

SCIENTIFIC OPINION

Scientific Opinion on the safety and efficacy of Natuphos[®] (3-phytase) for minor avian species (quails, pheasants, partridges, guinea fowl, geese, pigeons, ostriches, peacocks, flamingos) and ornamental birds¹

EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP)^{2,3}

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ABSTRACT

The additive Natuphos[®] is a preparation of 3-phytase produced by a genetically modified strain of *Aspergillus niger*. The product is currently authorised in the EU as a zootechnical feed additive for chickens and turkeys for fattening, laying hens, ducks, piglets, pigs for fattening and sows. The applicant is now asking for an extension of use to minor avian species and ornamental birds. The safety of phytase from Natuphos[®] has been previously established in physiologically similar major poultry species with a margin of safety of more than ten times the respective maximum recommended doses. Therefore, considering the established mode of action of phytase and the wide margin of safety shown in the species evaluated, the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) considers that Natuphos[®] is safe for minor avian species and ornamental birds at the maximum recommended dose (500 FTU/kg). Similarly, the efficacy of Natuphos[®] in physiologically related major species has already been established. The mode of action of phytase can be reasonably assumed to produce the same effect in the major and minor avian species. Taking this into account and the experimental evidence provided in a balance study with geese, which showed an effect at 150 FTU/kg, the FEEDAP Panel concludes that the efficacy of Natuphos[®] in minor avian species and ornamental birds can be assumed at the dose of 250 FTU/kg complete feed.

KEY WORDS

Zootechnical additive, digestibility enhancer, 3-phytase, minor avian species, ornamental birds, safety, efficacy

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SUMMARY

Following a request from European Commission, the European Food Safety Authority (EFSA) was asked to deliver a scientific opinion on the safety and efficacy for the additive Natuphos[®] as feed additive for minor avian species (including quails, pheasants, partridges, guinea fowl, geese, pigeons, ostriches, peacocks, flamingos) and ornamental birds.

The additive Natuphos[®] is a preparation of 3-phytase produced by a genetically modified strain of *Aspergillus niger*. The product is currently authorised in the EU as zootechnical feed additive (digestibility enhancer) for chickens and turkeys for fattening, laying hens, ducks, piglets, pigs for fattening and sows. The applicant is now asking for an extension of use of the product to minor avian species and ornamental birds.

The safety of phytase from Natuphos[®] has been previously established in physiologically similar major poultry species, both in growing (chickens and turkeys) and laying birds, with a margin of safety of more than ten times the respective maximum recommended doses. Therefore, considering the well-known mode of action of phytase, and the wide margin of safety shown in the species evaluated, the FEEDAP Panel considers that Natuphos[®] is safe for minor avian species and ornamental birds at the maximum recommended dose (500 FTU/kg).

The efficacy of Natuphos[®] in physiologically related major species has already been established at a minimum effective dose of 375 FTU/kg for chickens for fattening and 250 FTU/kg for turkeys for fattening and laying hens. The mode of action of phytase is well-known and can be reasonably assumed to produce the same effect in the major and minor avian species. Taking this into account and the experimental evidence provided in a balance study with geese, which showed an effect at 150 FTU/kg, the FEEDAP Panel concludes that the efficacy of Natuphos[®] in minor avian species and ornamental birds can be assumed at the dose of 250 FTU/kg complete feed.

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BACKGROUND

Regulation (EC) No 1831/2003⁴ 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.

The European Commission received a request from the company BASF SE⁵ for authorisation of the product Natuphos[®], 3-phytase, to be used as a feed additive for minor avian species (quails, pheasants, partridges, guinea fowl, geese, pigeons, ostriches, peacocks, flamingos) and ornamental birds (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 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.⁶ 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 7 September 2009.

The additive Natuphos is a preparation of 3-phytase (EC 3.1.3.8) produced by *Aspergillus niger* (CBS 101.672). This product is authorised (4a 1600) for use in piglets, pigs for fattening and chickens for fattening (until 2 April 2017),⁷ laying hens and turkeys for fattening (until 22 October 2017)⁸, ducks (until 14 March 2018)⁹ and sows (until 27 June 2018).¹⁰

The Scientific Committee on Animal Nutrition (SCAN) issued two opinions on the efficacy and safety of this enzyme preparation: one for piglets, pigs for fattening, sows, chickens for fattening and laying hens (SCAN, 2000), and the other for the same target species and the user, consumer and environment (SCAN, 2002). EFSA issued an opinion on the safety and efficacy of the enzyme preparation when the production strain was modified and for the use of new liquid and solid formulations with a double concentration compared to that of the preparation previously authorised (EFSA 2006); this opinion included the assessment of the safety for the consumer, the user and the environment, as well as the safety aspects of the genetic modification. EFSA adopted opinions on the safety of the enzyme preparation for laying hens and turkeys for fattening (EFSA, 2007a) and for sows (EFSA, 2007c), and on the efficacy and safety of the product as a feed additive for ducks (EFSA, 2007b). Finally, EFSA released an opinion on the modification of the conditions of use in pigs for fattening (EFSA, 2009).

