



Evangelia C. Pelonis  
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Washington DC 20005

Re: GRAS Notice No. GRN 000851

Dear Ms. Pelonis:

The Food and Drug Administration (FDA, we) completed our evaluation of GRN 000851. We received the notice you submitted on behalf of Roquette Freres (Roquette) on March 15, 2019, and filed it on June 10, 2019. Roquette submitted an amendment to the notice on December 11, 2019, that clarified the use of the enzymes in the manufacturing process, provided additional information on the peptide size distribution, described the differences in the functional properties of pea protein isolate, provided a revised table including all proposed food categories and use levels, provided an updated literature search, and clarified toxicological findings.

The subject of the notice is pea protein isolate for use as a source of protein in food categories at levels specified in Table 1, and as a binder and extender in meat and poultry applications at levels up to 3% of the total formulation, where the standard of identity permits such use.<sup>1</sup> The notice informs us of Roquette's view that this use of pea protein isolate is GRAS through scientific procedures.

Table 1. Food categories and intended maximum use levels of pea protein isolate.

<b>Food category</b>	<b>Use level %</b>
Bakery products: breads, rolls, bars, cakes, pasta, cookies	5-10
Cereals: cold cereals, oatmeal, cereal bars	1-30
Snack foods: chips, crackers, energy bars	2-30
Ready-to-drink beverages, soups, smoothies, fruit juices, high protein beverages	3-50
Dairy and dairy alternatives: cheeses, spreads, creamers, yogurt, drinkable yogurts, ice cream, refrigerated desserts, frozen desserts, milks, dips, whipped toppings	2-20
Meal replacement and nutritional bars	10-30

<sup>1</sup> Pea protein isolate is not intended for use in infant formula.

Meat analogs	10-30
Dry blend protein powders	20-90
Extruded products: pea crisps	30-90
Chocolate and confection compound coatings	10-25
Non-chocolate confection (chewy candies, gummies)	2-30

Our use of the term “pea protein isolate” 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 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 did not consult with ONFL regarding the appropriate common or usual name for “pea protein isolate.”

Roquette provides information about the identity and composition of pea protein isolate. Pea protein isolate is a beige powder extracted from dried yellow peas (*Pisum sativum* L.) and is composed of protein (> 80%), fat (9%), moisture (7%), fiber (1%), and other (salts, minerals, 3%). Roquette states that there are also lesser amounts of lectins, protease inhibitors and lipoxygenases. Roquette provides a comparison of the amino acids in peas and in their pea protein isolate.

Roquette describes the method of manufacture for pea protein isolate, which starts with a flour made by cleaning and grinding the dried yellow peas. The pea flour is reconstituted with water, and the pea starch and fiber are then removed. The remaining material is subjected to isoelectric precipitation and the soluble proteins are removed. The resulting product is then coagulated, purified, and buffered to a neutral pH. Roquette states that the resulting product is subjected to thermal heat treatment to prevent microbial growth. Food grade enzymes are then used to hydrolyze the peptide bonds releasing lower molecular weight peptides. These enzymes are inactivated using a thermal heat treatment, and the resulting product is spray dried to produce the final pea protein isolate powder. Roquette notes that there are three different pea protein isolate products that differ in their particle size and flocculation temperature, which allows for a range of applications.

Roquette provides specifications for the three pea protein isolate products that include loss on drying (<10%), protein content (dry basis) (> 84%), particle size of 200 µm (<10%), poured bulk density (0.35-0.50 kg/L for two of the products and not defined for the third product), pH (6.5-8.0), solubility (50%, 55%, or not defined, depending on the product), lead (< 0.2 mg/kg), arsenic (< 0.2 mg/kg), cadmium (< 0.2 mg/kg), mercury (< 0.2 mg/kg), mycotoxins (< 20 mg/kg Ochratoxin A), and limits on microorganisms. Roquette provides the results of 3 non-consecutive batch analyses of each different pea protein isolate product to demonstrate that the products can be manufactured to meet the stated specifications.

