

SCIENTIFIC OPINION

Safety and efficacy of Natugrain[®] Wheat TS (endo-1,4- β -xylanase) for use as feed additive for chickens for fattening and ducks¹

Scientific Opinion of the Panel on Additives and Products or Substances used in Animal Feed

(Question No EFSA-Q-2008-418)

Adopted on 17 June 2009

PANEL MEMBERS

Gabriele Aquilina, Georges Bories, Paul Brantom, Francesca Caloni, Andrew Chesson, Pier Sandro Cocconcelli, Noël Dierick, Mikolaj Antoni Gralak, Jürgen Gropp, Ingrid Halle, Nils-Gunnar Ilbäck, Joop de Knecht, Reinhard Kroker, Peadar Lawlor, Lubomir Leng, Sven Lindgren, Anne-Katrine Lundebye Haldorsen, Alberto Mantovani, Miklós Mézes, Derek Renshaw, Maria Saarela

SUMMARY

Following a request from the European Commission, the European Food Safety Authority (EFSA) was asked to deliver a scientific opinion on the safety and efficacy of Natugrain[®] Wheat TS (endo-1,4- β -xylanase) when used as a feed additive for chickens for fattening and ducks.

The additive Natugrain[®] Wheat TS is a preparation of endo-1,4- β -xylanase produced by a genetically modified strain of *Aspergillus niger*. This product is authorised as a feed additive for chickens and turkeys for fattening. EFSA has previously issued an opinion on the safety of this product for chickens for fattening, including the assessment of the safety for the consumer, the user and the environment, as well as the safety aspects of the genetic modifications.

The additive is presented in two formulations: Natugrain[®] Wheat TS for the solid form and Natugrain[®] Wheat TS L for the liquid form.

The product is intended for use as a feed additive in chickens for fattening and ducks, fed with feed containing high contents of non-starch polysaccharides, at a minimum dose of 280 TXU kg⁻¹ complete feed.

The solid (Natugrain[®] Wheat TS) and liquid (Natugrain[®] Wheat TS L) forms of the product are considered to be equivalent in terms of safety and efficacy at the same dose.

¹ For citation purposes: Scientific Opinion of the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) on a request from the European Commission on the safety and efficacy of Natugrain[®] Wheat TS (endo-1,4- β -xylanase) as feed additive for chickens for fattening and ducks. *The EFSA Journal* (2009) 1155, 1-14

Natugrain[®] Wheat TS is considered to be safe in chickens and ducks for fattening under the conditions of use proposed.

The safety for the consumer and for the user has been previously assessed by the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) and its conclusions are still valid: there are no concerns for the consumer safety, while for the user precautions are recommended to avoid dermal and inhalation exposure.

The active agent of Natugrain[®] Wheat TS is a protein and as such will be degraded/inactivated during the passage through the digestive tract of animals. Therefore, no risk for the environment is expected.

The efficacy of the product was demonstrated in three trials, in which supplementation with 560 TXU kg⁻¹ of Natugrain[®] Wheat TS significantly improved the weight gain and/or feed to gain ratio of chickens for fattening. There is also some evidence of the efficacy of this product in chickens for fattening at 280 TXU kg⁻¹, although this was insufficient to meet the formal requirements. Efficacy is also assumed in ducks for fattening at 560 TXU kg⁻¹, based on the efficacy for chickens and turkeys for fattening.

Key words: zootechnical additive, digestibility enhancer, endo-1,4- β -xylanase, chickens for fattening, ducks, safety, efficacy

TABLE OF CONTENTS

Panel Members	1
Summary	1
Table of Contents	3
Background	4
Terms of reference.....	4
Acknowledgements	5
Assessment	8
1. Introduction	8
2. Characterisation	8
2.1. Characterisation of the product.....	8
2.2. Qualitative and quantitative composition	8
2.3. Stability and homogeneity	9
2.3.1. Stability of Natugrain Wheat TS	9
2.3.2. Stability of Natugrain Wheat TS L.....	9
2.3.3. Homogeneity	9
2.4. Conditions of use	10
2.5. Evaluation of the analytical methods by the Community Reference Laboratory (CRL).....	10
3. Safety.....	10
3.1. Safety for chickens for fattening.....	10
3.1.1. Conclusions on the safety for the target species.....	10
3.2. Safety for the consumer	10
3.3. Safety for the user	11
3.4. Safety for the environment.....	11
4. Efficacy.....	11
4.1. Efficacy for chickens for fattening	11
4.1.1. Conclusions on the efficacy for the target species.....	12
5. Post-market monitoring	12
Conclusions	12
Documentation provided to EFSA	13
References	13
Appendix	14

