



## 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 BIOFEED PHYTASE® FOR USE AS FEED ADDITIVE FOR SOWS

(adopted on 18 October 2002)

#### 1. BACKGROUND

The product “Bio Feed Phytase” – 6-Phytase 3.1.3.26 produced by *Aspergillus oryzae* (DSM 11857) is already provisionally authorised for the use as feed additive for the animal category chickens for fattening, laying hens, turkeys for fattening, piglets, pigs for fattening, in the coated and in the liquid forms. The Commission received a request for a provisional Community authorisation for the animal category sows under the conditions set out in the following table 1 :

Table 1: Conditions of use proposed by the Company

No	Additive	Chemical formula, description	Species or category of animal	Minimum Content	Maximum Content	Other provisions
				CFU/kg of complete feedingstuff		
<b>ENZYMES</b>						
50	6-phytase EC 3.1.3.26	Preparation of 6-phytase produced by <i>Aspergillus oryzae</i> (DSM 11857) having a minimum activity of: Coated form: 2500 FYT <sup>1</sup> /g Liquid form: 5000 FYT <sup>1</sup> /g	Sows	750 FYT		1. Recommended dose per kilogram of complete feedingstuff: 750-1000 FYT 2. For use in compound feed containing more than 0.25% phytin bound phosphorous

<sup>1</sup> FYT is the amount of enzyme which liberates 1 micromole of inorganic phosphate per minute from sodium phytate at pH 5.5 and 37°C

The company producing “Bio Feed Phytase” prepared a dossier that has been submitted through the national rapporteur (DK) 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 18<sup>th</sup> of October 2001 that the dossier fulfilled these requirements.

#### 2. TERMS OF REFERENCE

The Scientific Committee for Animal Nutrition (SCAN) is requested to give an opinion on the safety of “Bio Feed Phytase” – 6-Phytase 3.1.3.26 produced by

*Aspergillus oryzae* (DSM 11857) for sows, when used as feed additive under the conditions presented in the above table 1.

### **3. INTRODUCTION**

The active substance of Bio-Feed® Phytase is phosphoric monoester hydrolase (6-phytase (3.1.3.26)). The enzyme is produced by *Aspergillus oryzae*, strain DSM 11857.

The general safety of the product has already been assessed by the Scientific Committee on Animal Nutrition and found satisfactory. The SCAN added this product to its report on the use of enzymes in feedingstuffs for use in piglets, pigs for fattening, chickens and turkeys for fattening and for laying hens.

The petitioner asks now for an extension of use of its product, phytase obtained from *Aspergillus oryzae* strain DSM 11857, to sows. Consequently, the following evaluation is limited to assessing the safety of the product for sows.

#### **3.1. Tolerance test in sows**

The experiment was conducted in The Netherlands, using the phytase produced by strain DSM 11857. The objective of this experiment was to study the apparent digestibility of phosphorus, calcium and copper. It was also used as a tolerance test to determine the effect in the target animals of an over-dosing at ten times the maximum recommended dose.

The experiment was conducted with 30 sows and covered the farrowing period, starting two weeks before farrowing and ending four weeks after (until the end of the lactation period). The length of the experiment was 43 days.

Sows were divided in 5 experimental groups of treatment. The efficacy of phytase was determined comparing the apparent digestibility of phosphorus. A negative control diet was used. In order to compare with three levels of phytase supplementation 750, 1000, 10000 FYT/kg of feed and a positive control diet.

The total phosphorus content of the negative and of the positive control diets was calculated. It amounted respectively to 4.5 g/kg and to 6 g/kg, of which, respectively, 1.3g/kg and 2.8 g/kg was digestible phosphorus. 0.07g/kg of monocalcium phosphate was added to the negative control diet (this was considered negligible) whereas 11.8g/kg of monocalcium phosphate were added to the positive control diet.

The experimental treatment with 10 000 FYT/kg, corresponding to ten times the recommended dose, was used as a tolerance study for sows. Analytical phytase recovery has been determined in the feed.

According to the results, a clear dose response was found for phosphorus apparent digestibility and also for calcium (see table 2). Significant effects of phytase supplementation were found on the apparent digestibility of ash, magnesium, sodium, potassium, copper, zinc and iron.

Table 2: Effect of phytase supplementation on the apparent digestibility of phosphorus, calcium and copper in sows. (6 sows per treatment)

	Treatment				Standard error	P-value	
	Feed with 1.3g digestible P/kg feed			Feed with 2.8g digestible P/kg feed (positive control)			
	Unsupplemented (negative control)	Phytase 750 FYT	Phytase 1000 FYT				Phytase 10 000 FYT
	Average (day 27 and 34) apparent digestibility expressed in percentage						
Phosphorus	21 <sup>a</sup>	37 <sup>b</sup>	38 <sup>b</sup>	45 <sup>c</sup>	35 <sup>b</sup>	2.03	0.001
Calcium	20 <sup>a</sup>	29 <sup>b</sup>	29 <sup>b</sup>	29 <sup>b</sup>	25 <sup>ab</sup>	3.23	0.03
Copper	1 <sup>a</sup>	2 <sup>a</sup>	8 <sup>bc</sup>	10 <sup>c</sup>	6 <sup>ab</sup>	1.98	0.002

Values with different superscript within rows are significantly different (P<0.05)

Health status and animal performance were measured by recording the reproduction parameters for each sow.

The following parameters were used:

- piglets born alive,
- piglets born dead,
- total litter weight (kg),
- individual birth weight of piglets
- piglets lost,
- lactation days,
- piglets lost per litter after 24h,
- piglets weaned per litter,
- growth per piglet (g/d) and
- weight change of each sow at the beginning of the experiment, at the farrowing time, and at the end of the lactation, as well as for the whole test period (pre-farrowing+lactation).

Treatments had no effect on any of the parameters studied. (see table 3)

Table 3: Effect of phytase supplementation on weight of piglets at birth and during the lactation

Treatment	Average number of piglets born alive per sow	Average number of piglets born dead per sow	Total birth weight of piglets expressed in kg	Average birth weight (kg)	Daily weight gain of piglets (g/d)
Negative control	12.2	2.0	16.4	1.26	197
Phytase 750 FYT	14.2	1.7	19.7	1.38	212
Phytase 1000 FYT	13.3	1.0	18.0	1.34	208
Phytase 10 000 FYT	13.5	1.3	18.1	1.31	212
Positive control	13.0	1.7	18.1	1.32	214
Standard error	-	-	2.47	0.10	14.3
P-value	0.91	0.69	0.78	0.82	0.56

#### 4. CONCLUSION

SCAN is of the opinion that **Bio-Feed® Phytase**, 6-Phytase 3.1.3.26 produced by *Aspergillus oryzae* (DSM 11857), does not pose any risk for the target species (sows) under the proposed conditions of use presented in table 1.