



Stephen Tallon, Ph.D.
Callaghan Innovation
69 Gracefield Road
Lower Hutt 5040
NEW ZEALAND

Re: GRAS Notice No. GRN 000695

Dear Dr. Tallon:

The Food and Drug Administration (FDA, we) is granting your request to cease our evaluation of GRN 000695, which we filed on April 4, 2017. We received your request dated July 25, 2017, on July 26, 2017.

The subject of the notice is dimethyl ether. The notice informs FDA of Callaghan Innovation's view that dimethyl ether is GRAS, through scientific procedures, for use as an extraction solvent in the processing of various food products such as marine lipids, egg phospholipids, bacteria-derived lipids, plant lipids, egg proteins, meat proteins, and fruit sugars at levels ranging from 5 to 6 volumes per unit volume of starting material (% v/v).

On June 19, 2017, we received an amendment dated June 14, 2017, in which Callaghan Innovation provided additional information in response to questions raised by our evaluation team. In an email dated July 18, 2017, and as further discussed in a telephone conversation on July 25, 2017, we explained that the amendment did not fully address our questions. In general, we noted remaining questions regarding the interpretation of the results of toxicity studies discussed in GRN 000695, the basis for selection of a NOAEL (No Observed Adverse Effect Level), and Callaghan Innovation's GRAS panel. Therefore, we discussed the opportunity for Callaghan Innovation to ask us to cease our evaluation of GRN 000695 and to re-submit a new GRAS notice in the future.

U.S. Food & Drug Administration
Center for Food Safety & Applied Nutrition
5001 Campus Drive
College Park, MD 20740

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 000695 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J.
Carlson -S

Digitally signed by Susan J. Carlson -S
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ou=HHS, ou=FDA, ou=People,
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Date: 2017.08.29 15:02:43 -04'00'

Susan J. Carlson, Ph.D.
Director
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