

New functional group for

AT THE MOST RECENT WORLD MYCOTOXIN FORUM, HELD IN THE NETHERLANDS, FEFANA PRESENTED ITS PLANS TO OPEN A NEW FUNCTIONAL GROUP FOR MYCOTOXIN ADSORBENTS AND DENATURANTS. WHAT DOES THIS NEW LEGAL PROPOSITION EXACTLY MEAN? DIDIER JANS EXPLAINS THE FACTS.

Mycotoxins constitute a relatively large and diverse group of fungal toxins which have been strongly implicated as agents that cause acute and chronic diseases in both, humans and animals. The problem of low level mycotoxin exposure expresses itself in countries where food and feed are of high quality. Preventive measures can reduce the development of mycotoxins and legal limits help operators to manage supply flows and to avoid obtaining grains and feeds clearly contaminated with mycotoxins. However, all these beneficial actions are far from preventing mycotoxins from entering the food chain entirely. Thus, feed additives for the control of mycotoxins are still necessary and play an important role in this picture. The contribution of these mycotoxin absorbing additives to the safety of the food chain in the EU has not yet been fully exploited. They are defined as substances (e.g. clay minerals, enzymes, micro-organisms, yeast cell walls) that are mixed into feed and that adsorb or denature (biologically detoxify) mycotoxins in the digestive tract of animals. They are not used or able to ameliorate adulterated feeds, but are intended to deal with low levels or synergistic effects of defined mycotoxins. Thus, they would not lower the hygiene expected in production and storage of raw materials.

LEGAL BACKGROUND

Currently mycotoxins in feeds are considered as undesirable substances and regulated by the Council Directive 2002/32. Additionally, concerning legal regulation of mycotoxins, the following regulations and recommendations have to be considered: Regulation (EC) 178/2002. This is the general food law, laying down the general principles and requirements for food law, establishing the European Food Safety Authority and procedures in matters of food safety.

Regulation (EC) 882/2004 is the feed/food control, laying down the general rules for the performance of official controls to verify the compliance with rules to guarantee fair practice in feed and food trade and

Mycotoxins in grains account for huge economic losses and animal health problems. To successfully limit the mycotoxin risk along the feed/food chain a comprehensive strategy has therefore to be implemented

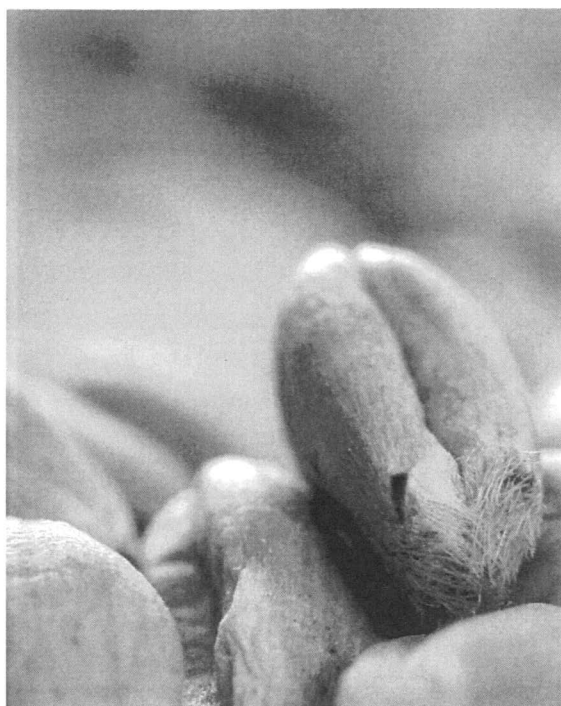


protecting consumer interests, which includes feed and food labelling and other forms of consumer information. Also Regulation (EC) 183/2005 also needs to be considered. This lays down requirements for feed hygiene. Commission recommendation 576/2006 is the legal framework that regulates deoxynivalenol- (DON), zearalenone- (ZEA), ochratoxin A- (OTA), fumonisin- (FB1+FB2) as well as T2- and HT2-toxin-levels in feed. Regulation (EC) 1831/2003 is the feed additives regulation, establishing a community wide procedure for authorising the placing on the market and use of feed additives, and laying down the rules for the supervision and labelling of feed additives and premixtures. Lastly, regulation (EC) 429/2008 – the feed additive guidelines – are important to consider as they establish implementation of rules concerning the procedure for the authorisation of feed additives under regulation (EC) 1831/2003.

