Evangelia C. Pelonis
Keller and Heckman LLP
1001 G Street, NW
Suite 500W
Washington, DC 20005

Re: GRAS Notice No. GRN 000803

Dear Ms. Pelonis:

This letter corrects our letter signed October 15, 2019, sent in response to GRN 000803. The purpose of this revised letter is to correct a statement in the letter regarding the use of pH adjustment agents in the method of manufacture discussion.

The Food and Drug Administration (FDA, we) completed our evaluation of GRN 000803. We received the notice that you submitted on behalf of Ingredion Incorporated and Shandong Jianyuan Bioengineering Company Limited's (Ingredion and Shandong; the notifier) on July 17, 2018, and filed it on August 6, 2018. Ingredion and Shandong submitted an amendment to the notice on March 15, 2019, regarding a minor change in the method of manufacturing originally described in the notice.

The subject of the notice is pea protein for use as a source of protein, formulation aid, stabilizer/thickener, and texturizer in various foods, including meat and poultry products, at levels that will not increase the consumer's overall exposure to protein.[1] The notice informs us of Ingredion and Shandong's view that this use of pea protein is GRAS through scientific procedures.

Our use of the term "pea protein" in this letter is not our recommendation of that 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 nonstandardized 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 Center for Food Safety and Applied Nutrition. The Office of Food Additive Safety (OFAS) did not consult with ONFL regarding the appropriate common or usual name for "pea protein."

Ingredion and Shandong provide information about the identity and composition of the pea protein. Ingredion and Shandong describe pea protein as a light cream to off-white

[1] Ingredion and Shandong state that pea protein is not intended for use in infant formula.

colored powder derived from *Pisum sativum* L. seed pods (peas).

Ingredion and Shandong describe the manufacturing process of the pea protein as follows. Upon receipt, peas are first screened for foreign material and then soaked in water. The soaked peas are then crushed, and the crushed material is pumped into centrifuge decanters. The pea fiber and pea starch are removed, and the remaining protein curd is pumped into a neutralization tank for further processing. The pH is then adjusted to 7.0 - 8.0 using safe and suitable pH adjusting agents. Following neutralization, the protein curd is pumped into automatic high temperature steam sterilizing equipment for sterilization. After sterilization, the protein curd is spray dried and packaged.

Ingredion and Shandong have established food-grade specifications for pea protein: protein (dry basis) ≥80.0%, moisture ≤8.0%, ash ≤6.0%, pH 7-8, particle size ≤95% through U.S.S. #80 screen, arsenic ≤0.2 mg/kg, cadmium ≤0.2 mg/kg, lead ≤0.5 mg/kg, mercury ≤0.2 mg/kg, and limits for microorganisms. To demonstrate the ability to manufacture the pea protein to conform with the food-grade specifications, Ingredion and Shandong provided analyses from three non-consecutive lots of pea protein.

Ingredion and Shandong state that pea protein is used as a substitute for, or in conjunction with, other proteins in conventional food products; and, that therefore, the pea protein will not contribute any additional exposure to protein for consumers. Shandong and Ingredion note that the use of pea protein is self-limiting due to the cost of the ingredient and an unpleasant taste at high use levels. The notifier does not expect that the actual consumption of foods containing pea protein products would result in a daily consumption of greater than the Daily Reference Value of 50 g/day for protein for adults and children 4 or more years of age, which is the Institute of Medicine's Reference Daily Amount, or the average daily intake for protein.

Ingredion and Shandong discuss published studies on pea protein metabolism demonstrating that pea protein is thoroughly digested and well absorbed in humans. In a published subchronic feeding study using pea protein, Ingredion and Shandang note that no treatment-related adverse effects were observed. Citing published studies, Ingredion and Shandong conclude that pea protein is not mutagenic or genotoxic. Ingredion and Shandong note that allergenicity to pea has been reported along with cross-reactivity among lentil, chick-pea, pea, and peanut. However, Ingredion and Shandong further note that allergy to pea protein is rare and pea is not one of the eight major allergenic foods.

Based on the totality of evidence, Ingredion and Shandong conclude that pea protein is GRAS for its intended use.

Standards of Identity

In the notice, Ingredion and Shandong state its intention to use pea protein 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.

Use in Products under USDA Jurisdiction

As provided under 21 CFR 170.270, during our evaluation of GRN 000803, we coordinated with the Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture. Under the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act, FSIS determines the efficacy and suitability of ingredients used in meat, poultry, and egg products, and prescribes safe conditions of use. Suitability relates to the ingredient's effectiveness in performing its intended technical effect and the assurance that the ingredient's use will not result in products that are adulterated or misleading for consumers.

FSIS has advised the following with respect to the statutes it administers: FSIS has completed its review and has no objection to the use of pea protein in meat and poultry products. USDA-regulated products are required to label the ingredient as "pea protein isolate" in the ingredients statement.

FSIS requested that we advise you to seek regulatory guidance from its Risk, Innovations, and Management Staff (RIMS) about the use of pea protein in meat, poultry, and egg products. You should direct such an inquiry to Dr. Melvin Carter, Director, RIMS, Office of Policy and Program Development, FSIS by email at Melvin.Carter@fsis.usda.gov.

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 Ingredion and Shandong's notice concluding that pea protein 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. Accordingly, our response should not be construed to be a statement that foods containing pea protein, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll).

Conclusions

Based on the information that Ingredion and Shandong provided, as well as other information available to FDA, we have no questions at this time regarding Ingredion and Shandong's conclusion that pea protein is GRAS under its intended conditions of use. This letter is not an affirmation that pea protein 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 000803 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J. Carlson -S

Digitally signed by Susan J. Carlson -S
Date: 2019.11.08 15:35:05 -05'00'

Susan Carlson, Ph.D.
Director
Division of Food Ingredients
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition

cc: Melvin Carter, Ph.D.
Director
USDA/FSIS/OPPD/RIMS
Stop Code 3782, Patriots Plaza III
1400 Independence Ave. SW
Washington, DC 20250-3700