



Joseph V. Rodricks, Ph.D., D.A.B.T.
Ramboll Environ
4350 North Fairfax Drive
Suite 300
Arlington, VA 22203

Re: GRAS Notice No. GRN 000710

Dear Dr. Rodricks:

The Food and Drug Administration (FDA, we) is granting Ramboll Environ's request to cease our evaluation of GRN 000710, which we filed on July 25, 2017. We received your request on October 30, 2017.

The subject of the notice is poly[(dimethylaminoethyl methacrylate)-co-(methyl methacrylate)-co-(butyl methacrylate)] (methacrylate copolymer) for use as a coating for various micronutrients to prevent degradation at a level up to 2.3 g/day. The notice informs us of Ramboll Environ's view that this use of methacrylate copolymer is GRAS through scientific procedures.

In a phone conversation with Ramboll Environ on September 6, 2017, we discussed several issues in the notice related to the identity and manufacturing of the methacrylate copolymer product and confidential business information that was included in the notice. In a follow-up email dated September 11, 2017, we sent Ramboll Environ questions primarily related to these issues. In an email dated September 25, 2017, Ramboll Environ provided additional information to the notice, which included confidential business information on the identity of the methacrylate copolymer, in response to questions from FDA. In a phone conversation and follow-up email on October 24, 2017, we informed Ramboll Environ that the GRAS conclusion described in GRN 000710 did not meet the general recognition standard due to the confidential business information related to the identity of the methacrylate copolymer. FDA informed Ramboll Environ that data and information identifying the methacrylate copolymer is essential for determining its safety and cannot be kept confidential (see 21 CFR 170.230). We advised Ramboll Environ to consider requesting that we cease our evaluation of the notice if the company chose not to make this data and information publicly available.

In accordance with 21 CFR 170.275(b)(3), the text of this letter responding to GRN 000710 is accessible to the public at www.fda.gov/grasnoticeinventory.

Sincerely,

Susan J. Carlson

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Susan J. Carlson, Ph.D.

Director

Division of Biotechnology
and GRAS Notice Review

Office of Food Additive Safety

Center for Food Safety

and Applied Nutrition

Digitally signed by Susan J. Carlson -S
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