Madhu G. Soni, Ph.D.
Soni & Associates Inc.
749 46th Square
Vero Beach, FL 32968

Re: GRAS Notice No. GRN 000788

Dear Dr. Soni:

The Food and Drug Administration (FDA, we) completed our evaluation of GRN 000788. We received the notice that you submitted on behalf of Yantai Oriental Protein Tech Co., Ltd. (Yantai) on June 4, 2018, and filed it on July 6, 2018. Yantai submitted an amendment to the notice on August 6, 2018, containing data and information that were inadvertently omitted in Part 6 of the original submission.

The subject of the notice is pea protein concentrate for use as an ingredient, formulation aid, source of protein, stabilizer, thickener, and texturizer in conventional foods, such as baked goods and baking mixes, beverages and beverage bases, breakfast cereals, milk products, dairy product analogs, fats and oils, grain products and pastas, plant protein products, processed fruits and fruit juices, processed vegetables and vegetable juices, and soups and soup mixes[1] at levels from 0.96 to 34.3%.[2] The notice informs us of Yantai's view that these uses of pea protein concentrate are GRAS through scientific procedures.

Yantai provides information about the identity and composition of pea protein concentrate, which they describe as a light cream-colored powder isolated from yellow peas (*Pisum sativum* L). Pea protein concentrate contains protein (≥80%), total fat (≤10%), carbohydrates (≤3%), ash (≤8%), and moisture (≤10%).

Yantai describes the method of manufacture for pea protein concentrate. Yantai states that raw yellow peas are cleaned, dehulled, and ground to a powder. The ground pea powder is mixed with water, homogenized, and subjected to protein precipitation with food-grade base and acid. The mixture is then centrifuged to separate the protein and starch fractions. The protein fraction is concentrated by additional centrifugation, followed by spray drying and packaging.

Yantai provides specifications for pea protein concentrate, including limits for lead (<0.1

[1] Yantai states that pea protein concentrate is not intended for use in products under the U.S. Department of Agriculture's jurisdiction.

[2] In the notice, Yantai states its intent to market pea protein as a directly consumed supplement, where consumers prepare their own beverages. FDA notes that this use may be under the purview of the Office of Dietary Supplement Programs in the Center for Food Safety and Applied Nutrition (CFSAN).

mg/kg), arsenic (<0.1 mg/kg), cadmium (<0.3 mg/kg), aflatoxin (<5 µg/kg), and specified limits for microorganisms. Yantai provides the results of five non-consecutive batch analyses to demonstrate that pea protein concentrate can be manufactured to meet the specifications.

Yantai discusses the estimated dietary exposure to pea protein concentrate and states that they use the same estimates as those presented in GRN 000608.[3] Using food consumption data from the National Health and Nutrition Examination Surveys (2011-2012) and the estimates from GRN 000608, Yantai presents the mean and 90th percentile dietary exposures for the U.S. population (users-only) to be 10.3 g/person (p)/day (d) (181 mg/kg body weight (bw)/d) and 17.3 g/p/d (388 mg/kg bw/d), respectively. The mean and 90th percentile background dietary intake of protein from the consumption of peas is 20.9 and 41.7 g/p/d, respectively. Yantai states that the use levels are self-limiting because of the bitter taste that develops when use levels are too high.

Yantai discusses the safety of pea protein concentrate and states that a literature search was conducted through February 2018. Yantai discusses published studies on pea protein metabolism demonstrating that pea protein is thoroughly digested and well absorbed in humans. In a published, subchronic feeding study of pea protein isolate, no treatment-related adverse effects were observed. Citing published studies, Yantai concludes that pea protein concentrate is not mutagenic or genotoxic. Yantai states that allergenicity to pea along with cross-reactivity to other allergens has been reported, though these reactions are rare, and pea protein concentrate is not produced from the eight major food allergens under the United States Food Allergen Labelling and Consumer Protection Act of 2004.

Yantai includes the statement of a panel of individuals (Yantai's GRAS panel). Based on its review, Yantai's GRAS panel concluded that pea protein concentrate is safe under the conditions of its intended use.

Based on the totality of evidence, Yantai concludes that pea protein concentrate is GRAS for its intended use.

Standards of Identity

In the notice, Yantai states its intention to use pea protein concentrate 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.

[3] Pea protein concentrate was the subject of GRN 000608. We evaluated this notice and responded in a letter dated May 27, 2016, stating that we had no questions at that time regarding Axiom Foods, Inc. and SPRIM Strategy and Intelligent Innovation's GRAS conclusion.

Potential Labeling Issues

Under section 403(a) of the Federal Food Drug & Cosmetic (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). The notice raises a potential issue under these labeling provisions. Yantai describes pea protein concentrate as having certain health benefits. If products containing pea 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 CFSAN. 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 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 Yantai's notice concluding that pea 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 pea protein concentrate. Accordingly, our response should not be construed to be a statement that foods containing pea protein concentrate, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll).

Conclusions

Based on the information that Yantai provided, as well as other information available to FDA, we have no questions at this time regarding Yantai's conclusion that pea protein concentrate is GRAS under its intended conditions of use. This letter is not an affirmation that pea 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 000788 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Michael A. Adams -S

Digitally signed by Michael A. Adams -S
Date: 2018.10.12 16:45:16 -04'00'

Dennis M. Keefe, Ph.D.
Director
Office of Food Additive Safety
Center for Food Safety
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