



PRESS RELEASE

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