Association of Veterinary Consultants raises concerns on EFSA's proposals to address Bacillus safety

EFSA food and feed panels should work together to improve processes, says AVC

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The <u>Association of Veterinary Consultants</u> (AVC) has joined the public debate launched by the <u>European Food Safety Authority</u> (EFSA) on how best to assess the safety of *Bacillus* strains used in the EU food chain.

The AVC said that the same *Bacillus* strains may be used as human food and animal feed supplements, and that EU member states increasingly look to the EFSA for guidance on issues common to food and feed, driven by food-feed hygiene and other EU regulations. For this reason the AVC said it recommends that EFSA food and feed panels work together to enlarge such public consultations, stimulate more robust and better-quality scientific inputs from a wider expert community, and ensure common grounds for food-feed safety criteria.

The AVC supports the EFSA's objective to use *in vitro* safety assays wherever possible, to reduce, refine and replace the use of laboratory animal tests, but said it recommends that *in vitro* tests be internationally validated prior to adoption by the EFSA. The AVC is also concerned that the *in vitro* tests suggested by the EFSA may yield false positive or false negative results and has made a number of detailed proposals to improve the EFSA's approach:

- For strains already used in the EU food chain, accept these based on a safe history of use and any existing in vitro and in vivo safety data.
- For new strains proposed for use in animal nutrition, use validated in vitro tests as an initial strain-selection filter, followed, if necessary, by suitable tolerance testing in target animals, combined with the already required dose-response and efficacy studies.
- For new strains to be used in food supplements, use validated in vitro tests as an
 initial strain-selection filter, followed, if necessary, by suitable laboratory animal
 studies. This approach is coherent with the EFSA's and other regulatory bodies'
 requirements for genotoxicity testing.

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