REGULATED PRODUCTS SAFETY ASSESSMENT

Assessment on the Safety and Efficacy of a Feed Additive Consisting of 6-Phytase Produced by *Trichoderma reesei* (CBS 126897) (Quantum® Blue) for All Avian Species and All Porcine Species (RP2006)

Food Standards Agency[1], Food Standards Scotland[2]

[1] Regulated Products Risk Assessment, Food Standards Agency, UK, [2] Risk Assessment, Food Standards Scotland, UK

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FSA Research and Evidence

An application was submitted to the Food Standards Agency and Food Standards Scotland in April 2023 by AB Enzymes Finland Oy ("the applicant") for the extension of use of an additive consisting of 6-phytase produced by *Trichoderma reesei* (CBS 126897) (Quantum® Blue) under the category 'zootechnical additive', functional group 'digestibility enhancer', to suckling and weaned piglets and other porcine species and ornamental birds so that the authorisation covers all avian species and all porcine species.

The European Food Safety Authority (EFSA) concluded that the final product does not give rise to any safety concerns with regards to the genetic modification of the production strain, as neither the viable cells of the production strain nor its DNA were detected (2013a, 2024). No antibiotic resistance genes from the genetic modification in the production strain were identified.

Under the intended conditions of use, Quantum® Blue is considered safe for the target species. The use of the additive in animal nutrition is considered safe for consumers and for the environment. All forms of the additive should be considered potential respiratory sensitisers, and any inhalation exposure presents a risk. Nevertheless, the Panel noted that the solid formulations are dust-free, which makes inhalation exposure unlikely. Due to the absence of new data, no conclusions could be drawn regarding the potential of the various formulations to cause skin or eye irritation, or to act as skin sensitisers.

Quantum® Blue is efficacious in poultry, pigs for fattening and sows at 250 FTU/kg and in weaned and suckling piglets at 500 FTU/kg, as well as in all laying avian species at 150 FTU/kg. Regarding the extension of use, the additive has the potential to be efficacious in ornamental birds and in

porcine species for fattening/reared for reproduction and reproductive animals at 250 FTU/kg, and in suckling and weaned piglets of minor porcine species at 500 FTU/kg complete feed.

FSA/FSS has reviewed the applicant's authorisation application, supporting documentation, and other regulators' risk assessments, most notably the EFSA risk assessment opinion, and considers sufficient evidence has been demonstrated to conclude without the need for further questions or risk assessment.

This is a joint FSA and FSS publication.

1. Introduction

The FSA and FSS have undertaken an assessment of a feed additive submitted by AB Enzymes Finland Oy (Tykkimäentie 15b, Rajamäki, Finland, 05200) consisting of 6-phytase (Quantum® Blue) produced by a genetically modified strain of *Trichoderma reesei* (CBS 126897) under assimilated Regulation (EC) No 1831/2003 (EC, 2003) in each nation of Great Britain (GB). The applicant seeks authorisation under the category 'zootechnical additive', functional group 'digestibility enhancer', for its use in poultry, piglets (suckling and weaned), other porcine species and ornamental birds. The additive is currently authorised for use in feed in GB for laying birds, poultry other than laying birds, weaned piglets, pigs for fattening and sows.

In line with Article 8 of assimilated Regulation (EC) No 1831/2003 (EC, 2003), the assessment has considered and concluded whether the feed additive complies with the conditions laid down in Article 5, including: safety considerations for human, animal and environmental health; efficacy of the additive for its intended effect; potential impairment of the distinctive features of animal products. This, and the guidance put in place by the European Food Safety Authority (EFSA) for the evaluation of feed additive applications, has formed the basis and structure for the assessment.

To ensure the regulatory systems of FSA/FSS are risk proportionate, and resources are used effectively, FSA and FSS have used the evidence submitted by the applicant and other information in the public domain, including the EFSA risk assessment opinion, to provide a summary assessment of the evidence of safety presented in this report.