BACKGROUND

Regulation (EC) No 1831/2003² establishes the rules governing the Community authorisation of additives for use in animal nutrition. In particular, Article 4(1) of that Regulation lays down that any person seeking authorisation for a feed additive or for a new use of a feed additive shall submit an application in accordance with Article 7. Article 10(2) of that Regulation also specifies that for existing products within the meaning of Article 10(1), an application shall be submitted in accordance with Article 7, at the latest one year before the expiry date of the authorisation given pursuant to Directive 70/525/EEC for additives with a limited authorisation period, and within a maximum of seven years after the entry into force of this Regulation for additives authorised without time limit or pursuant to Directive 82/471/EEC.

The European Commission received a request from the company BASF SE³ for the re-evaluation of the product Natugrain® Wheat TS as a feed additive for chickens for fattening and for the authorisation of Natugrain® Wheat TS as feed additive for ducks (category: zootechnical; functional group: digestibility enhancer) under the conditions mentioned in Table 1.

According to Article 7(1) of Regulation (EC) No 1831/2003, the Commission forwarded the application to the European Food Safety Authority (EFSA) as an application under Article 10(2) (re-evaluation of an existing feed additive), and under Article 4(1) (authorisation of a feed additive or new use of a feed additive). EFSA received directly from the applicant the technical dossier in support of this application.⁴ According to Article 8 of that Regulation, EFSA, after verifying the particulars and documents submitted by the applicant, shall undertake an assessment in order to determine whether the feed additive complies with the conditions laid down in Article 5. The particulars and documents in support of the application were considered valid by EFSA as of 10 October 2008.

The additive Natugrain® Wheat TS is a preparation of endo-1,4- β -xylanase (E.C. 3.2.1.8) produced by a genetically modified strain of *Aspergillus niger* (CBS 109.713). The FEEDAP Panel issued an opinion on the safety of Natugrain Wheat + (former name of the product) as feed additive for chickens for fattening (EFSA, 2005), and on the safety and efficacy of Natugrain® Wheat TS as feed additive for turkeys for fattening (EFSA, 2007).

This product is provisionally authorised as a feed additive for chickens for fattening (until 29 September 2009),⁵ and for use for turkeys for fattening (until 17 December 2017).^{6,7} The applicant is now seeking for the re-evaluation of the product as feed additive for chickens for fattening and for an extension of use to ducks.

TERMS OF REFERENCE

According to Article 8 of Regulation (EC) No 1831/2003, EFSA shall determine whether the feed additive complies with the conditions laid down in Article 5. EFSA shall deliver an opinion on the efficacy and the safety for the target animal(s), user and consumer and the environment of the product Natugrain® Wheat TS, containing endo-1,4- β -xylanase produced by a genetically modified strain of *Aspergillus niger* (CBS 109.713), when used under the conditions described in Table 1.

² OJ L 268, 18.10.2003, p.29

³ BASF SE, 67056 Ludwigshafen, Rhein, Germany

⁴ Dossier reference:FAD-2008-0023

⁵ OJ L 233, 09.09.2005, p. 3

⁶ OJ L 309, 27.11.2007, p. 21

⁷ Corrigenda OJ L 310, 28.11.2007, p.22

ACKNOWLEDGEMENTS

The European Food Safety Authority wishes to thank the Working Group on Enzymes as well as Friedrich Schöne and Pieter Wester for the preparation of this opinion.

Table 1. Description and conditions of use of the additive as proposed by the applicant

Additive	Endo-1,4-beta-xylanase
Registration number/EC No/No (if appropriate)	no. 4a 62
Category of additive	Zootechnical additive
Functional group of additive	Digestibility enhancers

Description			
Composition, description	Chemical formula	Purity criteria (if appropriate)	Method of analysis (if appropriate)
Endo-1,4-beta-xylanase EC 3.2.1.8	Preparation of endo-1,4-beta-xylanase produced by <i>Aspergillus niger</i> (CBS 109.713) having a minimum activity of: Solid form: 5600 TXU ⁸ g ⁻¹ Liquid form: 5600 TXU g ⁻¹	-	-

Trade name (if appropriate)	Natugrain® Wheat TS
Name of the holder of authorisation (if appropriate)	BASF SE, 67056 Ludwigshafen/Germany

