Marc C. Sanchez, Esq.
Contract In-house Counsel
Burcon NutraScience Corporation
1717 Pennsylvania Avenue #1025
Washington, D.C. 20006

Re: GRAS Notice No. GRN 000804

Dear Mr. Sanchez:

This letter corrects our letter signed October 15, 2019, sent in response to GRN 000804. The purpose of this revised letter is to correct typographical errors in the description of the method of manufacture, where "≥65%" and "≥85%" were inadvertently transposed in the first and second paragraph on the second page of the original response letter.

The Food and Drug Administration (FDA, we) completed our evaluation of GRN 000804. We received the notice that you submitted on behalf of Burcon NutraScience Corporation (Burcon) on June 18, 2018, and filed it on August 31, 2018. Burcon submitted amendments to the notice on November 11, 2018, and February 4, 2019, that clarified analytical data, and provided more specificity regarding safety information that was incorporated by reference, respectively.

The subject of the notice is pea protein for use as a source of protein in baked goods and baking mixes; beverages and beverage bases; breakfast cereals; cheeses; coffee and tea; confections and frostings; dairy product analogs; egg products; fats and oils; fish products; frozen dairy desserts; fruit and water ices; gelatins, puddings and fillings; grain products and pastas; gravies and sauces; milk products; nut and nut products; plant protein products; processed fruits and fruit juices; processed vegetables and vegetable juices; snack foods; soft candy; and soups and soup mixes at levels ranging from 1-35 g/100g of food as consumed.[1] The notice informs us of Burcon'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

[1] Burcon states that the intended use of pea protein excludes foods under the U.S. Department of Agriculture's jurisdiction.

consult with ONFL regarding the appropriate common or usual name for "pea protein."

Burcon provides information about the identity and composition of pea protein. Burcon notes that the pea protein products are two powders that are formulated to contain either ≥85% protein or ≥65% protein. The product containing ≥85% protein is an off-white to slightly yellow powder that is bland and has a very low or no pea flavor, while the product containing ≥65% protein is a yellow-beige powder that has a mild pea flavor. Both formulations may also contain small amounts of moisture, fat, fiber, and ash.

Burcon describes the manufacturing process for pea protein. The first step of the process is an aqueous extraction of a pea flour source material. The extraction slurry is passed through a decanter centrifuge to remove solids. The liquid extract is acidified by the addition of a food grade acid to solubilize the proteins in the extract. The acidified extract is then passed through a disc stack centrifuge to remove insoluble protein and other residual solids material. These solids are washed, re-collected, pasteurized and then spray dried. The resulting powder is a ≥65% pea protein concentrate.

To produce the ≥85% protein product, the liquid fraction from the first disc stack separation step is collected and may be further acidified and further clarified before being concentrated and diafiltered on an ultrafiltration system. The retentate from the concentration step is pasteurized and then spray dried to produce the final product.

Burcon notes that calcium chloride may be used in place of acidification to induce the protein split. Burcon also states that food grade enzymes[2] may be used in the process either prior to the pasteurization steps in each product line or prior to the acidification step to reduce viscosity and increase solubility of the proteins according to customer requirements.

Burcon provides specifications for both products that include a minimum content of protein ≥85% and ≥65%, respectively. Specifications also include fiber (≤1% or ≤2% for the ≥85% or ≥65% pea protein product, respectively), fat (≤1% or ≤6% for the ≥85% or ≥65% pea protein product, respectively), moisture (≤8% for both products), ash (≤12% for both products), lead (≤0.2 mg/kg for both products), arsenic (≤0.1 mg/kg for both products), cadmium (≤0.2 mg/kg for both products), mercury (≤0.1 mg/kg for both products), and limits for microorganisms. Burcon provides the results of nonconsecutive batch analyses for the ≥85% pea protein product (five batches) and for the ≥65% pea protein product (three batches) to demonstrate that both products can be manufactured to meet the specifications.

Burcon estimates the dietary exposure to protein from pea protein based on the intended food uses and use levels in conjunction with food consumption data included in the 2013-2014 National Health and Nutrition Examination Survey (NHANES). Burcon estimates that the resulting dietary exposure to protein from the intended use of

[2] Burcon notes that these optional enzymes are used in accordance with a regulation or are GRAS for this use.

pea protein by the U.S. population (all ages) from all intended food uses is 28.42 g/person/day (0.47 g/kg body weight/day) at the mean and 51.62 g/person/day (0.97 g/kg body weight/day) at the 90th percentile.

Burcon incorporates the safety information into GRN 000804 from GRN 000608 and GRN 000581,[3] and states that it concurs with the safety conclusions of both GRN 000608 and GRN 000581 and that the intended use of the pea protein is GRAS. Burcon also conducted a literature search through June 2018 with regard to any new information. Burcon did not find any new information that would contradict its GRAS conclusion.

Based on the information presented in the notice, Burcon concludes that pea protein is GRAS for its intended use in food.

Standards of Identity

In the notice, Burcon states it 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 standardized food only if it is permitted by the applicable food standard.

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 Burcon'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 Burcon provided, as well as other information available to FDA, we have no questions at this time regarding Burcon'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

[3] Pea protein concentrate was the subject of GRN 000608; un-hydrolyzed and hydrolyzed pea protein was the subject of GRN 000581. We evaluated these notices and responded in letters dated May 27, 2016, and March 20, 2016, respectively, stating that we had no questions at that time regarding the notifiers' GRAS conclusions.

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 000804 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 15:38:36 -05'00'

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