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 PRODUCT: "ROVABIO EXCEL" FOR PIGLETS

(Adopted on 27 March 2003)

1. BACKGROUND

An authorisation application for this enzymatic preparation for chickens for fattening was approved on the 1st of July 1999 (EC Regulation 866/1999). Subsequently an extension of authorisation to laying hens, turkeys and pigs for fattening was filed in 1999 and approved on the 1st of March 2001 (EC Regulation 418/2001). Dossiers in support of these applications were supplied, completed and evaluated within the framework of Directive 93/113/CE.

The safety for the user, the consumer and the environment was assessed at that time.

The Commission has received a request for extension of the provisional Community authorisation of this product for piglets under the conditions set out in the table 1.

Table 1

Additive	Chemical formula, description	Species or category of animal	Minimum Content Units of activity per Kg of complete feedingstuff	Other provisions
ENZYMES				
Endo-1,4-beta-xylanase EC 3.2.1.8 Endo-1,4-beta-glucanase EC 3.2.1.6.	Preparation of endo-1,4-beta-xylanase produced and Endo-1,4-beta-glucanase EC 3.2.1.6 by *Penicillium funiculosum* (IMI SD 101) having a minimum acitvity of: Solid form: Endo-1,4-beta-xylanase 1400 U */ kg Endo-1,4-beta-glucanase 2000 U **/kg Liquid form: Endo-1,4-beta-xylanase 350 U /ml Endo-1,4-beta-glucanas 500 U/ml	Piglets	Endo-1,4-beta-xylanase 70 U Endo-1,4-beta-glucanase 100 U	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 kg of complete feedingstuff: Endo-1,4-beta-glucanase 100 U; Endo-1,4-beta-glucanase 70 U 3. For use in compound feed rich in non-starch polysaccharides, (mainly arabinoxylans), e.g. containing more than 60% barley or 50% wheat

* 1U is the amount of enzymes which liberates 4.00 micromoles of reducing sugars (maltose equivalents) from birchwood xylan per minute at pH 5.5 and 50 º C.

** 1U is the amount of enzymes which liberates 5.55 micromoles of reducing sugars (maltose equivalents) from barley beta-glucan per minute at pH 5.0 and 50 º C.

The company producing "ROVABIO™ EXCEL LC AP" prepared a dossier that has been submitted through the national rapporteur (UK) 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 19 March 2003 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 the use of "ROVABIO™ EXCEL LC AP" preparation of endo-1,4-beta-xylanase EC 3.2.1.8 and endo-1,3(4)-beta-glucanase EC 3.2.1.6 produced by *Penicillium funiculosum* (IMI SD 101) (E.C. No. 30) for piglets

3. OPINION OF SCAN

3.1. Introduction

This enzyme preparation is produced by Adisseo SA (previously Aventis Animal Nutrition), France and Rhodia Food Uk Ltd. by fermentation of a selected strain of *Penicillium funiculosum* (IMI SD 101). The strain used has not been genetically modified. The active substance represents 6 % of the final liquid preparation and 24.1 % of the final powder preparation. The final powder preparation contains a minimum specified activity of 2000 U beta-glucanase and 1400 U xylanase units per gram. The liquid preparation contains a minimum specified activity of 500 U beta-glucanase and 350 U of xylanase units per milliliter. (see table 2).

Table 2 Composition of final enzyme preparations.

% Liquid form		% Powder form	
Active substances	6	Active substances	24.1
Potasium sorbate (E202)	0.25	Wheat flour	66.3
Sorbitol (E420)	25	Moisture	8.6
Monopropylene glycol(490)	20	Spray dried fermentation broth	to 100
Fermentation broth	To 100		

The fermentation broth is filtered–cell free and concentrated by ultra filtration.

The additive was previously assessed by SCAN for use in chickens for fattening (broilers) and other target species. The company proposed to extend the use of ROVABIO™ EXCEL LC AP in piglets and recommends to use that enzyme preparation a at 100U of beta-glucanase and 70U of xylanase per kg of complete feed. Therefore the recommended supplementation of ROVABIO™ EXCEL LC AP in the feed should be 0.2 L/t in liquid form and 50g/t in powder.

The assessment of the safety included: acute inhalation toxicity, skin and eye irritation, Ames test, chromosomal aberration and sub chronic toxicity such is

a 90-day oral toxicity in rats. Therefore the present assessment, being an extension of use to piglets, is limited to consideration of the tolerance of this target animal.

3.2. Tolerance test piglets.

The experiment was carried out on piglets with the aim to study the effect of overdosing of ROVABIO^{TM} EXCEL LC AP at ten times the maximum recommended dose. The doses used were 0 (negative control), 25, 50 (recommended) and 500g/t (tolerance). In the case of the tolerance group, the piglets were fed with 700 U (10x recommended) xylanase units/kg and 1000 U (10x recommended) of beta – glucanase of complete feed.

Sixty (Landrace x Large white) x Pietrain) piglets were used and divided in four treatments with 15 animals per treatment group. Fifteen individual pens were used per treatment. The experiments were conducted using three blocks, for each replication (block of time) five litters were weaned together at 26-28 days of age. The experiment lasted 35 days.

Health status were monitored daily trough the consistency of faeces. The body weight was measured at weaning and at the end of experiment. Feed consumption and feed conversion were measured at 35 days. The enzymatic activity was measured in the feed and the level found was in accordance with the enzyme supplementation (The percentage of enzyme recovery in the feed was in a range between 70-100 %).

At the end of the trial 10 piglets from the tolerance group were killed in order to conduct a post mortem examination of the gastro-intestinal tract, liver, spleen, kidneys, heart and ganglion. No blood chemistry was performed

No negative effects were found in piglets fed with ten times the maximum recommended dose. The animal performance parameters, weight gain, feed intake and were not modified. The feed conversion of piglets fed with enzyme supplementation was significantly improved (See table 3). The post mortem examination did not reveal any abnormality in the organs observed.

Table 3 Body weight, feed intake, feed conversion of piglets under a tolerance test.

Treatment	**Control**	**Excel 25 g/t**	**Excel 50 g/t**	**Excel 500 g/t**
Initial body weight (kg)	8.255±1.67	8.292± 1.4	8.148±1.49	8.207±1.33
Final body weight (kg)	26.4±4.67	27.0±3.12	26.5±3.29	27.37±3.47
Daily feed intake (g/day)	808	780	766	778
Daily weight gain (g)	518	535	526	547
Feed conversion	1.571 a	1.461 b	1.462 b	1.425 b

Data with different letters are statistically different at $P<0.01$

3.3. Conclusion

SCAN is of the opinion that ROVABIO^{TM} EXCEL LC AP does not pose any risk for piglets under the condition of use proposed by the company and presented in table 1.