Conditions of use				
Species or category of animal	Maximum Age	Minimum content	Maximum content	Withdrawal period (if appropriate)
		Units of activity kg ⁻¹ of complete feedingstuffs		
<i>Chickens for fattening</i>		280 TXU		
<i>Ducks</i>		280 TXU		

Other provisions and additional requirements for the labelling	
Specific conditions or restrictions for use (if appropriate)	<ol style="list-style-type: none"> <i>In the directions of use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.</i> <i>Recommended dose per kilogram of complete feedingstuff:</i>

⁸ 1 TXU is the amount of enzyme which liberates 5 micromole of reducing sugars (xylose equivalents) from wheat arabinoxylan per minute at pH 3,5 and 55°C.

	<p><i>Chickens for fattening: 280 – 800 TXU</i></p> <p><i>Ducks: 280 – 800 TXU</i></p> <p>3. <i>For use in compound feed rich in non-starch polysaccharides (mainly beta-glucans and arabinoxylans), e.g. containing more than 40 % wheat</i></p>
Specific conditions or restrictions for handling (if appropriate)	<i>not appropriate</i>
Post market monitoring (if appropriate)	<i>BASF has a general traceability system and a complaint procedure in place. An emergency telephone number is printed on each label.</i>
Specific conditions for use in complementary feedingstuffs (if appropriate)	<i>not appropriate.</i>

Maximum Residue Limit (MRL) (if appropriate)			
Marker residue	Species or category of animal	Target tissue(s) or food products	Maximum content in tissues
Not appropriate	-	-	-

ASSESSMENT

1. Introduction

The additive Natugrain® Wheat TS is a preparation of endo-1,4- β -xylanase (E.C. 3.2.1.8) produced by a genetically modified strain of *Aspergillus niger*. The production strain has been taxonomically identified by the Centraalbureau voor Schimmelcultures (CBS 109.713).

This product is authorised as a feed additive for chickens for fattening (until 29 September 2009). EFSA issued an opinion on the safety of this product for chickens for fattening, including the assessment of the safety for the consumer, the user and the environment, as well as the safety aspects of the genetic modifications (EFSA, 2005).

The applicant is now seeking for the re-evaluation of the product as feed additive for chickens for fattening and for an extension of use to ducks.

2. Characterisation

2.1. Characterisation of the product

The safety of the production strain *Aspergillus niger* (CBS 109.713) and the consequences of its genetic modification were previously assessed by EFSA (2005) and considered not to introduce concerns.

2.2. Qualitative and quantitative composition

The additive is presented in two different formulations, liquid (Natugrain® Wheat TS L) and solid (Natugrain® Wheat TS), both ensuring a minimum activity ≥ 5600 TXU g⁻¹. The liquid formulation contains 5 to 10 % of the liquid enzyme concentrate, with sorbitol, glycerol and sodium benzoate as excipients. The solid formulation contains 1-5 % of the solid enzyme concentrate, middlings as carrier, vegetable oil and magnesium sulphate.

A study⁹ of the batch to batch variation of the enzymatic activity in the final product (three batches) showed that the coefficient of variation of the enzymatic activity is 3.6% in the liquid form and 3.8% in the solid form. The mean enzymatic activity found in the batches evaluated was 6176 and 6190 TXU g⁻¹ for the liquid and the solid formulations, respectively.

Natugrain® Wheat TS L is a light brown to brown liquid that shows a density of 1.1–1.3 g mL⁻¹, with a pH of approximately of 3.4 and a viscosity of 20.3 mPa s⁻¹ at 20 °C. Natugrain® Wheat TS has a bulk density of approximately 0.35 g mL⁻¹, and more than the 90 % of the particles have a particle size ≤ 800 μ m, with 5.2 % < 100 μ m, 2.8 % < 50 μ m and 0.14 % < 10 μ m.¹⁰

Compliance with the joint FAO/Expert Committee on Food Additives (JECFA, 2006) specifications for enzymes on chemical (Pb, Cd, Hg and As) and microbiological (total coliforms, *Salmonella*, *E. coli*) purity criteria, antimicrobial activity and mycotoxins content (aflatoxins B1, B2, G1, G2, diacetoxyscirpenol, 3-acetyldeoxynivalenol, 15-acetyldeoxynivalenol, fusarenone X, sterigmatocystin, nivalenol, neosolaniol, T2 triol, in the ultrafiltrate, ochratoxin A, deoxynivalenol, zearalenone, HT2 toxin and T2 toxin in both the ultrafiltrate and final product) were proven in the ultra-filtrated enzyme (one batch)¹¹ and in the

⁹ Technical Dossier/Section II/Register 37a

¹⁰ Technical Dossier/Section II/Register 38

¹¹ Technical Dossier/Section II/Register 2

final product (three batches of each formulation).¹² The absence of the production strain was demonstrated in three batches of the final product.

