AG PROVISION LLC

February 4, 2021

Re: GRAS Determination Affirmation

To whom it may concern:

Danisco Animal Nutrition at IFF (formerly Dupont) has concluded that the enzyme components in the Axtra PHY GOLD product line are Generally Recognized as Safe (GRAS) for use as a feed additive in swine and poultry diets. This conclusion is supported by appropriate studies published in peer-reviewed scientific journals. Further, they are pursuing the voluntary GRAS notification process with CVM to facilitate placing the phytase in the AAFCO Official Publication. A summary of the current regulatory status of this line of phytase enzyme products dated February 3, 2021 follows this memo.

I have reviewed the studies as well as the content outline in the GRAS notification package and agree that the notice fulfills the GRAS Notice content requirements as laid out in 21 CFR 570 and has a high likelihood of acceptance by CVM. Based upon my review of the information provided, I concur with Danico Animal Nutrition at IFF that there is sufficient generally available evidence to conclude that the enzyme components in the Axtra PHY GOLD product line are safe under the conditions of its intended use.

The information supporting Ag ProVision's affirmation of Danisco Animal Nutrition at IFF's GRAS conclusion is available upon request.

Respectfully,

Teena F. Middleton, Ph.D.
Director of Regulatory and Technical Affairs
Cell: 910-290-0475
Teena@agprovision.com

February 3, 2021

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Re: Regulatory status of Axtra® PHY GOLD Product Range – Update:

Axtra® PHY GOLD Product Range:

- **Axtra® PHY GOLD 2.5G**
- **Axtra® PHY GOLD 5G**
- **Axtra® PHY GOLD 10G**
- **Axtra® PHY GOLD 65G**
- **Axtra® PHY GOLD 5L**
- **Axtra® PHY GOLD 10L**
- **Axtra® PHY GOLD 30L**
- **Axtra® PHY GOLD 2.5T**
- **Axtra® PHY GOLD 5T**
- **Axtra® PHY GOLD 10T**
- **Axtra® PHY GOLD 30T**

The enzyme components in the Axtra® PHY GOLD product range as listed above are Generally Recognized as Safe (GRAS) for use as feed additive in swine and poultry diets when the enzyme product is used within the product dose guidelines described in IFF product literature. Our GRAS determination is based, in part, on addressing all safety evaluation aspects outlined in the Sewalt et al. (2016) review and the Pariza and Cook (2010) decision tree, which updates the Pariza and Foster (1983) decision tree referenced in the AAFCO Official Publication as being adequate in assessing the safety of feed enzymes.

Our GRAS conclusion was further supported by appropriate studies published in peer-reviewed scientific journals. Our toxicology study indicated a complete lack of toxicological concern for this phytase preparation, supporting a margin of safety that is appropriate for the intended use in both pigs and poultry. The target animal studies also document utility by consistently restoring phosphorous status of pigs and poultry subjected to reduced inorganic phosphate supplementation.

GRAS conclusion based on publicly available, peer-reviewed pivotal data from relevant studies satisfies the federal requirements for commercialization of a feed ingredient in the USA, as the regulation states that “any substance that is intentionally added to food is a food additive is subject to premarket review and approval by FDA, unless the substance is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use”. Under the law, a substance that is GRAS for a particular use may be marketed for that use without the agency's review and approval that is normally required for a new food additive as defined in definition (s) of 21 U.S.C. § 321.

Filing a GRAS Notice to inform FDA’s Center for Veterinary Medicine (CVM) of our GRAS conclusion is entirely optional and lends no additional regulatory status to the GRAS substance (see also

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questions 8 and 10 in the FDA GRAS Q&A document retrievable here: https://www.fda.gov/media/101042/download.

Finally, we are currently pursuing the voluntary GRAS notification process with CVM to facilitate the administrative process of placing our phytase in the AAFCO Official Publication. Although listing in the AAFCO OP is desirable for transparency reasons both in the US and internationally, it is not a federal requirement. This GRAS notice was sent to CVM for review in December of 2020. The cover letter provided in the submission to CVM, table of contents of the notice as well as the expert concurrence on the GRAS status is attached for your reference. We expect initial screening of the file to occur in Q2 of 2021 which will result in the assignment of a file reference number allowing the file to begin its official review by CVM throughout the year.

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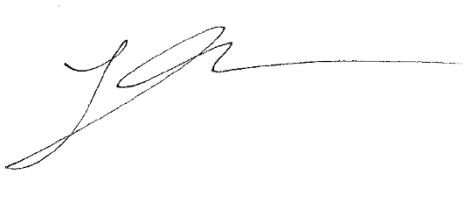
In addition to Federal Regulatory status of the enzyme components in the Axtra® PHY GOLD product range as listed above we have also registered the products in the various States as appropriate under each individual feed law. This compliance work with the States including required licenses and tonnage reporting will continue to be maintained for Axtra® PHY GOLD product range as appropriate and where subject to.

Should you have any further questions, we ‘d be happy to discuss those in a conference call.

Sincerely,



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