In 2025, EFSA published a risk assessment opinion on the safety and efficacy of a feed additive consisting of 6-phytase produced by *Trichoderma reesei* (CBS 126897) (Quantum® Blue) for the renewal of its authorisation for poultry, weaned piglets, pigs for fattening and sows, and its extension of use to other porcine species and ornamental birds (ROAL Oy). This opinion has been reviewed by FSA/FSS risk assessors. It has been verified that the standard approach, when compared to the relevant guidance applied in GB, has been followed and the conclusions made are consistent with the data summarised in the opinion.

The result of the assessment is that there is sufficient evidence of safety and efficacy for GB conclude on this assessment at this time. This assessment represents the opinion of the FSA and FSS.

Table 1. Table showing products included in this assessment.

Title	Product type	Intended use/s	Intended dose/intake
Quantum® Blue 5 G, 40 P, 5 L and 10 L.	Feed additive	Zootechnical additive / digestibility enhancer	Poultry other than laying birds at a minimum 250 FTU/kg complete feedingstuff; laying birds at minimum 150 FTU/kg complete feedingstuff; weaned piglets at minimum 500 FTU/kg complete feedingstuff; pigs for fattening and sows at minimum 250 FTU/kg complete feedingstuff; suckling piglets at minimum 500 FTU/kg complete feedingstuff; ornamental birds at minimum 250 FTU/kg complete feedingstuff, other porcine species at 250 FTU/kg complete feedingstuff.

2. Assessment

2.1. Details of other regulators opinions

2.1.1. Current authorisation

Under assimilated Regulation (EU) No 292/2014 (EC, 2014), following the EFSA 2013 (a and b) opinions, the additive was authorised in the European Union (EU) and GB for use in feed for poultry, weaned piglets and pigs for fattening and sows.

The additive is also authorised for use in fin fish under Commission Implementing Regulation (EU) No 2025/142, following the EFSA 2024a opinion.

2.1.2. Other regulators opinions

EFSA previously published two opinions on the safety and efficacy of a feed additive consisting of 6-phytase produced with *Trichoderma reesei* (CBS 126897) for use in poultry, weaned piglets, pigs for fattening and sows (EFSA FEEDAP Panel, 2013b, 2013a).

In 2025, EFSA published a scientific opinion on the safety and efficacy of the feed additive regarding its extension of use to suckling piglets and other porcine species and ornamental birds (EFSA, 2025).

2.1.3. Methodology applied in the EFSA opinion

EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) assessed the safety and the efficacy of the additive, in accordance with guidance documents:

- Guidance on the identity, characterisation and conditions of use of feed additives (EFSA FEEDAP Panel, 2017c);
- Guidance on the assessment of the efficacy of feed additives (EFSA FEEDAP Panel, 2024a);
- Guidance on the characterisation of microorganisms used as feed additives or as production organisms (EFSA FEEDAP Panel, 2018);
- Guidance on the assessment of the safety of feed additives for the consumer (EFSA FEEDAP Panel, 2017a);
- Guidance on the assessment of the safety of feed additives for the target species (EFSA FEEDAP Panel, 2017b);
- Guidance on studies concerning the safety of use of the additive for users (EFSA FEEDAP Panel, 2023);
- Guidance on the assessment of the safety of feed additives for the environment (EFSA FEEDAP Panel, 2019);

and principles in Assimilated Regulation (EC) No 429/2008.

These guidance documents also apply to the assessment framework of applications submitted to the FSA for authorisation.

2.2. Section II: Identity, characterisation and condition of use

2.2.1. Characterisation of the production microorganism

A genetically modified strain of *Trichoderma reesei* (CBS 126897) is deposited with the accession number CBS 126897. The identity of the production strain was confirmed by an analysis of the whole genome sequence (WGS).

The genetic modification of the production strain was assessed in previous evaluations by EFSA (2013b, 2024b) and no changes have been introduced since the previous assessment.

2.2.1.1 Information related to the genetic modification

The applicant provided characterisation of the genetically modified production strain, characterisation of the recipient and parental microorganism, and a description of the genetic modification process, which were previously assessed by the FEEDAP panel in 2013a and 2024a. The submitted information was considered sufficient by the FSA and FSS.

