SCIENTIFIC OPINION

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Safety and efficacy of Natuphos® E (6-phytase) as a feed additive for avian and porcine species

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Abstract

Natuphos® E is a feed additive that contains a 6-phytase available in powder, granulated and liquid forms which is intended to be used as a feed additive for avian and porcine species. The production strain of the phytase present in the product is a genetically modified strain of *Aspergillus niger.* The EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) concluded that the genetic modification of the production strain does not give rise to safety concerns. The production strain and its DNA were not detected in the concentrate used to formulate the products. Based on the tolerance studies provided, the Panel concluded that the additive is safe for the target species under the conditions of use with a wide margin of safety. The Panel also concluded that the use of the product as a feed additive does not give rise to concerns for consumers. Evidence was provided showing that the additive is not toxic by inhalation or irritant for skin or eyes, however, it should be regarded as a dermal sensitiser and a potential respiratory sensitiser. The use of the additive as a feed additive poses no risks to the environment. Based on the efficacy studies provided, the Panel concluded that the additive has the potential to be efficacious in chickens for fattening, turkeys for fattening, piglets, pigs for fattening and sows. These conclusions were extended to chickens reared for laying, turkeys reared for breeding and extrapolated to minor poultry species and other avian species for fattening and to the point of lay and to minor porcine species. The Panel considered that there was insufficient information to conclude on the efficacy in laying hens.

Keywords: safety, efficacy, zootechnical additives, 6-phytase, poultry and pigs

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Summary*

Following a request from the European Commission, the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) was asked to deliver a scientific opinion on the safety and efficacy of Natuphos® E (6-phytase) as a feed additive for avian and porcine species.

The additive Natuphos® E presents 6-phytase (phytase; Enzyme Commission Number 3.1.3.26) and it is intended to be used as a feed additive for all avian and pig species as a zootechnical additive, functional group of digestibility enhancers. The phytase present in the additive is produced by a genetically modified strain of *Aspergillus niger.* The FEEDAP Panel concluded that the genetic modification of the production strain does not give rise to safety concerns. The production strain and its DNA were not detected in the concentrate used to formulate the additive.

The results of the tolerance trials showed that chickens and turkeys for fattening tolerated 400-fold the minimum recommended dose, laying hens 250-fold, weaned piglets 500-fold and sows 25-fold. Therefore, the FEEDAP Panel concluded that the additive is safe at the respective minimum recommended levels, namely chickens for fattening 125 FTU/kg feed, turkeys for fattening 250 FTU/kg feed, laying hens 200 FTU/kg feed and piglets and sows at 100 FTU/kg feed, with a wide margin of safety. The conclusions were extended to chickens reared for laying, turkeys reared for breeding and pigs for fattening and extrapolated to other avian species and to porcine species.

The results obtained with the enzyme concentrates in the genotoxicity studies and in the subchronic oral toxicity study did not indicate any reason for concern for consumer safety arising from the use of the product as a feed additive. Therefore, the Panel considered that the additive is safe for the consumers of food products derived from animals fed with the additive.

The solid concentrate was not toxic by inhalation, not irritant to skin or eyes but showed a potential to be a dermal sensitiser, which has been demonstrated in exposed workers. No data were submitted for the liquid concentrate. Taking into account the composition of the final formulations, the Panel considered that the conclusions reached for the solid concentrate apply to the final formulations of the additive. Owing to the proteinaceous nature of the active substance, the FEEDAP Panel concluded that the additive has also to be considered a potential respiratory sensitiser.

The Panel concluded that the final product does not pose any environmental safety concern associated with the genetic modification. The active substance of the additive is a protein, and as such will be degraded/inactivated during passage through the digestive tract of animals or in the environment. Therefore, no risks to the environment are expected and no further environmental risk assessment is required.

The Panel assessed efficacy studies done in chickens for fattening, turkeys for fattening, laying hens, piglets, pigs for fattening and sows. Based on the results obtained, the Panel concluded that the additive has the potential to be efficacious in improving the performance and/or the phosphorus utilisation in chickens for fattening, turkeys for fattening, weaned piglets, pigs for fattening and sows. The conclusions on the chickens and turkeys for fattening were extended to chickens and turkeys reared for laying/breeding at the corresponding dose. Taking account of the mode of action of phytases, the conclusions drawn in turkeys for fattening were extrapolated to all minor poultry species and other avian species for fattening or up to the point of lay. Similarly, the conclusions drawn in pigs for fattening and sows were extrapolated to minor porcine species for growing and reproduction, respectively. The Panel concluded that there was insufficient data to conclude on the efficacy of the additive in laying hens and therefore could not conclude on minor poultry and other avian species for laying.

* The Summary has been modified according to the confidentiality claim made by the applicant.