2.3. Stability and homogeneity

2.3.1. Stability of Natugrain Wheat TS

The stability of Natugrain[®] Wheat TS was tested at 20 and 35 °C.¹³ Samples were monitored up to 52 weeks. The recovery of the enzyme activity was approximately 90 % of the initial activity when kept at 20 °C for 52 weeks. When stored at 35 °C, recovery was 80 % after 12 weeks and 70 % after 52 weeks.

The stability of Natugrain[®] Wheat TS in premixtures was studied when added to a premixture (containing trace elements) at 900 TXU g⁻¹ (three batches). After 26 weeks, kept at temperatures ranging from 20 to 25 °C, the recovery of the initial enzymatic activity was of 98 %.¹⁴

The stability of Natugrain[®] Wheat TS in mash feed (based on maize and soybean meal) was studied in three batches (two batches supplemented at 540 TXU kg⁻¹ and one at 280 TXU kg⁻¹) kept at 20 °C for up to four months. The recovery after four months was 99 % for those supplemented at 540 TXU kg⁻¹ and 91 % for that supplemented at 280 TXU kg⁻¹.¹⁵

The stability of Natugrain[®] Wheat TS to pelleting (86 °C, 16 % RH, 30s) was measured in one batch.¹⁶ The complete feed was based on maize and soybean meal and was supplemented at 2369 TXU kg⁻¹. At the end of the pelleting process, 74 % of the enzyme activity remained.

The stability of Natugrain[®] Wheat TS in pelleted feed (composition and supplementation were not provided) stored up to four months was studied in three batches when kept at 20 °C. The recovery of the initial values after four months was 98 %.

2.3.2. Stability of Natugrain Wheat TS L

The stability of Natugrain[®] Wheat TS L was tested at 4, 20 and 35 °C.¹⁷ Samples were monitored up to 44 weeks. The recovery ranged between 86–97 % after 44 weeks of storage.

The stability of Natugrain[®] Wheat TS L when sprayed at a concentration of 9000 TXU kg⁻¹ to pelleted feed was studied.¹⁸ The results after four weeks of storage at either 20 or 35 °C showed a 91 % of enzyme recovery.

2.3.3. Homogeneity

The homogeneity of Natugrain[®] Wheat TS when mixed in premixtures was tested in a mineral premix for poultry (three batches). The enzyme recovery was 88 % of the intended dose and the coefficient of variation was 9.2 %.

The homogeneity of Natugrain[®] Wheat TS (two batches) was further tested in a broiler feed at 6600 TXU kg⁻¹.¹⁹ The recovery, in six samples, was 108 % and the coefficient of variation was 2.4 %. However, the supplementation was eight times the maximum recommended dose.

¹² Technical Dossier/Section II/Register 37a

¹³ Technical Dossier/Section II/Register 41 and 47

¹⁴ Supplementary information February 2009/Reg04

¹⁵ Supplementary information February 2009/Reg04

¹⁶ Technical Dossier/Section II/Register 42

¹⁷ Technical Dossier/Section II/Register 41 and 47

¹⁸ Technical Dossier/Section II/Registers 45

2.4. Conditions of use

Natugrain[®] Wheat TS, in both formulations, is intended for use as feed additive in chickens for fattening and ducks fed with feed containing high contents of non-starch polysaccharides. The dosage proposed is the following: minimum dose of 280 TXU kg⁻¹ and maximum dose of 800 TXU kg⁻¹ complete feed in chickens for fattening and ducks.

2.5. Evaluation of the analytical methods by the Community Reference Laboratory (CRL)

EFSA has verified the CRL report as it relates to the method used for the control of the active substance in animal feed. The Executive Summary of the CRL report can be found in the Appendix.