2.2.2. Manufacturing process

The applicant stated that the manufacturing process of the additive under current assessment is the same as the manufacturing process previously assessed by the FEEDAP Panel for the product Quantum® Blue (produced with *Trichoderma reesei* (CBS 126897)) (2013b).

The manufacturing process was assessed by the FEEDAP Panel in 2013 prior to the UK's exit from the EU; thus, this opinion is applicable to GB.

2.2.3. Characterisation of the additive

The additive is proposed to be used in four formulations:

- Quantum® Blue 5 G, a granulated formulation with a minimum phytase activity of 5,000 FTU/g.
- Quantum® Blue 40 P, a concentrated powder formulation with a minimum phytase activity of 40,000 FTU/g.
- Quantum® Blue 5 L and Quantum® Blue 10 L, liquid formulations with a minimum phytase activity of 5,000 FTU/g and 10,000 FTU/g, respectively.

As detailed in Section 2.2.2, the manufacturing process has not been modified since the authorisation, however, some changes in the composition of the products have been introduced.

Particle size distribution was determined in five batches of Quantum® Blue 5 G by laser diffraction showing 97.3% (v/v) particles below 250 µm and 0.00004% (v/v) below 63 µm. The dusting potential determined in three batches by Stauber Heubach method equated to 0 mg/m^3. The solid, granulated formulation showed a density of 740 kg/m^3.

Particle size distribution was determined in five batches of Quantum® Blue 40 P by laser diffraction showing 14.9% (v/v) particles below 250 µm and 9.7% (v/v) below 63 µm. The dusting potential determined in three batches by Stauber Heubach method equated to 0 mg/m^3. The solid formulation showed a density of 610 kg/m^3.

Analysis of 5 batches of Quantum® Blue 5 L showed a density of 1180 kg/m^3 and specific weight of 11.6 kN/m^3.

Analysis of 5 batches of Quantum® Blue 10 L showed a density of 1230 kg/m^3 and specific weight of 12 kN/m^3.

The FEEDAP Panel concluded that the levels of microbial contamination and the other detected impurities, including mycotoxins and heavy metals, in the tested batches do not pose any safety concerns.

The potential for antimicrobial production was assessed using three batches of additive. No antimicrobial activity was observed.

Certain species of *Trichoderma* are known to produce various mycotoxins and antifungal compounds (Khan et al., 2020). To address this potential concern, the applicant submitted data on trichodermin concentrations measured in three batches used in the final additive formulations. Analytical results showed that trichodermin levels were below the method's limit of detection (LOD).

T. reesei is known to produce peptaibols (e.g. paracelsin A, C and D (Frisvad et al., 2018)), which are peptides with antimicrobial activity, under stress conditions. Although no analytical data on peptaibol production were provided, the absence of antimicrobial activity in the production strain under evaluation suggests that, if peptaibols are produced during fermentation, their levels are unlikely to pose a safety concern.

The presence of viable cells from the production strain was assessed in three batches used in the final additive formulations. No viable cells of the production strain were found.

Analysis of the same three batches as described above showed that no DNA of the production strain was detected. No DNA from the production strain was detected.

No new data on stability or homogeneity were submitted. However, since the manufacturing process and composition of the additive remain largely unchanged, the stability data provided in the previous assessment are still considered valid (EFSA FEEDAP Panel, 2013b, 2013a).

The FSA and FSS agree with the conclusions reached for the characterisation of the additive and production strain. The amounts of the detected impurities as well as microbial contamination, do not raise safety

concerns. The studies reviewed by EFSA in 2013 are applicable to GB as this was prior to the UK's exit from the EU. The certificates of analysis were reviewed by the FSA and FSS and confirmed compliance with the specifications.

