

## **Safety and efficacy of AveMix<sup>®</sup> 02 CS/L (endo-1,3(4)- $\beta$ -glucanase, endo-1,4- $\beta$ -xylanase and pectinase) as feed additive for weaned piglets**

### **Scientific Opinion of the Panel on Additives and Products or Substances used in Animal Feed**

(Question No EFSA-Q-2008-432)

**Adopted on 8 July 2009**

#### **SUMMARY**

Following a request from the European Commission, the European Food Safety Authority (EFSA) was asked to deliver a scientific opinion on the safety and efficacy of AveMix<sup>®</sup> 02 CS/L as feed additive for weaned piglets.

AveMix<sup>®</sup> 02 CS (solid) and AveMix<sup>®</sup> 02 CS L (liquid) are enzyme preparations of endo-1,4- $\beta$ -xylanase, endo-1,3(4)- $\beta$ -glucanase, and pectinase (polygalacturonase) which are intended for use as feed additive for weaned piglets. The proposed dose for both formulations corresponds to 2140 XU (from xylanase), 1230 BGU (from glucanase) and 46 PGLU (from pectinase) kg<sup>-1</sup> complete feed.

The solid and liquid forms of the additive are considered to be equivalent in terms of safety and efficacy.

Based on a tolerance study, in which piglets tolerated a 100-fold overdose of AveMix<sup>®</sup> 02 CS, the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) concludes that AveMix<sup>®</sup> 02 CS is safe for weaned piglets at the proposed dose.

The studies on genotoxicity and 90-day sub-chronic oral toxicity were conducted with the individual components. An interaction of the three components is not expected. The results do not indicate any reason for concern regarding consumer safety from the use of AveMix<sup>®</sup> 02 CS as a feed additive.

Based on the results from the tests performed with the individual components, AveMix<sup>®</sup> 02 CS is not considered to be a dermal or eye irritant. However, it is regarded as a dermal and respiratory sensitiser and should be handled accordingly.

The active substances in AveMix<sup>®</sup> 02 CS are proteins and as such will be degraded/inactivated during the passage through the digestive tract of animals. Therefore, no risks for the environment are expected and no further environmental risk assessment is required.

From the six efficacy trials considered, only one was conducted according to the applicable guidelines. This trial showed a significant improvement of body weight gain and feed to gain ratio at a dose of 100 mg AveMix 02 CS kg<sup>-1</sup> (equivalent to 2140 XU, 1230 BGU and 46 PGLU kg<sup>-1</sup> complete feed). Since three studies demonstrating efficacy are required, the FEEDAP Panel cannot conclude on the efficacy of this product in weaned piglets.

**Key words:** zootechnical additive, digestibility enhancer, enzyme, endo-1,4- $\beta$ -xylanase, endo-1,3(4)- $\beta$ -glucanase, pectinase, polygalacturonase, piglets, safety, efficacy