3. Safety

3.1. Safety for chickens for fattening

A tolerance study²⁰ was conducted with chickens for fattening over a 35-day period with wheat and barley-based diets (starter and finisher). The product tested also contained β -glucanase (2500 TGU g⁻¹). However, the origin and concentration of the β -xylanase contained in the tested product was identical to that contained in the Natugrain[®] Wheat TS. The basal diets (starter and finisher) were supplemented at 0, 280, 840 and 84000 TXU kg⁻¹ feed (minimum recommended dose: 280 TXU kg⁻¹, maximum recommended dose: 800 TXU kg⁻¹); the 84000 TXU kg⁻¹ dose was achieved by using a concentrated form of the enzyme preparation. The enzyme activities were confirmed by analysis. Feed intake, daily weight gain and feed to gain ratio of the chickens were measured and calculated. Mortality and health status were monitored throughout the experiment.

There were no adverse effects observed on animal health status (mortality: 4.4, 3.9, 8.9 and 3.9 %) or performance (body weight at 35 days: approximately 2.3 kg).

3.1.1. Conclusions on the safety for the target species

Based on the data provided it is concluded that Natugrain[®] Wheat TS is safe for chickens for fattening at the maximum recommended dose (800 TXU kg⁻¹). No specific tolerance study was performed in ducks. However, given the fact that the safety of Natugrain[®] Wheat TS has been established in chickens for fattening (100-fold) and in turkeys for fattening (EFSA, 2007; 100-fold), the safety for ducks for fattening can be assumed based on the tolerance trials in the major species.

3.2. Safety for the consumer

The safety for the consumer has been previously assessed by EFSA (2005). In the absence of new data that would make the Panel reconsider its previous assessment, the conclusions of that opinion are still considered valid:

¹⁹ Supplementary information February 2009/Reg04

²⁰ Supplementary information February 2009/Reg07

‘All of the studies required (...) for an enzyme product have been adequately conducted and show no evidence of any effects that would be of concern regarding consumer safety. The NOAEL established by the 90-day study is 6400 mg kg⁻¹ (BW) day⁻¹. It should be noted that the material tested in the toxicological studies is 20 times more concentrated than that in normal commercial use thus this provides a further significant safety margin.’

3.3. Safety for the user

The safety for the user has been previously assessed by EFSA (2005) and was based on studies on dermal and eye irritation and assumptions of a potential for sensitisation. In the absence of new data that would make the Panel reconsider its previous assessment the conclusions of that opinion are still considered valid:

‘The product is not considered to present a risk to users provided appropriate protective measures are employed to avoid dermal exposure and inhalation of dusts or aerosols.’

3.4. Safety for the environment

The active ingredient of Natugrain® Wheat TS is a protein and as such will be degraded/inactivated during the passage through the digestive tract of animals. Therefore, no risks for the environment are expected and no further environmental risk assessment is required.

4. Efficacy

4.1. Efficacy for chickens for fattening

Five performance trials were provided by the applicant to support the efficacy of Natugrain® Wheat TS in chickens for fattening. Two of the trials were not considered due to the short duration of the experimental period.²¹ The design and main results of the overall experimental period of the three remaining trials are summarised in Table 2.

In general, the chickens for fattening had a similar genetic background (Ross Strain). In the first trial, male chickens were used, while in trial 2 and 3 both males and females were used. The birds were kept in floor pens in all the trials. A basal diet based on wheat and soybean meal, including rye in trials 1 and 3, was taken as a control and was supplemented with Natugrain® Wheat TS (solid formulation) at different doses. In all cases, analyses were carried out to confirm the intended doses. The aim of the experiments was to study the performance of the birds when fed the product; feed intake and body weight were measured, and feed to gain ratio calculated.

In all trials, mortality was within the normal ranges and not affected by the experimental treatments. In trials 2 and 3, the weight gain and feed conversion rate were improved at the minimum recommended dose (280 TXU kg⁻¹), while in trial 1 the feed conversion rate was improved at 560 TXU kg⁻¹.