2.2.4. Conditions of use

Quantum® Blue is currently authorised for use in feed for poultry other than laying birds and pigs for fattening and sows at a proposed minimum use level of 250 FTU/kg complete feedingstuff; for laying birds at a proposed minimum use level of 150 FTU/kg complete feedingstuff; and, for weaned piglets at a proposed minimum use level of 500 FTU/kg complete feedingstuff. The recommended maximum dose for poultry is 2500 FTU/kg of complete feedingstuff and for weaned piglets, pigs for fattening and sows is 1750 FTU/kg of complete feedingstuff. The proposed concentrations are the same as for the currently authorised product produced by *T. reesei* (CBS 126897).

In this application the proposed extension of use for Quantum® Blue is: suckling piglets at the proposed minimum content of 500 FTU/kg and in other porcine species and ornamental birds at a proposed minimum content of 250 FTU/kg complete feed.

The applicant requested the same conditions of use for GB as EFSA evaluated in their latest opinion (EFSA, 2025). The FSA/FSS agrees with proposed conditions of use by the applicant.

2.2.5. Conclusion on Section II: Identity, characterisation and conditions of use

The additive was fully characterised, and the identity of the production strain confirmed. The FEEDAP Panel concluded that the amounts of the detected impurities, as well as microbial contamination, do not raise safety concerns. The additive's stability and homogeneity were assessed in 2013, but the FEEDAP Panel concluded that the results are applicable to the current assessment as the manufacturing process and the composition of the additive have not been significantly changed.

The proposed conditions of use are the same as for the currently authorised product produced by *T. reesei* (CBS 126897), in addition to an extension of use in suckling piglets and other porcine species and all avian species except laying birds.

FSA and FSS agree with the conclusions reached for the characterisation of the additive and active agent. The FSA/FSS agree with the conditions of use proposed by the applicant.

2.3. Section III: Safety

2.3.1. Safety of the genetic modification and the production strain

The genetic modification of the production strain *T. reesei* (CBS 126897) had been evaluated previously, wherein the Panel concluded that the genetic modification does not raise any safety concerns (EFSA FEEDAP Panel, 2013b, 2024b). The applicant submitted WGS data demonstrating that the production strain has not undergone any further genetic modification. Furthermore, tests were performed to show that neither the production strain nor its recombinant DNA are present in the final product. Additionally, no new information has been identified that would affect the previous conclusion.

The FSA and FSS therefore agree with the conclusions reached regarding the safety of the genetic modification and agree that the production strain does not raise any safety concerns.

2.3.2. Safety for the target species

The applicant did not provide the original tolerance studies for chickens for fattening and for laying hens obtained with the 6-phytase manufactured with *T. reesei* (CBS 126897), however the original tolerance studies for weaned piglets and sows were provided upon request. The applicant stated that EFSA had previously evaluated these studies and concluded that the additive is safe for the target species at the recommended dosages (EFSA FEEDAP Panel, 2013a, 2013b). Given that the literature search did not identify any new relevant publications from the past ten years, the additive remains safe for the target species.

An extension of use of the additive in feed for suckling piglets at the minimum inclusion level of 500 FTU/kg and in other porcine species and all avian species except laying birds at the minimum inclusion level of 250 FTU/kg complete feed was requested by the applicant. The tolerance studies previously evaluated by the Panel, described above, allow for extrapolation from poultry to ornamental birds, and from pigs to suckling piglets and other porcine species.

The FSA and FSS agree with the conclusions reached on safety for the target species and agree with the extrapolation allowing for use of the additive in feed for suckling piglets, other porcine species and all avian species except laying birds.

2.3.3. Safety for the consumer

The FEEDAP Panel previously evaluated two *in vitro* genotoxicity studies - a bacterial reverse mutation assay in compliance with OECD Guideline 471 to assess gene mutations and an *in vitro* micronucleus test in compliance with OECD Guideline 473 to assess chromosomal damage – as well as an *in vivo* micronucleus test in compliance with OECD Guideline 474. The genotoxicity testing of the fermentation product used to prepare the final formulations of Quantum® Blue yielded negative results, indicating no genotoxic potential. The Panel had also previously assessed a sub-chronic oral toxicity study to allow for the assessment of safety for the consumer (EFSA FEEDAP Panel, 2013a, 2024b), concluding that the results obtained raised no concerns regarding the safety of the additive. For this application, the applicant resubmitted this toxicological data set that was previously evaluated. The Panel maintains that these studies remain valid for the current assessment and reaffirmed the conclusions previously drawn regarding the additive's toxicological profile.

