of 50% by weight in extruded snacks and non-dairy nutritional drinks and shakes; at a maximum level of 90% by weight in dry-blend protein powders; at a maximum level of 60% by weight in meal replacement and nutritional bars; at a level of 13.3-53.3% by weight in plant-based protein products and meat alternatives; at a maximum level of 25% by weight in dairy alternatives (non-dairy milk, cheese, cream cheese, coffee creamer, frozen desserts, yogurt, and whipped topping); and at a maximum level of 10% by weight in vegetarian soups.¹ The notice informs us of Tate & Lyle's view that these uses of chickpea protein concentrate are GRAS through scientific procedures.

Tate & Lyle describes chickpea protein concentrate as a white powder obtained from the seeds (chickpeas) of *Cicer arietinum* and containing $\geq 60\%$ protein and smaller amounts of carbohydrates and fat.

Tate & Lyle describes the manufacturing process for chickpea protein concentrate that begins with dehulling commercially available raw chickpeas. The oil is removed from the dehulled chickpeas via extraction with ethanol. The defatted, dehulled chickpeas are then milled and dry-fractionated to obtain chickpea protein concentrate. Tate & Lyle states that chickpea protein concentrate is manufactured according to current good manufacturing practices using food-grade raw materials and processing aids.

Tate & Lyle provides specifications for chickpea protein concentrate that include protein

¹ Tate & Lyle states that chickpea protein concentrate is not intended for use in infant formula or any products under the jurisdiction of the United States Department of Agriculture.

(≥60%), moisture (<10%), gluten (<10 mg/kg), residual ethanol (<200 mg/kg), methanol (<50 mg/kg), lead and mercury (each <0.02 mg/kg), arsenic and cadmium (each <0.05 mg/kg), and limits for microorganisms. Tate & Lyle provides the results from the analyses of three non-consecutive batches to demonstrate that chickpea protein concentrate can be manufactured to meet these specifications. Tate & Lyle states that chickpea protein concentrate is stable for 2 years when stored in a closed container below 25 °C.

Tate & Lyle estimates the dietary exposure to chickpea protein concentrate from the intended uses using food consumption data from the 2015-2018 National Health and Nutrition Examination Survey. Tate & Lyle estimates the eaters-only dietary exposure to chickpea protein concentrate to be 24.5 g/person (p)/d (0.44 g/kg body weight (bw)/d) at the mean and 57.8 g/p/d (1.07 g/kg bw/d) at the 90th percentile for the U.S. population aged 1 year and older. To estimate the dietary exposure to protein, Tate & Lyle applies the typical protein content in chickpea protein concentrate of 60% to the dietary exposure estimates based on the intended uses of chickpea protein concentrate. For the U.S. population aged 1 year and older, the eaters-only dietary exposure to protein from the intended uses of chickpea protein concentrate is estimated to be 14.7 g/p/d (0.27 g/kg bw/d) at the mean and 34.7 g/p/d (0.64 g/kg bw/d) at the 90th percentile. Tate & Lyle states that the intended uses of chickpea protein concentrate will be substitutional for other plant-based protein ingredients and concludes that the cumulative dietary exposure to protein is not expected to increase with the use of chickpea protein concentrate.

Tate & Lyle reports that chickpea, the starting material for chickpea protein concentrate, is one of the oldest historically consumed legumes worldwide. Tate & Lyle discusses publicly available data and information sourced from a literature search on chickpea protein concentrate and summarizes the publications relevant to the safety of chickpea protein concentrate or whole chickpea-supplemented diets in animals and humans. Tate & Lyle notes the potential for anti-nutritional components in chickpea protein concentrate, including protease inhibitors, amylase inhibitors, phytolectins, and oligosaccharides, and concludes that anti-nutritional components found in chickpeas are reduced or eliminated during chickpea protein concentrate processing². Tate & Lyle discusses the safety of methanol and ethanol residues, and phytoestrogens in chickpea protein concentrate and concludes that dietary exposure to these constituents from the intended uses is negligible and do not present any safety concern for consumers. Additionally, Tate & Lyle notes that the angiotensin-converting enzyme (ACE)-inhibitory bioactive peptides found natively in chickpeas may be concentrated in chickpea protein concentrate, but dietary exposure from its intended uses is unlikely to pose a safety concern in the general population, including in individuals taking antihypertensive medications. Tate & Lyle discusses published reports of chickpea allergenicity and cross-reactivity with other allergens, including peanut. However, Tate & Lyle concludes the likelihood chickpea protein concentrate will elicit an allergic

² Tate & Lyle provides analytical results for the levels of lectin, phytic acid, raffinose, stachyose, verbascose, tannins, total polyphenols, and trypsin inhibitor activity in chickpea protein concentrate.

reaction is relatively rare and consistent with similar, known allergies to other legumes³. Tate & Lyle discusses the safety of protein consumption in general, and notes that dietary exposure to protein from chickpea protein concentrate under its intended conditions of use does not exceed the Institute of Medicine's Recommended Dietary Allowance for protein (0.8 g/kg bw/d).

Based on the available data and information, Tate & Lyle concludes that chickpea protein concentrate is GRAS for its intended uses.

Standards of Identity

In the notice, Tate & Lyle states its intention to use chickpea protein concentrate in several food categories, including foods for which standards of identity exist, located in Title 21 of the CFR. 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 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 chickpea protein concentrate 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 the Office of Nutrition and Food Labeling (ONFL) in the Center for Food Safety and Applied Nutrition. The Office of Food Additive Safety 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.

Section 301(ll) of the Federal Food, Drug, and Cosmetic Act (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 Tate & Lyle's notice concluding that chickpea protein concentrate 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 chickpea protein concentrate. Accordingly, our response should not be construed to be a

³ Chickpea is not one of the nine major allergens. Chickpea proteins are similar to those from other legumes. These include legumes considered clinically significant allergens in the United States (e.g., peanut). We are not aware of any clinically significant cross-reactivity events in peanut-allergic consumers in the United States that were attributed to exposure to chickpeas or chickpea proteins.

statement that foods containing chickpea protein concentrate, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll).

Conclusions

Based on the information that Tate & Lyle provided, as well as other information available to FDA, we have no questions at this time regarding Tate & Lyle's conclusion that chickpea protein concentrate is GRAS under its intended conditions of use. This letter is not an affirmation that chickpea protein concentrate 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 001098 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

**Susan J.
Carlson -S**

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JCarlson -S
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Susan J. Carlson, Ph.D.

Director

Division of Food Ingredients

Office of Food Additive Safety

Center for Food Safety

and Applied Nutrition