Table 2. Summary of the performance trials on the efficacy of Natugrain® Wheat TS in chickens

Trial Sex	Total No of animals	Trial duration	Basal diet	Natugrain® Wheat TS	Weight gain ²	Feed/gain (g g ⁻¹)	Mortality n (%) ³
--------------	------------------------	-------------------	------------	------------------------	-----------------------------	-----------------------------------	---------------------------------

²¹ Technical Dossier/Efficacy/Reg. La -Lb and Ma-Mb

	(replicates/ treatment x birds/replicate)	(days)		(TXU kg ⁻¹ feed) ¹			
				0 (<60, <60)	2100	1.59 ^{ab}	-
1 ²² ♂	540 (6 x 15)	40 ⁴	Wheat	140 (<60, 103)	2090	1.60 ^a	-
			Soybean meal	280 (180, 206)	2099	1.56 ^{bc}	-
			rye	560 (380, 402)	2153	1.55 ^{cd}	-
				1120 (786, 840)	2101	1.56 ^{bc}	-
				11200 (7900, 8980)	2098	1.53 ^d	-
2 ²³ ♂/♀	720 (12 x 20)	35	Wheat	0 (0, 0, 0)	56.4 ^b	1.88 ^a	17 (7.1)
			Soybean meal	280 (110, 127, 162)	61.0 ^a	1.70 ^b	5 (2.1)
				560 (281, 271, 192)	60.9 ^a	1.72 ^b	11 (4.6)
3 ²⁴ ♂/♀	720 (12 x 20)	35	Wheat	0 (0, 0, 0)	52.2 ^b	1.93 ^a	16 (6.7)
			Soybean meal	280 (107, 127, 132)	59.8 ^a	1.75 ^b	7 (2.5)
			rye	560 (236, 280, 259)	59.9 ^a	1.73 ^b	7 (2.9)

¹ Within brackets the measured enzyme activity for the two or three diets administered to the birds.

² Weight gain as g bird⁻¹ for Trial 1 and as g bird⁻¹ day⁻¹ for Trial 2 and 3.

³ Mean mortality in trial 1 was 2 % . In trial 2 and 3 values include culled animals.

⁴ Starting with 4 days adaptation period.

^{a, b, c, d} Means within a column for a given trial not sharing a common superscript are significantly different (P < 0.05).

4.1.1. Conclusions on the efficacy for the target species

The efficacy in chickens for fattening was demonstrated in three trials in which supplementation with 560 TXU kg⁻¹ of Natugrain® Wheat TS significantly improved weight gain and/or feed to gain ratio. There is also some evidence of the efficacy of this product in chickens for fattening at 280 TXU kg⁻¹, although this was insufficient to meet the formal requirements.

With the present data, the efficacy of Natugrain® Wheat TS has been demonstrated in chickens for fattening at 560 TXU kg⁻¹. The efficacy of Natugrain® Wheat TS in turkeys for fattening was also demonstrated at this dose (EFSA, 2007). The FEEDAP Panel considers the mode of action of xylanases to be the same in ducks as in chickens and turkeys for fattening. Thus, no further demonstration of efficacy in this minor species is needed. Therefore, the efficacy of Natugrain® Wheat TS in ducks for fattening can be assumed at 560 TXU kg⁻¹.

The solid (Natugrain® Wheat TS) and liquid (Natugrain® Wheat TS L) forms of the product are considered to be equivalent in terms of efficacy at the same dose.

5. Post-market monitoring

No risks associated with the use of the product are foreseen. It is considered that there is no need for specific requirements for a post-market monitoring plan other than those established in the Feed Hygiene Regulation²⁵ and Good Manufacturing Practice.

CONCLUSIONS

The solid and liquid forms of the product are considered to be equivalent in terms of safety and efficacy at the same dose.

Natugrain® Wheat TS is considered to be safe in chickens and ducks for fattening under the conditions of use proposed.

²² Technical Dossier/Efficacy/Reg. NOa and Nob

²³ Technical Dossier/Efficacy/Reg. PQa and PQb

²⁴ Technical Dossier/Efficacy/Reg. Ra and Rb

²⁵ OJ L 35, 8.2.2005, p.1

The safety for the consumer and the user has been previously assessed by the FEEDAP Panel and its conclusions are still valid: there are no concerns for the consumer safety while for the user precautions are recommended to avoid dermal and inhalation exposure.

The active agent of Natugrain[®] Wheat TS is a protein and as such will be degraded/inactivated during the passage through the digestive tract of animals. Therefore, no risk for the environment is expected.

The efficacy of the product was demonstrated in three trials, in which supplementation with 560 TXU kg⁻¹ of Natugrain[®] Wheat TS significantly improved the weight gain and/or feed to gain ratio of chickens for fattening. There is also some evidence of the efficacy of this product in chickens for fattening at 280 TXU kg⁻¹, although this was insufficient to meet the formal requirements. Efficacy is also assumed in ducks for fattening at 560 TXU kg⁻¹, based on the efficacy for chickens and turkeys for fattening.

