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SCIENTIFIC OPINION

Safety and efficacy of a feed additive consisting of 6-phytase produced with *Trichoderma reesei* (CBS 126897) (Quantum® Blue) for fin fish (ROAL Oy)

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Abstract

Following a request from the European Commission, EFSA was asked to deliver a scientific opinion on the safety and efficacy of 6-phytase (Quantum® Blue) as a zootechnical feed additive for fin fish. The additive is authorised for use in poultry and pigs. The additive is available in solid and liquid forms, and the 6-phytase contained in the product is produced by fermentation with a genetically modified strain of *Trichoderma reesei*. The 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; viable cells of the production strain and its DNA were not detected in the final products. The FEEDAP Panel concluded that, based on the data available, the additive tested is safe for fin fish at the highest recommended level of 2500 phytase activity unit (FTU)/kg complete feed. The Panel concluded that Quantum® Blue is not an irritant to skin and eyes nor a skin sensitiser. Owing to the proteinaceous nature of the active substance, 6-phytase (Quantum® Blue) is considered a respiratory sensitiser. The use of Quantum® Blue as a feed additive is considered safe for the environment. The additive is considered to be efficacious as a zootechnical additive for salmonids and ornamental fish at 500 FTU/kg complete feed and other fin fish at 2500 FTU/kg complete feed.

KEYWORDS

digestibility enhancers, efficacy, fin fish, safety, zootechnical additive

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1 | INTRODUCTION

1.1 | Background and Terms of Reference

Regulation (EC) No 1831/2003[1] 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 feed additive shall submit an application in accordance with Article 7.

The European Commission received a request from ROAL Oy[2] for the authorisation of the additive consisting of 6-phytase produced by fermentation with *Trichoderma reesei* (CBS 126897) (Quantum® Blue), when used as a feed additive for fin fish (category: zootechnical additives; functional group: digestibility enhancers).

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). The particulars and documents in support of the application were considered valid by EFSA as of 04 August 2021.

According to Article 8 of Regulation (EC) No 1831/2003, 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. EFSA shall deliver an opinion on the safety for the target animals, consumer, user and the environment and on the efficacy of the feed additive consisting of 6-phytase (Quantum® Blue), when used under the proposed conditions of use (see **Section 3.1.5**).

1.2 | Additional information

The subject of the assessment is the feed additive consisting of an enzyme preparation (solid and liquid forms) of 6-phytase, produced with a genetically modified strain of *Trichoderma reesei* (CBS 126897), intended for use as a zootechnical additive (functional group digestibility enhancers) for fin fish. The additive is currently authorised for use in feed for poultry and pigs (4a19).[3]

The Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) issued two opinions on the safety and efficacy of this product when used in feed for poultry and pigs (EFSA FEEDAP Panel, 2013a, 2013b).

2 | DATA AND METHODOLOGIES

2.1 | Data

The present assessment is based on data submitted by the applicant in the form of a technical dossier[4] in support of the authorisation request for the use of 6-phytase (Quantum® Blue) as a feed additive. The dossier was received on 20 April 2021, and the general information and supporting documentation are available at https://open.efsa.europa.eu/questions/EFSA-Q-2021-00313.

The European Union Reference Laboratory (EURL) considered that the conclusions and recommendations reached in the previous assessment regarding the methods used for the control of the 6-phytase (Quantum® Blue) in animal feed are valid and applicable for the current application.[5]

2.2 | Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of 6-phytase (Quantum® Blue) is in line with the principles laid down in Regulation (EC) No 429/2008[6] and the relevant guidance documents: Guidance on the assessment of the safety of feed additives for the consumer (EFSA FEEDAP Panel, 2017a), Guidance on the identity, characterisation and conditions of use of feed additives (EFSA FEEEDAP Panel, 2017b), Guidance on the assessment of the safety of feed additives for the target species (EFSA FEEDAP Panel, 2017c), Guidance on the assessment of the efficacy of feed additives (EFSA FEEDAP Panel, 2018a), Guidance on the characterisation of microorganisms used as feed additives or as production organisms (EFSA FEEDAP Panel, 2018b), Guidance on the assessment of the safety of feed additives for the environment (EFSA FEEDAP Panel, 2019) and Guidance on the safety of feed additives for the users (EFSA FEEDAP Panel, 2023).

