



**REPORT OF THE SCIENTIFIC COMMITTEE ON ANIMAL NUTRITION ON
THE SAFETY OF THE ENZYMATIC PRODUCT QUATRAZYME HP®
FOR USE AS FEED ADDITIVE IN TURKEYS FOR FATTENING**

(adopted on 4 December 2002)

1. BACKGROUND

The product « Quatrazyme HP » preparation of endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase produced by *Aspergillus niger* (CNCM I-1517), (E.C. No. 24), is already provisionally authorised for the use as feed additive for the animal category chickens for fattening. The Commission received a request for a provisional Community authorisation for the animal category “Turkeys for fattening” under the conditions set out in the following table 1:

Table 1 : Annex entry proposed by the petitioner for Quatrazyme HP for turkeys

| Additive | Chemical formula, description | Species or category of animal | Minimum content | Maximum content | Other provisions |
|--|--|-------------------------------|---|-----------------|---|
| | | | Units of activity/kg of complete feedingstuff | | |
| Enzymes | | | | | |
| Endo-1,4-beta-xylanase EC 3.2.1.8 | Preparation of endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase produced by <i>Aspergillus niger</i> (CNCM I-1517) having a minimum activity of: 28 000 QXU ¹ /g 140 000 QGU ² /g | Turkeys for fattening | 420 QXU | 840 QXU | 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: 560 QXU 2 800 QGU. Containing xylanes and/or glucanes, for example diets containing a minimum of 20% wheat and/or barley. |
| Endo-1,3(4)-beta-glucanase EC 3.2.1.6 | | | 2 100 QGU | 4200 QGU | |

The company producing Quatrazyme HP prepared a dossier that has been submitted through the national rapporteur (France) to the Commission. The dossier was checked by the Member States for its compliance with the requirements of Council Directive 87/153/EEC fixing guidelines for the assessment of additives in animal

¹ 1 QXU is the amount of enzyme which liberates 1 micromole of reducing sugars (xylose equivalents) from oat xylan per minute at pH 5.1 and 50°C
² 1 QGU is the amount of enzyme which liberates 1 micromole of reducing sugars (glucose equivalents) from barley beta-glucan per minute at pH 4.8 and 50°C

nutrition. The Member States concluded in the Standing Committee for Animal Nutrition on 20 November 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 20 November 2001.

2. TERMS OF REFERENCE

The Scientific Committee for Animal Nutrition (SCAN) is requested to assess the safety of "Quatrazyme HP" preparation of endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase produced by *Aspergillus niger* (CNCM I-1517) for the turkeys for fattening.

3. OPINION OF SCAN

3.1. History

Quatrazyme HP[®] is an enzymatic product with two declared enzymatic activities. The same product proposed for use in chickens for fattening has already been the subject of SCAN evaluation. The outcome of that evaluation was satisfactory and led to the addition of the product Quatrazyme HP[®] for chickens for fattening in the "*SCAN report on the use of certain enzymes in animal feedingstuffs*" on 25 January 1999.

The safety assessment of that product included check of the absence of toxic effects in a bacterial mutagenicity study and *in vitro* test for chromosomal aberrations, absence of skin and eye irritations in rabbits and acute inhalation toxicity in rats, and absence of adverse effects in 13-week toxicity study by oral route in rats.

The enzyme preparation has not been modified and the final presentation and carrier is the same. The enzyme fermentation is presented in powder using dextrin as carrier.

The Committee issued also a favourable opinion on the extension of use of that product to laying hens on 19 June 2002.

Considering that the new claim covers an extension of use to an other animal species, turkeys, only impact on the new target animal will be checked.

3.2. Tolerance test in turkeys for fattening

An experiment was performed in turkeys for fattening in 1999 to evaluate the effect of overdosing of Quatrazyme HP[®] at 10 times the maximum recommended dose.

A total of 90 1-day old male BUT turkeys were divided into three treatment groups of 30 turkeys and reared during 28 days in individual cages. The

purpose of the trial was to compare the turkeys for fattening performance fed with three different diets:

- control diet (11.7% wheat, 12.9% soybean meal, 7.2% meat meal),
- control diet + 20 mg of Quatrazyme HP® (560 IU of xylanase + 2 800 IU of β -glucanase) per kg feed (recommended dose), and
- control diet + 300 mg of Quatrazyme HP® (8 400 IU of xylanase + 42 000 IU of β -glucanase) per kg feed (tolerance level).

In the experiment, xylanase and β -glucanase activities were analyzed for 5 samples of each diet in order to check their homogeneity.

Health status and mortality were daily recorded. No blood chemistry and hematological measurement during the experiment were performed.

All turkeys were weighed individually at 28 days. At the end of the experiment, the birds were weighed individually and then sacrificed and necropsied. Liver, kidneys, spleen, heart, lungs, pancreas and digestive tract were examined.

The individual feed intakes were recorded for the whole period.

The influence of enzyme addition in diet on performance parameters at 28 days of age is shown in Table 2.

Table 2 Performance parameters of male turkeys (from day 1 to 28) receiving feed supplemented with Quatrazyme HP®

| Level of inclusion of Quatrazyme HP® | Body weights (g) | Feed intake (g) | Feed conversion ratio |
|--------------------------------------|-------------------------|-----------------|----------------------------|
| Control | 970 ± 63 ^a | 1 400 ± 61 | 1.447 ± 0.084 ^a |
| 20 mg/kg | 1 010 ± 61 ^b | 1 410 ± 55 | 1.401 ± 0.088 ^b |
| 300 mg/kg | 1 014 ± 56 ^b | 1 414 ± 54 | 1.397 ± 0.068 ^b |

*Values in the same column followed by different letters are significantly different at $P \leq 0.05$

No adverse effects were noted when Quatrazyme HP® was consumed by the turkeys at 10 times the maximum recommended dose during the 28 days of the experiment. There was a significant difference in the body weight between control and birds fed with 20 and 300 mg/kg; however no difference between treated groups was observed. No difference in the feed intake was observed between groups. Feed conversion ratio was significantly different between control and Quatrazyme HP® supplemented groups. Macroscopic examination did not reveal treatment-related effects by the supplementation of diets with Quatrazyme HP® at doses of 20 and 300 mg/kg.

3.3. Conclusion

Based on the data performed in male turkeys for fattening, the SCAN can conclude that Quatrazyme HP was well tolerated at ten times the maximum recommended dose and is therefore safe for the turkeys for fattening when used at the recommended dose.