



Joseph V Rodricks, Ph.D., DABT
Ramboll
4350 North Fairfax Drive
Suite 300
Arlington, VA 22203

Re: GRAS Notice No. GRN 000930

Dear Dr. Rodricks:

The Food and Drug Administration (FDA, we) is granting the request on behalf of Cambridge Crops, Inc. (Cambridge Crops) to cease our evaluation of GRN 000930, which we filed on July 7, 2020. We received this request on March 22, 2021.

The subject of the notice is silk fibroin derived from *Bombyx mori* cocoons (silk fibroin) for use as a coating to preserve fruits, vegetables, fish, cheeses, and candy at levels up to 880 mg silk fibroin per kg of food. The notice informs FDA of Cambridge Crops' view that this use of silk fibroin is GRAS through scientific procedures.

In teleconferences on September 15, 2020, October 29, 2020, November 13, 2020, and February 16, 2021, we summarized the deficiencies we identified in GRN 000930, recommended that Cambridge Crops request that we cease to evaluate the notice, and advised Cambridge Crops to later submit a new notice based on our recommendations. In the teleconference on September 15, 2020, we informed Cambridge Crops of our concerns regarding the approach used to estimate dietary exposure, questions about the regulatory status of substances used in the manufacturing process, issues with variability in the batch analyses for heavy metals, lack of publication of key toxicology studies, and the need for additional bioinformatics and digestibility studies. In the teleconference on October 29, 2020, we emphasized to Cambridge Crops that safety data need to be published in a peer-reviewed journal, and that some substances used to manufacture silk fibroin may not be suitable for that use and therefore raised concerns about the manufacturing process. In the teleconference on November 13, 2020, Cambridge Crops summarized how an amendment could address our concerns about the manufacturing process, estimation of dietary exposure, and publication of toxicology studies. Cambridge Crops submitted an amendment on November 18, 2020.

U.S. Food and Drug Administration
Center for Food Safety & Applied Nutrition
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College Park, MD 20740
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In the teleconference on February 16, 2021, we informed Cambridge Crops that the amendment had not adequately addressed our concerns. FDA emphasized that GRN 000930 did not meet the requirement that a GRAS conclusion be based on safety data which are generally available and generally accepted by the scientific community. In an email dated March 22, 2021, Cambridge Crops requested that we cease our evaluation of the notice.

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 000930 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J.
Carlson -S

Digitally signed by Susan
J. Carlson -S
Date: 2021.05.25
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Susan Carlson, Ph.D.
Director
Division of Food Ingredients
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and Applied Nutrition