U.S. FOOD & DRUG ADMINISTRATION

September 25, 2026

Splitrock Regulatory Solutions, LLC
Attention: James La Marta, Ph.D.
Principal Consultant
107 Decker Road
Boonton, NJ 07005

Re: Animal Food Ingredient Consultation 0004 – Pea Solubles

Dear Dr. La Marta:

The Division of Animal Food Ingredients in the Food and Drug Administration's (FDA) Center for Veterinary Medicine (CVM) received a request, dated July 22, 2025, submitted on behalf of your client, Louis Dreyfus Company Plant Proteins, LLC (the firm) in which the firm requested the submission be reviewed under the Animal Food Ingredient Consultation (AFIC) process. On August 7, 2025, CVM requested additional information on the proposed ingredient name and definition; the information was received on August 14, 2025. The request was designated as AFIC 0004 and added to the AFIC Inventory on August 27, 2025.

All issues associated with the consultation of this animal food ingredient have been adequately addressed.

Chemistry, Manufacturing, and Controls

To address the identity, method of manufacture, and specifications of the proposed ingredient, CVM considered the raw materials used in the manufacture, the manufacturing process and controls, analytical methods, and analysis results including composition, and potential impurities and contaminants. The analysis results from multiple batches were provided to demonstrate consistency in composition, and control of undesirable microorganisms, heavy metals, pesticides, mycotoxins, and antinutritional factors. Provided stability data from multiple batches also demonstrate that microbial contents are within established specifications throughout the proposed shelf-life under recommended storage conditions.

Intended Use

The intended use of Pea solubles is in food for animals as a pelleting aid or binder when incorporated in canola meal prior to pelleting at up to 2%. To address the intended use, CVM considered two pelleting studies, one study investigating technical effectiveness at three inclusion levels of Pea solubles and the second study investigating technical effectiveness of one inclusion level under conditions representative of commercial production. The pelleting studies demonstrated an acceptable intended use via the analysis of pellet durability index and

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pellet hardness of canola meal treated with the proposed ingredient versus a negative control. In the two technical utility studies, reproducibility of the pelleting effectiveness was demonstrated by the use of one batch each of canola meal and Pea solubles.

Target Animal Safety

To address target animal safety, CVM considered information relative to a safety assessment of potential impurities and contaminants and data and information from feeding studies conducted in cattle, swine, and poultry. The firm also addressed the regulatory status of the Pea solubles or similar ingredients in the United States and other regions, and the antinutritional content in the Pea solubles compared to other types of ingredients commonly used in animal diets. Although aqueous fractions tend to concentrate residues/contaminants during processing (e.g., alkaloids, heavy metals), exposure assessment of the ingredient indicates that heavy metals, mycotoxins, pesticides, dioxins, and microbial hazards do not represent a target animal safety concern when added as a pelleting aid or binder in canola meal pellets for use in animal food at no more than 3% on an as is basis.

Studies available in the literature showed that cattle had no adverse effects when fed diets containing up to 40%, and swine and poultry had no adverse effects when fed diets containing 18 to 20% pea-derived ingredients. Overall, the information included by the firm supports the target animal safety of the maximum intended use level of Pea solubles of 3% on an as is basis as a pelleting aid or binder in canola meal pellets.

Human Food Safety

The firm did not submit human food safety information in the AFIC request. However, the components of Pea solubles are not expected to accumulate in edible tissues of target species. Anti-nutritional factors are water-soluble and metabolized rather than stored in animal tissues. Therefore, no human food safety concerns are expected due to the maximum intended use level of Pea solubles of 3% on an as is basis as a pelleting aid or binder in canola meal pellets for use in animal food.

This letter concludes Louis Dreyfus Company Plant Proteins, LLC's consultation with the FDA regarding Pea solubles. The ingredient and its use in animal food are defined as follows:

> **Pea Solubles** is a concentrated fluid by-product from the production of pea protein (for human consumption) from sound, cleaned, dehulled, and dry milled field peas (Pisum sativum). It must contain not more than 62% moisture, not less than 15% crude protein, not more than 4% fat, not more than 2% crude fiber, and not more than 15% ash on dry matter basis. It is to be directly added in the canola meal pelleting process for use as a pelleting aid or binder at no more than 2% on an as is basis.

At this time, we have no questions or concerns about the safety of this ingredient when used in accordance with the conditions of intended use described in this letter. FDA generally does not anticipate initiating enforcement action with respect to the food additive approval requirements of the Federal Food, Drug and Cosmetic Act for this ingredient or animal food containing this ingredient as long as there continues to be no questions or concerns about the safety of this ingredient. However, it is Louis Dreyfus Company Plant Proteins, LLC.'s continuing responsibility to ensure that foods marketed by the firm are safe, wholesome, and otherwise in compliance with all applicable legal and regulatory requirements. A copy of this letter will be made available to the public at Current Animal Food Ingredient Consultation Inventory | FDA.

If you have any questions or comments regarding this letter, please contact Ms. Wasima Wahid at animalfood-premarket@fda.hhs.gov.

Sincerely,

DAVID B. EDWARDS -S
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David Edwards, Ph.D.
Director, Division of Animal Food Ingredients
Office of Surveillance and Compliance
Center for Veterinary Medicine