



Enzymes in Animal Feed

In the animal food industry, enzymes can help improve animal performance and production economics through a variety of mechanisms: breakdown of substrates in feed and reduction of anti-nutritional substances, such as hydrolysis of phytic acid to improve phosphorus availability. Marketed enzyme preparations contain the enzyme protein as well as preservatives, stabilizers (liquid formulations) and carriers (dry formulations) acceptable for use in animal food. The regulatory framework for feed enzymes differs by country, and ETA maintains a leading role to influence regulatory authorities in the Americas for reasonable, science-based regulations. Recent regulatory changes disallowing the use of antimicrobial drugs with productivity claims may have opened more opportunities for feed enzymes.

United States

In the US, feed enzymes are regulated at both the federal and state levels. The US Food and Drug Administration's (FDA) Center for Veterinary Medicine (CVM) Division of Animal Feed regulates animal food at the federal level, and each US state maintains and upholds its own state feed law and regulations. Feed enzymes are regulated as food additives subject to a Food Additive Petition, unless the enzyme is Generally Recognized as Safe (GRAS) for an intended use in accordance with federal law. The CVM also reviews Animal Food GRAS Notices voluntarily submitted by firms. The Association of American Feed Control Officials (AAFCO) maintains a list of enzymes and source organisms that CVM accepts for use in animal feed in Table 30.1 of the AAFCO Official Publication (OP). In addition, the AAFCO OP contains the Enzyme Marketing Coordination document (EMC) which describes the information typically needed for new feed enzyme submissions. According to the EMC, "all marketed enzymes must meet at least one of the following criteria: 1) be published in the OP; 2) be subject of a Food Additive regulation under 21CFR573; 3) be affirmed as GRAS; 4) be GRAS; or 5) be the subject of an informal no objection letter from FDA." CVM accepts the ingredients defined in the AAFCO OP by virtue of a Memorandum of Understanding with AAFCO, which includes that CVM provides technical review of new ingredient submissions made to AAFCO.

ETA holds an advisory position on the AAFCO Ingredient Definitions Committee (IDC) and the AAFCO Model Bill and Regulations Committee and actively advocates on behalf of the enzyme industry. The ETA Feed Committee often meets with the FDA and AAFCO Members to advance the interests of the industry.

Canada

Feed enzymes are regulated by the Canadian Food Inspection Agency (CFIA), and those enzymes (and their sources) currently approved by CFIA are listed in Schedule IV of the Feeds Regulations and are referred to as "enzyme supplements". When a product is marketed for its



enzyme content, a guarantee of the minimum amount of enzyme activity(ies) must be stated on the label.

The CFIA regulatory framework for animal feed ingredients is in the process of being modernized. ETA has submitted comments and participated in CFIA open meetings. The final proposed regulatory system is expected to be published in 2019.

Additional examples of ETA advocacy on behalf of both the enzyme and feed industry in Canada include the establishment of the CFIA RG-6 Regulatory Guidance document for acceptable enzymes used as processing aids in the manufacture of fuel ethanol and ethanol distillers' grains.

Latin America (LATAM)

In Brazil, feed enzymes are regulated at the federal level by the Ministry of Agriculture, Livestock, and Food Supply (MAPA); however, there has been a recent change in the approval process and the dossiers are now being evaluated at the state level. A template for the state level registration was recently released, and the ETA Latin America Committee is working on advocating for appropriate regulatory requirements. Currently, Brazil is the only LATAM country that requests stability testing be performed according to Climate Zone 4 (30 °C / 65% relative humidity) on the enzyme product, the enzyme-containing premix, and the final feed containing the enzyme. Another mandatory requirement for imported enzymes is a production quality, or cGMP, certification or statement issued by local authorities.

In Argentina, feed enzymes are regulated and evaluated at the federal level by The National Service of Agricultural Food Health and Quality (SENASA -Servicio Nacional de Sanidad y Calidad Agroalimentaria).

In Mexico, feed enzymes are no longer regulated. However, there are some exceptions including, for example, if a pharmacological, therapeutic, or preventative (disease) claim is made for the product or if the product contains an animal-derived ingredient.