DOCUMENTATION PROVIDED TO EFSA

1. Natugrain[®] Wheat TS for chickens for fattening and ducks. June 2008. Submitted by BASF SE.
2. Supplementary information on Natugrain[®] Wheat TS for chickens for fattening and ducks. February 2009. Submitted by BASF SE.
3. Evaluation report of the Community Reference Laboratory for Feed Additives on the methods(s) of analysis for Natugrain Wheat TS and Natugrain Wheat TS L.
4. Comments from Member States received through the ScienceNet.

REFERENCES

- EFSA (European Food Safety Authority), 2005. Opinion on the Scientific Panel on Additives and Products or Substances used in Animal Feed on a request from the Commission on the safety of the enzyme preparation Natugrain Wheat + for chickens for fattening. *The EFSA Journal* (2005) 198, 1-8.
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620782150.htm
- EFSA (European Food Safety Authority), 2007. Opinion on the Scientific Panel on Additives and Products or Substances used in Animal Feed on the safety and efficacy of the enzymatic preparation Natugrain[®] Wheat TS (endo-1,4-beta-xylanase) as a feed additive for turkeys for fattening according to Regulation (EC) No 1831/2003. *The EFSA Journal* (2007) 474, 1-11.
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620781683.htm
- Joint FAO//WHO Expert Committee on Food Additives (JECFA), 2006. General Specifications and Considerations for Enzyme Preparations Used in Food Processing. Compendium of food additive specifications. FAO JECFA monographs 3.

APPENDIX

Executive Summary of the Evaluation Report of the Community Reference Laboratory for Feed Additives on the Method(s) of Analysis for Natugrain Wheat TS and Natugrain Wheat TS L

In the current application authorisation is sought for *Natugrain Wheat TS* and *Natugrain Wheat TS L*, in accordance with article 4(1) and 10(2) of Regulation (EC) No 1831/2003. Authorisation is sought to use *Natugrain Wheat TS* and *Natugrain Wheat TS L* as a digestibility enhancer for chicken for fattening and ducks under the category 'zootechnical additives' and the functional group 4(a), according to the classification system of Annex I of Regulation (EC) No 1831/2003.

The active agent of *Natugrain Wheat TS* and *Natugrain Wheat TS L* is thermostable endo-1,4- β -xylanase, produced by a strain of *Aspergillus niger*-CBS 109.713. The additive is intended to be marketed as powder (*Natugrain Wheat TS*) and as liquid formulation (*Natugrain Wheat TS L*). Both formulations contain an endo-1,4- β -xylanase activity of 5600 TXU/g product. They are intended to be mixed into *premixtures* and/or *feedingstuffs* to obtain a recommended endo-1,4- β -xylanase activity level ranging from 280 to 800 TXU per kg *feedingstuffs*. Enzymatic activity of endo-1,4- β -xylanase is expressed in thermostable xylanase units (TXU). One TXU is defined as the amount of enzyme that liberates 5 μ mol of reducing sugars (xylose equivalents) from wheat arabinoxylan per minute at pH = 3.3 and 55°C.

For the determination of the activity of endo-1,4- β -xylanase in the *feed additive*, *premixtures* and *feedingstuffs*, the applicant proposes an *in-house* validated viscosimetric method. Endo-1,4- β -xylanase catalyses the hydrolysis of glycosidic bonds in the substrate wheat arabinoxylan to yield xylose and reduces consequently the viscosity of sample solution. The decrease in viscosity of sample solution, expressed in terms of a drop time, is a measure for the endo-1,4- β -xylanase activity and is determined using a falling ball viscosimeter at pH = 3.3 and 55°C. The quantification is performed using an endo-1,4- β -xylanase standard curve based on reference enzyme with known activity provided by the applicant. The method performance characteristics, determined for the *feed additive*, *premixtures* and *feedingstuffs* matrices are: - a relative standard deviation for repeatability (RSD_r) ranging from 2.4 to 5.7%; - a relative intermediate precision (RSD_R) ranging from 3.4 to 11.8%; - a recovery rate ranging from 82 to 115%; - a limit of detection (LOD) of 11 TXU/kg *feedingstuffs* and - a limit of quantification (LOQ) of 36 TXU/kg *feedingstuffs*.

Based on acceptable performance characteristics, the applicant method is considered to be suitable for official control purposes in the frame of authorisation.

Further testing or validation is not considered necessary.