



PRESS RELEASE

FEFANA and AMFEP welcome EFSA revised Guidance on Bacillus safety

Brussels, 10 June 2014

In September 2013 FEFANA and AMFEP provided a common [response](#) to the [EFSA public consultation](#) on the updated 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.

During the public consultation numerous sound scientific comments were given on reasonable tests for Bacilli with QPS status. **We are glad that a number of key issues have been taken into account in the [new Guidance document](#):**

LIPOPEPTIDES

- **EFSA acknowledged that the link between food-poisoning/toxicity and lipopeptides has not been established.** Recent literature showed 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 that toxic effects seen in *in vitro* cell tests are not related to an *in vivo* toxicity. Therefore such concern is most likely unfounded.

ASSAYS

- **EFSA acknowledged that the link between the haemolysis assay and toxicity is not clear**, and removed the request for this test altogether.
- **The cell assay has been kept but opened up for different epithelial cell lines.** In addition, better references and threshold values for propidium iodide and the LDH assays were provided.
- **No list of positive or negative controls to be included in the assays is recommended;** thus, it is up to the applicants to choose the proper controls.
- EFSA recognized that ***in vitro* cell assays are not ideal for assessing the - poorly understood / potential - toxicity of these bacteria**, and opened up for other ways of showing that the strains are safe.

We strongly believe that the only way to meet highest scientific standards is an open dialogue and consultation with all parties and available technical experts. FEFANA and AMFEP consider this revised Guidance the fruit of such an approach and welcome this improved document.

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