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 ML® FOR USE AS FEED ADDITIVE FOR CHICKENS FOR FATTENING

Adopted on 18 April 2002

1. BACKGROUND

The product Belfeed B 1100 ML® preparation of endo-1,4-beta-xylanase EC 3.2.1.8 produced by *Bacillus subtilis* (LMG S-15136) (E.C. No. 51) is already provisionally authorised for the use as feed additive for the animal category chickens for fattening, in the solid form. The Commission received a request for a provisional Community authorisation for the liquid form for the animal category chickens for fattening under the conditions set out in the following table:

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: Solid and **liquid**: Endo-1,4-beta-xylanase: 100 IU/g[1]	Chickens 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 arabinoxylan, 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 B 1100 ML®, 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 7th of June 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 7th of June 2001.

2. TERMS OF REFERENCE

The Scientific Committee for Animal Nutrition (SCAN) is requested to give an opinion on the safety of Belfeed B 1100 ML® liquid preparation of endo-1,4-beta-xylanase produced by *Bacillus subtilis* (LMG S-15136) for the chickens 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 assessement 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.

The present request for approval concerns the same enzyme preparation derived from the same microorganism. The only difference appears to be the formulation in liquid form (in glycerol) instead of the solid form (mixed in flour), both at 100 IU/g.

For the specific target species a tolerance study is required.

3.2. Target animal category safety

The Company did not present any tolerance study in broilers chickens performed with Belfeed 1100ML. It justifies the non provision of a dedicated tolerance test by the fact that the activity of Belfeed 1100MP and Belfeed B1100ML are the same (min 100 IU/g) and that the carrier (wheat flour or glycerol) is food grade.

It seems reasonable to assume that the general toxicological aspects as studied in laboratory studies and which are mainly aimed at possible toxic contaminants or irritation, are not influenced by this different formulation. For the target species, the only difference is the carrier glycerol instead of flour. As glycerol is approved unconditionally as additive, a tolerance test for this formulation is indeed not considered necessary.

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

In the light of the above, SCAN concludes that the new liquid formulation of this enzyme preparation is acceptable for feed additive use in broilers at the level of 10 IU/kg feed.