EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate C - Scientific Opinions
C2 - Management of scientific committees; scientific co-operation and networks

REPORT OF THE SCIENTIFIC COMMITTEE ON ANIMAL NUTRITION ON THE SAFETY OF THE ENZYMATIC PRODUCT BELFEED B1100 MP® FOR USE AS FEED ADDITIVE FOR PIGS FOR FATTENING

Adopted on 18 April 2002

1. BACKGROUND

The product "Belfeed B1100 MP" preparation of endo-1,4-beta-xylanase EC 3.2.1.8 produced by *Bacillus subtilis* (LMG S-15136) is already provisionally authorised for the use as feed additive for the animal category chickens for fattening under the name of "Belfeed B1100 MP for chickens for fattening". The Commission received a request for a provisional Community authorisation for the animal category pigs for fattening under the conditions set out in the following table:

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No	Additive	Chemical formula, description	Species or category of animal	Minimum Content	Maximum Content	Other provisions
				IU/kg of complete feedingstuff		
ENZYMES						
51	Endo-1,4-beta-xylanase EC 3.2.1.8	Preparation of endo-1,4-beta-xylanase produced by *Bacillus subtilis* (LMG S-15136) having a minimum acitvity of: Endo-1,4-beta-xylanase: 100 IU/g[1]	Pigs for fattening	10 IU		1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting. 2. Recommended dose per kilogram of complete feedingstuff: Endo-1,4-beta-xylanase: 10 IU/Kg 3. For use in compound feed rich in arabinoxylans e.g. minimum 40% wheat or barley.

[1] IU is the amount of enzyme which liberates 1 micromole of reducing sugars (expressed in equivalent of xylose) from xylan per minute at pH 4.5 and 30°C

The company producing "Belfeed B1100 MP", prepared a dossier that has been submitted through the national rapporteur (Belgium) to the Commission. The dossier was checked by the Member States for its compliance with the requirements of Council Directive 87/153/EEC fixing the guidelines for the assessment of additives in animal nutrition. The Member States concluded in the Standing Committee for Animal Nutrition on 18th of September 2001 that the dossier fulfilled these requirements.

The authorisation procedure laid down in article 4 of Council Directive 70/524/EEC as last amended by Council Directive 96/51/EC includes a period of 320 days for the evaluation of the dossier submitted to the Commission. The Standing Committee for Animal Nutrition started the evaluation of the product on 18th of September 2001.

2. TERMS OF REFERENCE

The Scientific Committee for Animal Nutrition (SCAN) is requested to give an opinion on the safety of "Belfeed B1100 MP®" preparation of endo-1,4-beta-xylanase EC 3.2.1.8 produced by *Bacillus subtilis* (LMG S-15136) for Pigs for fattening, when used as feed additive under the conditions presented in the above table.

3. SCAN OPINION

3.1. History

Belfeed 1100 MP is an enzymatic preparation already assessed for feed additive use in broilers and piglets (January 25, 2001).

Such assessment implies compliance with safety assessment requirements; these requirements include absence of toxic effects in a bacterial mutagenicity assay and an *in vitro* test for chromosome aberrations, absence of skin and eye irritation and acute inhalation toxicity, and absence of adverse effects in a 90day rodent repeated dose toxicity study. For the specific target species a tolerance study is required.

3.2. Target animal category safety

The product is intended for pigs for fattening.

A tolerance study in piglets was submitted in the dossier, which was carried out in animals (40 per experimental group) from the age of 5-6 weeks to 2.5 months (weight 7-23 kg), in which feeding up to 20 x recommended dose during 38 days did not show adverse effects. Parameters were general clinical signs, feed conversion and weight gain.

Although the guidelines require in principle tolerance studies for each category of animals, the tolerance study in piglets can be considered justified as substitute for a fattening pig study because the submitted study was in a more sensitive category of animals and, in addition, at a higher dose (20 x) than formally required.

On the basis of these observations and the previous opinions SCAN concludes that Belfeed MP can be considered safe for fattening pigs.

3.3. Toxin production by the enzyme producing strain

For enzymes and micro-organisms from the *Bacillus* family additional safety requirements apply with respect to the toxin production potential.

The strain used for the production of Belfeed 1100M, *B. subtilis* 168 has undergone transformation with multicopy xylanase gene from another *B. subtilis* strain. No other extra DNA in addition to Bacillus sequences is added in the construct.

The host strain has been tested for the production of enterotoxin-like and bacillar toxins and emetic toxins. The assays were the Vero cell test (as recommended in the SCAN opinion on the safety of bacillus species) for enterotoxin detection and the boar sperm motility test for the detection of emetic toxins. Both tests were negative.

On the basis of these data the SCAN considers that the absence of toxin production potential of the bacillus strain used for the production of Belfeed 1100 M has been satisfactorily demonstrated.

3.4. Conclusion

The SCAN has previously examined the data on the response of piglets to Belfeed 1100 MP and has concluded that the product was well tolerated. This study adequately represents the entire growing period to slaughter weight and, in the view of the SCAN, an additional study made with older animals (weight >25kg) is unnecessary.

On the basis of the data submitted, the Scientific Committee on Animal Nutrition considers that the product is safe for use in pigs for fattening under the proposed conditions of use described in the background (part 1).