



Donald F. Schmitt, MPH
ToxStrategies, Inc.
931 W. 75th Street
Suite 137, PMB 255
Naperville, IL 60565

Re: GRAS Notice No. GRN 000962

Dear Mr. Schmitt:

The Food and Drug Administration (FDA, we) is granting the request that you submitted on behalf of McCain Foods Ltd. (McCain Foods) to cease our evaluation of GRN 000962, which we filed on January 11, 2021. We received this request on November 24, 2021.

The subject of the notice is rice bran wax for use in oils at levels up to 0.15% to improve heat transfer and stability for frying select potato products. The notice informs us of McCain Foods' view that these uses of rice bran wax are GRAS through scientific procedures.

On July 6, 2021, we sent a list of questions regarding dietary exposure estimates, specifications, and safety of rice bran wax. In an email dated August 10, 2021, McCain Foods provided an amendment which included revised estimates of dietary exposures to rice bran wax from the intended use, a discussion of estimated background and cumulative dietary exposures from uses of rice bran wax and carnauba wax, clarifications regarding the calculated weighted residual levels of rice bran wax, specific NHANES food codes used in the dietary exposure estimates, potential dietary exposure to degradation products, and additional safety information.

In a phone conversation with McCain Foods on November 15, 2021, we stated that we still had questions regarding their GRAS conclusion given the expanded intended use from GRN 000720¹ and the other authorized uses of rice bran wax.² FDA noted that the estimated dietary exposure to rice bran wax from the intended use would be increased, especially for children (2-5 years old), and be substantially greater than the estimated dietary exposure to rice bran wax from the approved uses under 21 CFR 172.890 and the uses described in GRN 000720.

¹ The subject of GRN 000720 is rice bran wax for use as a texturizing agent at levels up to 3% in peanut butter in bar products. We evaluated this notice and responded in a letter dated January 16, 2018 stating that we had no questions at the time regarding the notifier's GRAS conclusion.

² Rice bran wax is permitted for specific uses in food under 21 CFR 172.890.

In an email dated November 24, 2021, McCain Foods requested that we cease to evaluate GRN 000962 so that the company could evaluate possible paths forward to submit a revised GRAS notice.

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 000962 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J. Carlson -S

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Susan J. Carlson -S
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Susan Carlson, Ph.D.
Director
Division of Food Ingredients
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