NEW FUNCTIONAL GROUP

To successfully limit the mycotoxin risk along the feed/food chain a comprehensive strategy has to be implemented. Besides preventive measures (e.g. plant selection, breeding, adapted planting, use of mould inhibitors, temperature-, pH-, moisture control during storage), setting of legal limits and analytical control of feed and food, this strategy also has to include the use of feed additives for the control of mycotoxins.

mycotoxin binders?



These additives shall not substitute preventive measures and good practices but are a must for responsible management of food chain safety. The feed additive Regulation (EC) 1831/2003, however, does not recognise yet "substances for the control of mycotoxins". Thus it is at present not possible to submit an application for a respective feed additive. In order to close the legislative gap, FEFANA proposes opening a new functional group in the category of technological additives, defined as "mycotoxin adsorbents or denaturants".

By definition, technological additives are intended to improve or stabilise the characteristics of feed but have generally no direct biological effect on animal production. This definition exactly fits for "mycotoxin adsorbents or denaturants": They act on feed quality (= primary action) by reducing the hazardous potential of mycotoxins. "Mycotoxin adsorbents and/or denaturants" are substances which - included into feed - inactivate mycotoxins in feed during the transit through the digestive tract. They have no direct effect on the ingredients during preparation and storage. They also do not affect digestion, absorption of nutrients and the animal itself. Any reported modification in animal performance would be a secondary consequence of using such a product. Hence this type of action should be considered an indirect consequence of the inactivation effect.

EU PROCEDURE

According to article 6.3 of Regulation (EC) 1831/2003 additional categories and functional groups may - as a result of technological progress or scientific development - be established by means of a Standing Committee Procedure. If a positive decision is arrived at, a new functional group will be opened in the Technological Feed Additive category. Consequently, companies will be able to officially apply for authorisation of substances for the control of mycotoxins. The authorisation of these feed additives should comply with the general safety and efficacy rules provided by the feed additive Regulation (EC) 1831/2003 and the corresponding Regulation (EC) 429/2008. It should also be without prejudice to the existing risk management measures of mycotoxins, in particular those set under Council Directive 2002/32 on undesirable substances. Due to the importance of the problem, the European Federation of the Feed Additive Manufacturers (FEFANA) decided two years ago to provide consistent scientific information to the Commission to facilitate the decisions and the member states' vote for the establishment of a new functional group in the category of technological feed additives.

SCIENTIFIC DRAFT

FEFANA has therefore made a scientific draft "Mycotoxin adsorbents and/or denaturants: A new functional group in the category of technological feed additives closing the regulatory and quality assurance gaps". The following end points were defined to demonstrate efficacy of these products: 1. Reduction of the hazardous potential of mycotoxins and possible harmful metabolites within the gastro-intestinal tract. 2. Specific spectrum of activity (defined by the applicant). 3. Absence of nutritional side effects and 4. No hiding effect of mycotoxins and other guaranteed components in feed/premixtures. This should be demonstrated with already established lab assays using levels of mycotoxins below the maximum limit mentioned in EU feed legislation (e.g. Council Directive 2002/32 and Commission Recommendation 2006/576).

The Commission plans to have a draft proposal of a new functional group of feed additives ready for the second quarter 2009.

The draft proposal will be submitted to the Member States for vote. As soon as the new annex will be published and the official recognition of the new functionality, the companies will have the possibility to deposit dossiers for this new feed additive. <-