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 species, consumer, user and the environment of the product Natuphos[®], 3-phytase, when used under the conditions described in Table 1.

⁴ OJ L 268, 18.10.2003, p.29

⁵ BASF SE, Ludwigshafen/Rhein 67056, Germany.

⁶ EFSA Dossier reference: FAD-2009-0016

⁷ OJ L 73, 13.3.2007, p.4

⁸ OJ L 256, 2.10.2007, p.20

⁹ OJ L 50, 23.2.2008, p.8

¹⁰ OJ L 149, 7.6.2008, p.33

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

Additive	3-phytase
Registration number/EC No/No (if appropriate)	4a1600
Category(-ies) of additive	4.Zootechnical additives
Functional group(s) of additive	(a) Digestibility enhancers

Description			
Composition, description	Chemical formula	Purity criteria (if appropriate)	Method of analysis (if appropriate)
3-phytase EC 3.1.3.8	<p>Additive composition:</p> <p>Preparation of 3-phytase produced by <i>Aspergillus niger</i> (CBS 101.672) having a minimum activity of:</p> <p>Solid form: 5000 – 10000 FTU(1)/g</p> <p>Liquid form: 5000 – 10000 FTU/ml</p> <p>(1) 1 FTU is the amount of enzyme which liberates 1 micromole of inorganic phosphate per minute from sodium phytate at pH 5.5 and 37°C.</p>	-	<p>Analytical methode(2):</p> <p>Colorimetric method measuring inorganic phosphate released by the enzyme from phytate substrate</p> <p>(2) Details of the analytical method are available at the following address of the Community Reference Laboratory: www.irmm.jrc.be/html/crlf_aa/</p>

Trade name (if appropriate)	Natuphos®
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/kg of complete feedingstuffs		
Other minor bird species Ornamental birds	-	250 FTU	-	-

Other provisions and additional requirements for the labelling																			
Specific conditions or restrictions for use (if appropriate)	<p>1. Weaned piglets until approx. 35 kg</p> <p>2. In the directions of use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.</p> <p>3. Recommended dose per kilogram of complete feedingstuff:</p> <table border="0"> <tr> <td>Piglets:</td> <td>500 FTU</td> </tr> <tr> <td>Pigs for fattening:</td> <td>100 FTU*</td> </tr> <tr> <td>Sows:</td> <td>500 FTU</td> </tr> <tr> <td>Chickens for fattening:</td> <td>375 FTU</td> </tr> <tr> <td>Laying hens:</td> <td>250 FTU</td> </tr> <tr> <td>Turkeys for fattening:</td> <td>250 FTU</td> </tr> <tr> <td>Ducks:</td> <td>300 FTU</td> </tr> <tr> <td>Other minor poultry species:</td> <td>250 FTU</td> </tr> <tr> <td>Ornamental birds:</td> <td>250 FTU</td> </tr> </table> <p>* under application, current minimum value is 280 FTU</p> <p>4. For use in compound feed containing more than 0.23 % phytin bound phosphorus, respectively 0.36 % in compound feed for sows.</p>	Piglets:	500 FTU	Pigs for fattening:	100 FTU*	Sows:	500 FTU	Chickens for fattening:	375 FTU	Laying hens:	250 FTU	Turkeys for fattening:	250 FTU	Ducks:	300 FTU	Other minor poultry species:	250 FTU	Ornamental birds:	250 FTU
Piglets:	500 FTU																		
Pigs for fattening:	100 FTU*																		
Sows:	500 FTU																		
Chickens for fattening:	375 FTU																		
Laying hens:	250 FTU																		
Turkeys for fattening:	250 FTU																		
Ducks:	300 FTU																		
Other minor poultry species:	250 FTU																		
Ornamental birds:	250 FTU																		
Specific conditions or restrictions for handling (if appropriate)	Not appropriate																		
Post-market monitoring (if appropriate)	BASF has a general traceability and a complaint procedure in place. An emergency telephone number is printed on each label.																		
Specific conditions for use in complementary feedingstuffs (if appropriate)	Not appropriate																		

Maximum Residue Limit (MRL) (if appropriate)			
Marker residue	Species or category of animal	Target tissue(s) or food products	Maximum content in tissues
-	-	-	-

ASSESSMENT

1. Introduction

The additive Natuphos[®] is a preparation of 3-phytase (EC 3.1.3.8) produced by a genetically modified strain of *Aspergillus niger* (CBS 101.672), presented in solid (granulated, G and powder) and liquid (L) forms. The three forms are presented with a concentration of 5000 FTU/g or mL and the granulated and the liquid forms are also presented with a concentration of 10000 FTU/g or mL, respectively.

