FEFANA & AMFEP respond to EFSA public consultation on the guidance on Bacillus safety

Brussels, 16 December 2013 - FEFANA and AMFEP have recently responded to the EFSA public consultation on the updated safety guidance on the assessment of the toxigenic potential of Bacillus species used in animal nutrition.

The Bacillus species have been widely used for decades as microbial feed additives (probiotics and silage inoculant) and as production organisms for enzymes and other fermentation products for feed and food use.

The feed additive and enzyme industry welcome EFSA’s wish to secure safety and harmonize the safety assessment criteria, based on scientific sound methods. However FEFANA and AMFEP have strong concerns about the approach used by EFSA in their new draft Bacillus guidance document.

EFSA questions the safety of Bacillus strains with an established, long history of safe use, based on their potential to produce lipopeptides. Recent literature shows that the traditional Japanese food and health product natto contains strong lipopeptide-producing Bacillus spp. Natto has been consumed without any adverse effects upon daily intake for centuries in Asia. It is also known from the scientific literature cited by EFSA that toxic effects seen in in vitro cell tests is not related to an in vivo toxicity. Therefore EFSA’s concern about lipopeptides is most likely unfounded.

As there is no international recognized in vitro assay developed for measurement of lipopeptides, EFSA suggests using assays developed for other purposes. We believe that these assays may lead to wrong conclusions on the potential risk of Bacillus strains and the present test may leave some uncertainties on how they should be performed and interpreted.

This could have impact for already authorized additives with a known effect and already tested in animals, as well as limiting the development of new products based on Bacillus strains.

Independent scientists shared our concerns on the scientific robustness of the draft EFSA approaches to Bacillus safety.

AMFEP & FEFANA appreciated the chance to comment on the EFSA guidance document (comments available here) and look forward to a well-based scientifically-justified final version of the text.
FEFANA - the EU Association of Specialty Feed Ingredients and their Mixtures - is the united voice of the specialty feed ingredients industry in the European Union. With more than 100 Members from 28 countries, it is the organization representing the interests of the specialty ingredients industry that enter the food chain via feed. Manufacturers and traders of feed additives, functional feed ingredients, premixes and other mixtures of specialty ingredients are amongst our member companies. The association is the interface between the additives and functional ingredients industry and the European Union authorities, including Member States authorities, in order to promote, safeguard and defend common and general interests of its industry. For more information please contact the FEFANA secretariat at info@fefana.org or visit our website at www.fefana.org.

AMFEP - the Association of Manufacturers and Formulators of Enzyme Products - is a non-profit European industry association created in 1977. Amfep’s mission is to contribute to a comprehensible and workable regulatory environment for enzymes, which provides legal certainty to its members and customers. Amfep serves as a hub for the information exchange and dialogue between enzymes producers and formulators, industry organisations, the scientific community and policy makers and promotes co-operation on regulatory and safety aspects of enzymes. More information: www.amfep.org.