[1]Regulation (EC) No 1831/2003 of the European Parliament and of the council of 22 September 2003 on the additives for use in animal nutrition. OJ L 268, 18.10.2003, p. 29.
[2]ROAL Oy, Tykkimäentie 15b, 05200 Rajamäki, Finland.
[3]Commission Implementing Regulation (EU) No 292/2014 of 21 March 2014 concerning the authorisation of a preparation of 6-phytase produced by Trichoderma reesei (CBS 126897) as a feed additive for poultry, weaned piglets, pigs for fattening and sows (holder of the authorisation ROAL Oy). OJ L 87, 22.3.2014, p. 90.
[4]FEED dossier reference: FAD-2021-0061.
[5]The full report is available on the EURL website: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en
[6]Commission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives. OJ L 133, 22.5.2008, p. 1.

3 | ASSESSMENT

The product under assessment contains the 6-phytase (phytase; Enzyme Commission number 3.1.3.26) produced by fermentation with a genetically modified strain of *Trichoderma reesei* (CBS 126897), intended for use as a zootechnical additive (functional group: digestibility enhancers) in feed for fin fish.

3.1 | Characterisation

3.1.1 | Characterisation of the production organism

The 6-phytase present in the additive is produced with a genetically modified strain of *Trichoderma reesei*, deposited at the [redacted] with the deposition number CBS 126897.[7] [redacted][8] [redacted][9] [redacted][10] [redacted]

The assessment of the genetic modification of the production strain was performed in a previous evaluation (EFSA FEEDAP Panel, 2013a), and the Panel concluded that the genetic modification does not raise any safety concern. The data submitted for the current authorisation is not different from the previously evaluated one, and therefore, the same conclusions apply.

3.1.2 | Manufacturing process

According to the applicant, the manufacturing process has not been modified compared to the one described in the previous opinion (EFSA FEEDAP Panel, 2013a). [redacted][11]

3.1.3 | Characterisation of the additive

The additive is presented in four different forms.

Quantum® Blue 5 G and Quantum® Blue 40 P are solid forms of the additive that contain a minimum phytase activity of 5000 FTU[12]/g and 40,000 FTU/g, respectively. Quantum® Blue 5 G is a granular formulation that contains [redacted][13]; Quantum® Blue 40 P is a powder formulation that contains [redacted]. Quantum® Blue 5 L and Quantum® Blue 10 L are liquid formulations that ensure a minimum phytase activity of 5000 FTU/g and 10,000 FTU/g, respectively. [redacted]

[7]Technical dossier/ADR/Annex 7.

[8]Technical dossier/ADR/Annex 6.

[9]Technical dossier/ADR/Annex AA.

[10]Technical dossier/Setion II/Annex_II_026.

[11]Technical dossier/ADR/Annex 11.

[12]One phytase unit (FTU) is the quantity of enzyme that liberates 1 μmol of inorganic phosphate per minute from sodium phytate at 37 °C, pH 5.5, under standard assay conditions.

[13][redacted]

[redacted].

The batch-to-batch variation of phytase activity was assessed in five batches of each final formulation.[14] The average phytase activities were [redacted] FTU/g (range [redacted] FTU/g) for Quantum® Blue 5 G, [redacted] FTU/g (range [redacted] FTU/g) for Quantum® Blue 40 P, [redacted] FTU/g (range [redacted] FTU/g) for Quantum® Blue 5 L and [redacted] FTU/g ([redacted] FTU/g) for Quantum® Blue 10 L.

Three batches of each final formulation were analysed for the content of lead, cadmium, mercury and arsenic. All values were below the limit of quantification (LOQ) of the analytical methods except for cadmium in the Quantum® Blue 5 G ([redacted] mg/kg).[15]

Three batches of each final formulation were analysed for the content of mycotoxins, including aflatoxins B1, B2, G1 and G2, fumonisins B1, B2 and B3, ochratoxin A, sterigmatocystin, zearalenone, HT-2 and T2 toxins and deoxynivalenol. All were found below their respective LOQ, except for deoxynivalenol in the Quantum® Blue 5 G (range [redacted] µg/kg).[16]

The presence of trichodermin was analysed in three recent batches of [redacted] FTU/g) [redacted].[17] The results showed that trichodermin was below the corresponding limit of detection (LOD) of the analytical method ([redacted] µg/kg) in all samples.