The safety and efficacy of this product for piglets, pigs for fattening, sows, chickens for fattening, laying hens, turkeys for fattening and ducks, including the assessment of the safety for the consumer, the user and the environment, as well as the safety aspects of the genetic modification were previously assessed by EFSA (see background). The applicant is now asking for an extension of use of this product as a zootechnical additive for minor avian species (quails, pheasants, partridges, guinea fowl, geese, pigeons, ostriches, peacocks, flamingos) and ornamental birds, at a minimum recommended dose of 250 FTU/kg complete feedingstuff, being the recommended dosage 300–500 FTU/kg complete feedingstuffs.

The FEEDAP Panel considers that the safety aspects other than for the new target species are covered in the previous opinions and would not be affected by the requested extension of use. Therefore, the present opinion focuses only on the safety and efficacy of this enzyme preparation for the new target species.

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

The CRL considered that the conclusions and/or recommendations reached in previous assessments are still valid.

3. Safety for the target species

The safety of phytase from Natuphos[®] has been previously established in species physiologically similar to the ones that the application is made for, both in growing (chickens, turkeys and ducks, EFSA 2006, 2007a and 2007b, respectively) and laying birds (laying hens, EFSA, 2007a) with a margin of safety of more than ten times the respective maximum recommended doses. Therefore, considering the well-known mode of action of phytase, and the wide margin of safety shown in the species evaluated, the FEEDAP Panel considers that Natuphos[®] is safe for minor avian species (growing and laying) and ornamental birds at the maximum recommended dose (500 FTU/kg).

4. Efficacy for the target species

The efficacy of Natuphos[®] in physiologically related major species has already been established (SCAN 2000; EFSA 2006) at a minimum effective dose of 375 FTU/kg for chickens for fattening and 250 FTU/kg for turkeys for fattening and laying hens.

The digestibility and retention of P and Ca was investigated in 40 cannulated male geese¹¹ (Andocsi Feher strain, 4.4 kg initial body weight). A basal diet based on maize and soyabean meal without added P (0.34 % total P) was supplemented with Natuphos[®] 5000 at 0, 150, 300 and 450 FTU/kg (confirmed by analyses); a positive control with added P (0.44 % total P) was also included. After 7 days of adaptation to the diets, faeces and urine were collected during a five day period. P digestibility and retention was significantly increased already at a dose of 150 FTU/kg complete feed.

Considering that the mode of action of phytase is well-known and can be reasonably assumed to produce the same effect in the major and minor avian species and taking into account the experimental evidence provided in geese, the FEEDAP Panel concludes that the efficacy of Natuphos[®] in minor

¹¹ Technical dossier/Section IV/Reg21

avian species (e.g. quails, pheasants, partridges, guinea fowl, geese, pigeons, ostriches, peacocks, flamingos) and ornamental birds can be assumed at the dose of 250 FTU/kg complete feed.

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 Regulation¹² and Good Manufacturing Practice.

CONCLUSIONS

The FEEDAP Panel considers that use of Natuphos[®] in minor (growing and laying) avian species and ornamental birds under the proposed conditions of use is safe and effective.

DOCUMENTATION PROVIDED TO EFSA

1. Natuphos[®] for minor bird species and ornamental birds. April 2009. Submitted by BASF SE.
2. Comments from Member States received through the ScienceNet.

REFERENCES

- EFSA (European Food Safety Authority), 2006. Opinion of the Scientific Panel on Additives and Products or Substances used in Animal Feed and of the Scientific Panel on Genetically Modified Organism on the safety and efficacy of the enzyme preparation Natuphos[®] (3-phytase) produced by *Aspergillus niger*. *The EFSA Journal* (2006) 369, 1–19.
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<http://ec.europa.eu/food/fs/sc/scan/out44_en.pdf>

¹² OJ L 35, 8.2.2005, p.1

SCAN (Scientific Committee on Animal Nutrition) 2002. Opinion of the Scientific Committee on Animal Nutrition on the use of certain enzymes in animal feedingstuffs.

<http://ec.europa.eu/food/fs/sc/scan/out96_en.pdf>