



Madhu G. Soni, PhD, FACN, FATS
Soni and Associates Incorporated
749 46th Square
Vero Beach FL, 32968

Re: GRAS Notice No. GRN 000948

Dear Dr. Soni:

The Food and Drug Administration (FDA, we) completed our evaluation of GRN 000948. We received the notice that you submitted on behalf of Yantai Oriental Protein Tech Co., Ltd. (Yantai) on June 2, 2020 and filed it on November 5, 2020. Yantai submitted amendments to the notice on February 15, 2021 and March 4, 2021 that provided clarifications on the identity, manufacturing process, intended use, analytical methods, and allergenicity.

The subject of the notice is enzyme-treated pea protein for use as an ingredient, formulation aid, nutrient supplement, stabilizer and thickener, and texturizer in breads, rolls, bagels, and English muffins; non-milk based meal replacements; ready-to-eat breakfast cereals; soy/imitation milk; margarine and salad dressings; grain-based bars containing fruits and vegetables; flavored milk drinks, milk-based meal replacements, and yogurt; meat alternatives; processed fruits and fruit juices; processed vegetables and vegetable juices; and soups and soup mixes at levels from 0.96 to 34.3%.¹ The notice informs us of Yantai's view that these uses of enzyme-treated pea protein are GRAS through scientific procedures.

Our use of the term, "enzyme-treated 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 did not consult with ONFL regarding the appropriate common or usual name for "enzyme-treated pea protein."

¹ Yantai states that enzyme-treated pea protein is not intended to be used in infant formula or in products that are under the jurisdiction of the United States Department of Agriculture.

Yantai describes enzyme-treated pea protein as a light cream-colored powder isolated from yellow peas (*Pisum sativum* L) that is comprised of protein ($\geq 80\%$), fat ($\leq 10\%$), ash ($\leq 8\%$), and moisture ($\leq 10\%$). Yantai states that the molecular weight of the enzyme-treated pea protein ranges from 1,000 to 20,000 Daltons with the majority of the protein over 5,000 Daltons.

Yantai describes the manufacturing process for enzyme-treated pea protein, which starts with dry yellow peas. The peas are cleaned, dehulled, and ground to a powder. The ground peas are mixed with water, homogenized, and the protein precipitated using food-grade base and acid. The mixture is separated into the protein and starch fractions, and the protein fraction is centrifuged, and food grade enzymes added to break the protein aggregation. Finally, the resulting enzyme-treated protein is isolated via filtration or centrifugation and then subjected to flash evaporation and spray drying. Yantai states that enzyme-treated pea protein is manufactured in accordance with current good manufacturing practices.

Yantai provides specifications for enzyme-treated pea protein that include protein (dry basis) ($\geq 80\%$), fat ($\leq 10\%$), fiber ($\leq 0.5\%$), ash ($\leq 8\%$), moisture ($\leq 10\%$), lead (< 0.1 mg/kg), arsenic (< 0.1 mg/kg), cadmium (< 0.3 mg/kg), mercury (< 0.02 mg/kg), aflatoxin B1 (< 5 $\mu\text{g}/\text{kg}$), and limits for microorganisms. Yantai provides the analyses of five non-consecutive batches to demonstrate that enzyme-treated pea protein can be manufactured to meet the specifications.

Yantai states that enzyme-treated pea protein is intended to be used in the same food categories and at the same use levels as those in GRNs 000608 and 000788². Therefore, the intended use is substitutional for those in GRNs 000608 and 000788, and the dietary exposure to enzyme-treated pea protein would be the same as that presented in those notices; the mean and 90th percentile eaters-only dietary exposures for the U.S. population were estimated to be 10.3 g/person (p)/d (181 mg/kg body weight (bw)/d) and 17.3 g/p/d (388 mg/kg bw/d), respectively, based on food consumption data from the 2011-2012 National Health and Examination Survey. Yantai states that enzyme-treated pea protein will be used as a substitute for, or in conjunction with, soy protein and whey protein in conventional foods and therefore, there will be no additional exposure to protein for consumers.

Yantai states that the safety discussions of the pea protein in GRNs 000608 and 000788 also applies to that of the enzyme treated pea protein. Yantai establishes the safety of consumption of pea protein by discussing the long history of use of pea, amino acid composition of pea proteins including essential amino acids, metabolism of pea proteins, 90-day toxicity study in rats, mutagenicity and genotoxicity studies, as well as several human tolerance studies. Yantai states that allergenicity to pea has been reported along with cross-reactivity among lentil, chick-pea, pea and peanut. However,

² Pea protein concentrate was the subject of GRNs 000608 and 000788. We evaluated these notices and responded in letters dated May 27, 2016 and October 12, 2018 respectively, stating that we had no questions at that time regarding the notifiers' GRAS conclusions.

allergy to pea protein is rare and pea is not a major food allergen.

Yantai provided an updated literature search for safety and toxicity information on pea and its protein through March 2020 and did not identify any information that raises safety concerns.

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

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

Standards of Identity

In the notice, Yantai states its intention to use enzyme-treated 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.

Potential Labeling Issues

Under section 403(a) of the Federal Food, Drug, and Cosmetic Act (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 enzyme-treated pea protein 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 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(II) of the FD&C Act

Section 301(II) 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(II)(1)-(4) applies. In our evaluation of Yantai's notice concluding that enzyme-treated pea protein is GRAS under its intended conditions of use, we did not consider whether section 301(II) or any of its exemptions apply to foods containing enzyme-treated pea protein. Accordingly, our response should not be construed to be a statement that foods containing enzyme-treated pea protein, 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 enzyme-treated pea protein is GRAS under its intended conditions of use. This letter is not an affirmation that enzyme-treated 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 000948 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J.
Carlson -S

 Digitally signed by Susan J.
Carlson -S
Date: 2021.09.09 17:38:25
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Susan Carlson, Ph.D.
Director
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