Escherichia coli and *Salmonella* spp. were analysed in three batches of each formulation and were not detected in 25 g. Five batches of each formulation were analysed for microbiological parameters including total viable cells count, which were in all cases [redacted] colony forming unit (CFU/g), except for the batches of Quantum® Blue 5 G (range [redacted] CFU/g), total coliforms ([redacted] CFU/g), yeast and filamentous fungi ([redacted] CFU/g).[18] No information on the presence of *Enterobacteriaceae* was made available.

No antimicrobial activity was detected in three batches of the [redacted] (enzymatic activity range [redacted] FTU/g),[19] following the provisions of the Guidance on the characterisation of microorganisms used as feed additives or as production organisms (EFSA FEEDAP Panel, 2018b). [redacted].

The presence of viable cells of the production strain was investigated [redacted][20] [redacted]. No cells of the production strain were detected.

The presence of DNA of the production strain was investigated [redacted][21] [redacted] No DNA of the production strain was detected.

The FEEDAP Panel considers that the microbial contamination and the amounts of the detected impurities do not raise safety concerns.

Since the manufacturing process and the composition of the additive have not been modified according to the applicant, the data described with regards the physical properties of the additive in the previous opinions (EFSA FEEDAP Panel, 2013a, 2013b) are still valid.

3.1.4 | Stability and homogeneity

The additive has not been changed since the previous assessment (EFSA FEEDAP Panel, 2013a); thus, the FEEDAP Panel considers that the data on the shelf life evaluated in 2013 are still valid.[22,23] The applicant submitted new data on the stability and capacity of the liquid forms of the additive to homogeneously distribute when added to feed for fin fish.

[14]Technical dossier/ADR/Annex 1.

[15]Technical dossier/ADR/Annex 2. LOQ for mercury, cadmium and lead: [redacted] mg/kg. LOQ for arsenic: [redacted] mg/kg.

[16]Technical dossier/ADR/Annex 3. LOQ for aflatoxin B1, B2, G1 and G2: [redacted] µg/kg; fumonisin B1, B2, B3 and deoxynivalenol: [redacted] µg/kg; ochratoxin A: [redacted] µg/kg; sterigmatocystin, zearalenone, HT-2 toxin and T2-Toxin: [redacted] µg/kg.

[17]Technical dossier/ADR/Annex 4.

[18][redacted]

[19]Technical dossier/ADR/Annex 8.

[20]Technical dossier/ADR/Annex 9 and Annex B.

[21]Technical dossier/ADR/Annex 10.

[22]Technical dossier/Section II/Annex_II_057 and Annex_II_058.

[23]Technical dossier/Section II/Annex_II_056.

The stability of three batches of Quantum® Blue 5 L in feed for rainbow trout,[24] seabream[25] and turbot[26] was studied when supplemented at the intended level of 500 FTU/kg and 2500 FTU/kg and stored at 15°C and 25°C for 4 months. In pelleted feed for trout, [redacted] in the seabream and turbot feed, respectively. These results can be extrapolated to the Quantum® Blue 10 L. No information on the stability of the solid formulations in feed for fin fish was submitted.

The capacity of the Quantum® Blue 5 L to homogeneously distribute in feed was studied in 20 subsamples of pelleted feeds used for the stability studies.[27] The coefficient of variation (CV) in pelleted feed for rainbow trout supplemented at 500 and 2500 FTU/kg were [redacted]%, respectively. The corresponding CV in seabream's feed were [redacted]%, respectively; the ones in turbot's feed were [redacted]%, respectively. The capacity of the Quantum® Blue 10 L to homogeneously distribute was studied in 10 subsamples of pelleted feeds for salmon, showing an average phytase activity of [redacted] FTU/kg.[28] The CV was [redacted]%.

3.1.5 | Conditions of use

6-phytase (Quantum® Blue) is intended to be used in feed for fin fish at minimum recommended enzyme activity of 500 FTU/kg feed and a recommended level raging between 500 and 2500 FTU/kg complete feed.

3.2 | Safety

3.2.1 | Safety of the production microorganism

The assessment of the genetic modification of the production strain of the 6-phytase present in the additive, *T. reesei* CBS 126897, was performed in a previous evaluation (EFSA FEEDAP Panel, 2013a), and the Panel concluded that the genetic modification does not raise any safety concern. The production strain has not been subject to any further genetic modification, and no new information has been made available that would lead the Panel to reconsider its previous conclusion. Moreover, viable cells and DNA of the production strain were not detected in a [redacted] representing the additive. Therefore, the use of *T. reesei* CBS 126897 in the production of the 6-phytase under assessment does not raise any safety concern with regard to the genetically modified production strain.