The Panel concluded that the proposed extension of use to suckling pigs, other porcine species and all avian species except laying birds would not present any additional hazards to the consumer.

The FSA and FSS agree with the conclusions reached on safety for the consumer.

2.3.4. Safety for the user

In the assessment of safety for the user, the FEEDAP Panel previously concluded that the additive is not an irritant to skin and eyes nor is it a skin sensitiser. Due to the proteinaceous nature of the active substance, 6-phytase was determined a potential respiratory sensitiser (EFSA FEEDAP Panel, 2013b). The Panel noted that modifications were introduced to the composition of the different formulations of Quantum® Blue and that no new data had been provided for these new formulations. Given the proteinaceous nature of the additive, all forms should be regarded as potential respiratory sensitisers, and any inhalation exposure by users should be considered a risk. However, exposure via inhalation is unlikely as the solid formulations are dust-free. As no new data has been provided for the modified formulations, no conclusions could be reached regarding skin and eye irritancy and skin sensitisation.

The FSA and FSS agree with the conclusions reached on safety for the user.

2.3.5. Safety for the environment

The FEEDAP Panel previously concluded that there are no environmental safety concerns associated with the genetic modification of the production strain as neither the production strain itself nor its DNA were detected in

the final product. Additionally, no risks to the environment are expected as the active substance of Quantum® Blue is a protein and is therefore likely to be degraded/inactivated during passage through the digestive tract of the animals or in the environment (EFSA FEEDAP Panel, 2013b).

In reference to the proposed extension of use for suckling piglets, other porcine species and all avian species except laying birds, the Panel concluded that this extension would not present any additional hazards to the environment.

The FSA and FSS agree with the conclusions reached on safety for the environment.

2.3.6. Conclusion on Section III: Safety

The applicant reported that, since the additive's initial authorisation, no incidents or safety concerns have been documented or reported for the target species, consumers, users or the environment. Additionally, the applicant conducted a comprehensive literature search covering the period from 2012 to 2022. Searches in two databases (CAB Abstracts and NIH NLM PubMed), without language restrictions, identified 336 publications, of which 30 were deemed relevant. The FEEDAP Panel reviewed these publications and found no new evidence that would alter their previous conclusions regarding the safety of the additive for target species, consumer, user or the environment.

Consequently, the FEEDAP Panel concluded that the use of Quantum® Blue remains safe for the target species, consumers, users and the environment, under the approved conditions of the authorisation.

The FSA and FSS agree with the conclusions reached on the safety of the additive for target species, the consumer, user and the environment. The studies were reviewed by EFSA in 2013, prior to the UK's exit from the EU; thus, this opinion is applicable to GB.

2.4. Section IV: Efficacy as a zootechnical additive

The current application does not propose any modifications or additions to the original conditions of use that would affect the additive's efficacy. Accordingly, there is no need for assessing efficacy of the additive in the context of this authorisation.

Efficacy studies were previously evaluated by the FEEDAP Panel in 2013, wherein they concluded that the additive is efficacious in poultry, pigs for fattening and sows at 250 FTU/kg and in weaned piglets at 500 FTU/kg. The efficacy data assessed in the previous opinion (EFSA FEEDAP Panel, 2013b,

2013a) remain valid and are considered sufficient to support the newly proposed use as digestibility enhancers in ornamental birds, suckling piglets, and other porcine species.

Hence, the Panel concluded that the additive has the potential to be efficacious in ornamental birds and in porcine species for fattening/reared for reproduction and reproductive animals at 250 FTU/kg, and in suckling and weaned piglets of minor porcine species at 500 FTU/kg complete feed.