Roquette states that pea protein isolate will be added to food products as a protein substitute and therefore, will not contribute any additional exposure to protein for consumers. Further, Roquette describes that the consumption of foods containing pea protein isolate would not result in a daily consumption that is greater than the Daily Reference Value (DRV) of 50 grams/person/day (g/p/d) of protein for adults and children 4 years and older. Roquette also discusses the background dietary exposure of protein for the U.S. population using food consumption data from the 1994-1996 Continuing Survey of Food Intakes by Individuals and 1998 Supplemental Children's Survey (CSFII 1994-1996, 1998). The mean dietary exposure of protein for the U.S. population ranged from 56 to 104 g/p/d, depending on the age group. Roquette noted that the Institute of Medicine (IOM) had established a Dietary Reference Intake (DRI) for protein of 56 g/d for adult males and 46 g/d for adult females. Roquette states that they do not expect the exposure to pea protein isolate from the notified uses would result in an exposure that would be greater than the DRV or DRI for protein.

Roquette states that peas, *P. sativum*, both yellow and green varieties, have a long history of safe use as food in virtually all countries of the world, and Roquette notes that uses of a variety of pea derived substances have been the subject of GRNs 000182, 000525, 000608, and 000788.<sup>2</sup>

Roquette notes that peas contain anti-nutrient factors (ANFs), including protease inhibitors, lectins, tannins, saponins, phytic acid (phytates) and  $\alpha$ -galactosides. The ANFs can reduce the nutritive value of peas by reducing the digestibility of the protein and binding other essential nutrients, thereby making them less bioavailable. Roquette presents data showing the reduction of ANFs in its pea protein isolate resulting from both the selection of cultivars lowest in anti-nutrients, and by production processes that reduce ANFs.

Roquette discusses a published 90-day study in rats where no toxicologically relevant effects were observed, and the highest level of pea protein isolate consumed was 100,000 ppm (8,726 mg/kg bw/d for males and 9,965 mg/kg bw/d for females). Roquette also notes that pea protein isolate was non-mutagenic and non-genotoxic at the conditions employed in the Ames test, *in vitro* chromosomal aberration test, and *in vivo* micronucleus test.

Roquette discusses the potential allergenicity of pea proteins. Roquette states that pea is not a major source of food allergy and is not one of the eight major food allergens. The available data suggests that a small fraction (~1%) of consumers with a food allergy may have pea allergies, but in the general population pea allergies are expected to be rare.

Based on the totality of evidence, Roquette concludes that pea protein isolate is GRAS

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<sup>2</sup> Hydrolyzed wheat gluten and pea protein isolate were the subject of GRN 000182; pea fiber was the subject of GRN 000525; pea protein concentrate was the subject of GRN 000608; and pea protein concentrate was the subject of GRN 000788. We evaluated these notices and responded in letters dated June 27, 2006, June 30, 2014, May 27, 2016, and October 12, 2018, respectively, stating that we had no questions at that time regarding the notifiers' GRAS conclusion.

for its intended use.

### **Standards of Identity**

In the notice, Roquette states its intention to use pea protein isolate 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 000851, 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 completed its review in accordance with the procedures outlined in the Memorandum of Understanding between FDA and FSIS to provide restrictions, conditions of use, or prohibitions that FSIS may have regarding the use of the substance. FSIS has advised the following with respect to the statutes it administers: FSIS has no objection to the use of pea protein isolate for use as a binder and extender in meat and poultry products at a use level up to 3% of the total formulation, where the standard of identity permits such use. 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](mailto: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 Roquette's notice concluding that pea protein isolate 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 isolate. Accordingly, our response should not be construed to be a statement that foods

containing pea protein isolate, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll).

## **Conclusions**

Based on the information that Roquette provided, as well as other information available to FDA, we have no questions at this time regarding Roquette's conclusion that pea protein isolate is GRAS under its intended conditions of use. This letter is not an affirmation that pea protein isolate 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 000851 is accessible to the public at [www.fda.gov/grasnoticeinventory](http://www.fda.gov/grasnoticeinventory).

Sincerely,

**Susan J.  
Carlson -S**

Susan Carlson, Ph.D.

Director

Division of Food Ingredients

Office of Food Additive Safety

Center for Food Safety

and Applied Nutrition

 Digitally signed by Susan J.  
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