3.2.2 | Toxicological studies

In a previous assessment (EFSA FEEDAP Panel, 2013a), the FEEDAP Panel evaluated the toxicological dataset available and, based on the Ames test and an in vitro chromosomal aberration test, concluded that the fermentation product used to prepare the final formulations of Quantum® Blue, did not induce gene mutation and was not clastogenic. In addition, the results obtained in a sub-chronic oral toxicity study, conducted in rats, raised no concerns regarding the product.

For the current assessment, the applicant provided an in vitro micronucleus test, which is described below.

An in vitro micronucleus assay was performed to evaluate the potential of the [redacted] of Quantum® Blue ([redacted]) to induce chromosomal damage in peripheral blood human lymphocytes.[29] Three independent experiments were carried out in the presence and absence of metabolic activation following Organisation for Economic Co-operation and Development (OECD) Testing Guideline (TG) 487 and claimed to be Good Laboratory Practice (GLP) compliant. [redacted] The Panel concludes that the [redacted] of Quantum® Blue did not induce structural and numerical chromosomal aberrations in mammalian cells under the experimental conditions employed in this study.

[24]Technical dossier/Section II/Annex_II_075a.
[25]Technical dossier/Section II/Annex_II_076a.
[26]Technical dossier/Section II/Annex_II_077a.
[27]Technical dossier/Section II/Annex_II_086a, Annex_II_086b and Annex_II_086c.
[28]Technical dossier/ADR/Annex 12.
[29]Technical dossier/ADR/Annex 15.

The FEEDAP Panel re-evaluated the sub-chronic oral toxicity study already assessed in 2013 (EFSA FEEDAP Panel, 2013a) and reiterates the same conclusions on the lack of adverse effects at any of the levels tested. In addition, the FEEDAP Panel identifies a no observed adverse effect level (NOAEL) of 1000 mg/kg body weight (bw) per day (corresponding to 227,000 FTU/kg/bw per day), the highest level tested.[30]

3.2.2.1 | *Conclusions on toxicological studies*

Based on the dataset available, the FEEDAP Panel concludes that the additive does not induce gene mutation nor structural and numerical chromosomal aberrations and identified a NOAEL of 1000 mg/kg bw per day (corresponding to 227,000 FTU/kg/bw per day), the highest level tested.

3.2.3 | Safety for the target species

The maximum safe concentration of the additive in complete feed can be derived using the results of the toxicological studies (EFSA FEEDAP Panel, 2017c). From the results of the toxicological studies available (see Section 3.2.2), the FEEDAP Panel considers that the NOAEL of 1000 mg phytase/kg bw and day (227,000 FTU/kg) in the sub-chronic (90 days) toxicity study in rats is the appropriate value to calculate the safe level in feed for the target species.[31] The NOAEL identified, 227,000 FTU/kg bw per day, was used to calculate the maximum safe level for salmon and ornamental fish. The maximum safe level of Quantum® Blue in complete feed corresponds to 114,149 FTU/kg feed for salmon and to 443,911 FTU/kg feed for ornamental fish.

In addition, the applicant provided two tolerance studies in fin fish, one in rainbow trout and one in seabass, to support the safety for the target species for which the application was made.

3.2.3.1 | *Tolerance study in rainbow trout*

[redacted], [32] [redacted] rainbow trout (*Oncorhynchus mykiss*, [redacted]

Based on the results of the tolerance trial, the Panel considers that Quantum® Blue is well tolerated in rainbow trout at 2500 FTU/kg feed, with a wide margin of safety.

3.2.3.2 | *Tolerance study in seabass (Dicentrarchus labrax)*

[redacted] European seabass [redacted] (*Dicentrarchus labrax*; [redacted] [33] [redacted] [34] [redacted]

[30]Technical dossier/ Section III/Annex_III_08.
[31]Technical dossier/ Section III/Annex_III_08.
[32]Technical dossier/Section III/Annex_III_01 and Annex_III_02.
[33]Technical dossier/Section III/Annex_III_03 and Annex_III_04.
[34]Enzyme activity in feed (FTU/kg feed) = [redacted].

[redacted]

Based on the results of the tolerance trial, the Panel considers that Quantum® Blue is well tolerated in seabass at 2500 FTU/kg feed, with a wide margin of safety.