The FSA and FSS agree with the conclusions reached on the efficacy of Quantum® Blue and the extrapolation from the existing authorised uses. It has been demonstrated that the additive favourably affects animal production, performance or welfare, particularly by affecting the gastro-intestinal flora or digestibility of feedingstuffs.

3. Analytical method evaluation

The FSA/FSS evaluated the EURL analytical method evaluation, noting it was carried out in 2013, when the UK was still part of the EU and would have participated of their approval. No concerns are raised at this stage for the validity of the methods for UK/GB use, and therefore the FSA/FSS accept the EURL analytical method evaluation report (EURL, 2013). The FSA/FSS determined the analytical method as appropriate for official controls for this feed additive.

4. Conclusions

The additive containing 6-phytase (Quantum® Blue) manufactured with the production strain *Trichoderma reesei* (CBS 126897), does not give rise to safety concerns regarding the genetically modified production strain as neither viable cells nor the DNA of the production strain were found. The additive was fully characterised, and the identity of the production strain confirmed. The FEEDAP Panel concluded that the amounts of the detected impurities, as well as microbial contamination, do not raise safety concerns. The additive's stability and homogeneity were assessed in 2013, but the FEEDAP Panel concluded that the results are applicable to the current assessment as the manufacturing process and the composition of the additive have not been significantly changed.

The FEEDAP Panel concludes that, under the current conditions of authorisation, the additive continues to be safe for poultry, laying birds, weaned piglets, pigs for fattening, and sows, as well as for consumers and the environment. Furthermore, the Panel considers the additive under the proposed extension of use to be safe at the maximum recommendation for ornamental birds at 2500 FTU/kg complete feed, and for suckling piglets and other porcine species at 1750 FTU/kg complete feed. The proposed extension of use to these additional species is deemed safe for consumers

and the environment. All forms of the additive should be regarded as potential respiratory sensitisers, and any inhalation exposure should be considered a risk. However, the Panel notes that the solid formulations are dust-free, making user exposure via inhalation unlikely. No conclusions can be drawn regarding the potential of the various formulations to cause skin or eye irritation, or to act as skin sensitisers as no new data was provided.

The FEEDAP Panel concluded in the previous assessments that Quantum® Blue is efficacious in poultry, pigs for fattening and sows at 250 FTU/kg and in weaned piglets at 500 FTU/kg. Regarding the extension of use, the Panel concluded that the additive has the potential to be efficacious in ornamental birds and in porcine species for fattening/reared for reproduction and reproductive animals at 250 FTU/kg, and in suckling and weaned piglets of minor porcine species at 500 FTU/kg complete feed.

5. Caveats and uncertainties

No new data had been provided for the modified formulations; therefore, no conclusions could be reached regarding skin and eye irritancy and skin sensitisation. No specific studies were submitted to assess the effects on the respiratory system; hence all forms should be regarded as potential respiratory sensitisers due to the proteinaceous nature of the additive.

6. FSA/FSS conclusions for GB risk analysis

The application has been assessed in line with the applicable guidance and is partially based on considerations of detailed proprietary information available to the Panel, which were also submitted to the FSA and FSS. The EFSA opinion (EFSA, 2025) identified and characterised the hazards present from the proposed use and concluded there is sufficient information to enable an assessment of exposure, which is also relevant to GB. The conclusions of the EFSA opinion have been reviewed in detail by the FSA and FSS, and are considered appropriate and consistent, including the caveats and uncertainties identified in the opinion which are applicable to GB. Sufficient evidence has been demonstrated to conclude without further questions or risk assessment.

Abbreviations

Abbreviation	Definition
CFU	Colony forming unit
EFSA	European Food Safety Authority
EU	European Union
EURL	European Union Reference Laboratory
FEEDAP	EFSA Panel on Additives and Products or Substances used in Animal Feed
FSA	Food Standards Agency

Abbreviation	Definition
FSS	Food Standards Scotland
FTU	Phytase unit
GB	Great Britain
LOD	Limit of Detection
LOQ	Limit of Quantification
RP	Regulated product
UK	United Kingdom
WGS	Whole genome sequence

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