



**REPORT OF THE SCIENTIFIC COMMITTEE ON ANIMAL NUTRITION ON
THE SAFETY OF PRODUCT: "ROVABIO EXCEL" FOR DUCKS FOR FATTENING**

(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 ducks for fattening under the conditions set out in the table 1.

Table 1

Additive	Chemical formula, description	Species or category of animal	Minimum Content	Other provisions
			Units of activity per Kg of complete feedingstuff	
ENZYMES				
Endo-1,4-beta-xylanase EC 3.2.1.8	Preparation of endo-1,4-beta-xylanase produced and Endo-1,4-beta-glucanase EC 3.2.1.6 by <i>Penicillium funiculosum</i> (IMI SD 101) having a minimum activity of:	Ducks for fattening	Endo-1,4-beta-xylanase 70 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
Endo-1,4-beta-glucanase EC 3.2.1.6.	Solid form: Endo-1,4-beta-xylanase 1400 U */ kg Endo-1,4-beta-glucanase 2000 U **/kg		Endo-1,4-beta-glucanase 100 U	
	Liquid form: Endo-1,4-beta-xylanase 350 U /ml Endo-1,4-beta-glucanase 500 U/ml			

* 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 ° 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 ° 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 ducks for fattening

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
Potassium sorbate (E202)	0.25	Wheat flour	66.3
Sorbitol (E420)	25	Moisture	8.6
Monopropylene glycol(490)	20	Spray dried fermentation	to 100
Fermentation broth	To 100	broth	

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 ducks for fattening and recommends to use that enzyme preparation a at 100U of beta-glucanase and 70U of xylanase per kg of complete feed.

The assessment of the safety included: acute inhalation toxicity, skin and eye irritation, Ames test, chromosomal aberration and sub chronic toxicity such as a 90-day oral toxicity in rats. Therefore the present assessment, being an extension of use to ducks for fattening, is limited to consideration of the tolerance of this target animal.

3.2. Tolerance test in ducks for fattening.

The experiment was carried out on ducks for fattening with the aim to study the effect of overdosing of ROVABIO™ EXCEL LC AP at ten times the maximum recommended dose. The doses used were 100 (recommended) and 1000 (tolerance) U beta-glucanase or 70 (recommended) and 700 (recommended) U xylanase units /kg of complete feed.

540 (Barbary ducks) were used and divided in three treatments with 180 animals per treatment group; five pens of 36 animals were used per treatment. The experiment lasted 85 days. Health status and mortality were monitored daily. The body weight, feed consumption and feed conversion were measured at 28, 55 and 85 days. The enzymatic activity was measured in the feed and the level found was in accordance with the enzyme supplementation.

No negative effects were found in birds fed with ten times the maximum recommended dose. The animal performance parameters, weight gain, feed intake and feed to gain ratio were not modified. (See table 3). The mortality found in this experiment was not related to the dietary treatment. No gross pathology and blood chemistry was performed. However, information is given about (carcass quality) yield upon slaughter and the percentage of birds showing leg problems. No effects were found due to the dietary effect on carcass quality and leg problems.

Table 3 Body weight, feed intake, feed conversion and mortality of ducks for fattening under a tolerance test.

Treatment	Control	Excel 50 g/t	Excel 500 g/t
Body weight 85 days (g)	4908	4900	4822
Feed Intake (g)	13837	13815	13522
Daily weight gain (g)	57.8	57.7	56.8
Feed conversion	2.811	2.812	2.838
Mortality (%)	5	10.5	6.9

3.3. Conclusion

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