3.2.3.3 | *Conclusions on safety for the target species*

Based on the data available, the FEEDAP Panel concludes that the additive, in all its forms, is safe for all fish species at the highest recommended level of 2500 FTU/kg complete feed.

3.2.4 | Safety for the consumer

The results obtained in the genotoxicity studies and the sub-chronic oral toxicity study, do not indicate any reason for concern for consumer safety arising from the use of the product as a feed additive. Therefore, the FEEDAP Panel concludes that the use of Quantum® Blue (all forms) in feed for fin fish under the proposed conditions of use is safe for the consumer.

3.2.5 | Safety for the users

The reported dusting potential of Quantum® Blue 5 G and 40 P is 0 and 0.018 mg/m^3, respectively (EFSA FEEDAP Panel, 2013a, 2013b). Quantum® Blue 5 L and 10 L are in liquid form. Exposure of the users via inhalation cannot be excluded. Owing to the proteinaceous nature of the active substance, 6-phytase (Quantum® Blue) is considered a respiratory sensitiser.

The safety for the users was already assessed in the previous evaluation (EFSA FEEDAP Panel, 2013a). In that assessment, three final formulations, Quantum® Blue 5 G, 40 P and 10 L, were tested for skin and eye irritation and skin sensitisation. The results revealed no evidence of dermal or eye irritation or skin sensitisation. The other final liquid formulation, Quantum® Blue 5 L, was not tested, but based on its composition, the Panel concluded that it is unlikely that its irritant potential or skin sensitisation potential to be significantly different from that of its tested counterpart (Quantum® Blue 10 L).

Since the manufacturing process and the composition of the additive have not been modified according to the applicant, the Panel considers that there is no evidence to reconsider the conclusions reached in the previous assessment. Therefore, Quantum® Blue 5 G, 40 P, 5 L and 10 L are not considered skin and eye irritant nor skin sensitiser but are considered respiratory sensitisers.

3.2.6 | Safety for the environment

Neither the production strain nor its DNA was detected in the final product. The final product does not raise any environmental safety concern associated with the genetic modification. The active substance of the additive is a protein, and as such, it will likely 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.

3.3 | Efficacy

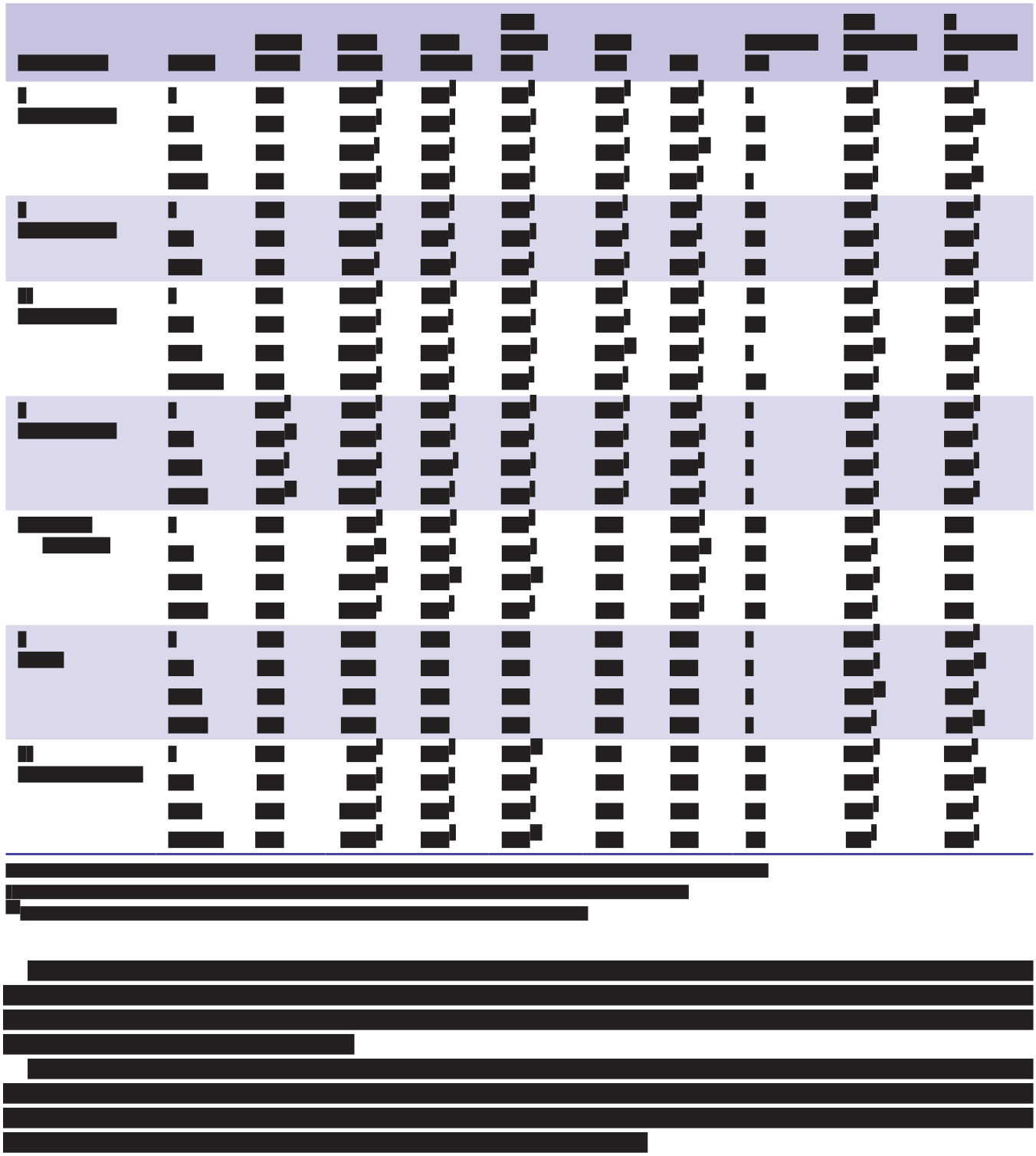
Seven trials performed in different fish species were submitted in order to demonstrate the efficacy of Quantum® Blue.

