



Gary Yingling
Morgan Lewis Bockius LLP
1111 Pennsylvania Ave., NW
Washington D. C. 2004

Re: GRAS Notice No. GRN 000183

Dear Mr. Yingling:

The Food and Drug Administration (FDA) is responding to the supplement, dated April 10, 2014, that you submitted on behalf of DSM Food Specialties (DSM) regarding additional uses of phospholipase A2 (PLA2) enzyme preparation from *Aspergillus niger* expressing a gene encoding porcine phospholipase A2 (PLA2 (porcine) enzyme preparation), the subject of GRN 000183. You submitted GRN 000183 in accordance with the agency's proposed regulation, proposed 21 CFR 170.36 (62 FR 18938; April 17, 1997; Substances Generally Recognized as Safe (GRAS); the GRAS proposal). The notice informed FDA of the view of DSM that PLA2 (porcine) enzyme preparation is GRAS, through scientific procedures, for use as an enzyme in baked goods, egg-yolk based sauces and dressings, at levels not to exceed good manufacturing practices. In a letter dated May 11, 2006, FDA informed DSM that the agency had no questions at that time regarding DSM's conclusion that PLA2 enzyme preparation is GRAS under the intended conditions of use.

In a supplement dated April 10, 2014, DSM informs FDA of its view that PLA2 (porcine) enzyme preparation is GRAS, through scientific procedures, for an additional use, degumming oils at 30-60 milligrams Total Organic Solids per kilogram of raw material.

As part of the supplement, DSM confirms that the manufacture of PLA2 (porcine) enzyme preparation from *A. niger* meets specifications established for enzyme preparations in the Food Chemicals Codex (FCC, 9th edition), and to the current General Specifications and Considerations for Enzyme Preparations Used in Food Processing established by the FAO/WHO Joint Expert Committee on Food Additives (JECFA, 2006). The additional use of PLA2 (porcine) enzyme preparation for degumming of oils does not contribute to the dietary exposure from previous uses outlined in GRN 000183, because the enzyme is removed from the oil prior to use in food, via a water wash and a centrifugation step. DSM also confirms performing a review of current scientific literature regarding PLA2 (porcine) enzyme preparation from *A. niger*, through April 10, 2014. DSM reported no new safety data. DSM also states that the safety data discussed in the original notice, GRN000183, are still applicable to this additional use.

Conclusions

Based on the information provided by DSM in GRN 000183, the supplement dated April 10, 2014, as well as other information available to FDA, the agency has no questions at this time regarding DSM's conclusion that phospholipase A2 enzyme preparation from *Aspergillus niger* expressing a gene encoding porcine phospholipase A2 is GRAS under the intended conditions of use. The agency has not, however, made its own determination regarding the GRAS status of the subject use of phospholipase A2 enzyme preparation from *Aspergillus niger* expressing a gene encoding porcine phospholipase A2. As always, it is

the continuing responsibility of DSM to ensure that food ingredients that the firm markets are safe, and are otherwise in compliance with all applicable legal and regulatory requirements.

In accordance with proposed 21 CFR 170.36(f), a copy of the text of this letter responding to the supplement to GRN 00 0183, as well as a copy of the information in this notice that conforms to the information in the GRAS exemption claim (proposed 21 CFR 170.36(c)(1)), is available for public review and copying at www.fda.gov/grasnoticeinventory.

Sincerely,

Antonia Mattia -S

Digitally signed by Antonia Mattia -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People,
email=Antonia.Mattia-S, 0.9.2342.19200300.100.1.1=1300071500
Date: 2014.11.18 12:35:20 -0500

Antonia Mattia, Ph.D.

Director

Division of Biotechnology and GRAS Notice
Review

Office of Food Additive Safety

Center for Food Safety

and Applied Nutrition