[redacted][35][redacted][36][redacted][37][redacted]

[35]Technical dossier/Section IV/Annex_IV_01 to Annex_IV_14.
[36]Technical dossier/Section IV/Annex_IV_05 and Annex_IV_06.
[37]Technical dossier/Section IV/Annex_IV_13 and Annex_IV_14.

TABLE 1 Trial design of the efficacy studies considered for the assessment.

TABLE 2 Effect of Quantum® Blue [redacted]



3.3.1 | Conclusions on efficacy

The additive has the potential to be efficacious for salmonids and ornamental fish at 500 FTU/kg complete feed and for other fin fish at 2500 FTU/kg complete feed.

3.4 | Post-market monitoring

The FEEDAP Panel considers that there is no need for specific requirements for a post-market monitoring plan other than those established in the Feed Hygiene Regulation[38] and Good Manufacturing Practice.

[38]Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005, laying down requirements for feed hygiene. OJ L 35, 8.2.2005, p. 1.

4 | CONCLUSIONS

No viable cells and/or DNA of the production strain were detected in the final formulations of the additive. Quantum® Blue (liquid/solid) produced with *Trichoderma reesei* CBS 126897 does not pose any safety concern regarding the production strain.

The additive is safe for all fin fish species at the highest recommended level of 2500 FTU/kg complete feed.

The use of the feed additive in fin fish nutrition is of no concern for consumer safety.

Quantum® Blue (all formulations) are not considered skin and eye irritant nor skin sensitiser but are considered respiratory sensitisers.

The use of Quantum® Blue as a feed additive raises no safety concerns for the environment.

The additive is considered efficacious as a zootechnical additive for salmonids and ornamental fish at a minimum use level of 500 FTU/kg complete feed and for other fin fish at 2500 FTU/kg complete feed.

ABBREVIATIONS

bw	body weight
[redacted]	[redacted]
CFU	colony forming unit
CV	coefficient of variation
[redacted]	[redacted]
FEEDAP	EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed
[redacted]	[redacted]
FTU	phytase activity unit
GLP	Good laboratory practice
LOD	limit of detection
LOQ	limit of quantification
NOAEL	no observed adverse effect level
OECD	Organisation for Economic Co-operation and Development
[redacted]	[redacted]
[redacted]	[redacted]

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CONFLICT OF INTEREST

If you wish to access the declaration of interests of any expert contributing to an EFSA scientific assessment, please contact interestmanagement@efsa.europa.eu.

REQUESTOR

European Commission

QUESTION NUMBER

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