SCIENTIFIC OPINION

efsa JOURNAL

ADOPTED: 5 July 2023

doi: 10.2903/j.efsa.2023.8171

Safety and efficacy of a feed additive consisting of endo-1,4-β-xylanase produced by *Trichoderma citrinoviride* DSM 34663 (Hostazym® X) for use in all poultry species, ornamental birds, all growing *Suidae* and carp (Huvepharma NV)

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Abstract

Following a request from the European Commission, the EFSA 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 a feed additive containing endo-1,4-β-xylanase produced by *Trichoderma citrinoviride* DSM 34663 (Hostazym® X). The product is authorised as a zootechnical additive (digestibility enhancers) for use in all poultry species for fattening, for laying and reared for laying, weaned piglets, pigs for fattening and carp. The current opinion concerns the request for the renewal of the authorisation for the use in those species/categories and the extension of use to all poultry species for breeding and reared for breeding, ornamental birds, suckling piglets and minor porcine species for fattening. The applicant provided evidence that the additive in the market complies with the conditions of the authorisation. There is no new evidence that would lead the Panel to reconsider previous conclusions that the additive is safe for the target species, the consumers and the environment under the authorised conditions of use. This conclusion also applies to the target species for which a request for extension of use is made. The additive is considered not a skin corrosive or skin sensitiser, but it is an eye irritant. The Panel cannot conclude on the potential of the additive to be a skin irritant. Due to the proteinaceous nature of the active substance, the additive is considered a respiratory sensitiser. The Panel considers that the additive has the potential to be efficacious in all poultry species, ornamental birds, all growing *Suidae* and carp at the proposed conditions of use.

Keywords: zootechnical additives, digestibility enhancers, Hostazym® X, endo-1,4-beta-xylanase, *Trichoderma citrinoviride*, renewal, extension of use

Requestor: European Commission

Question number: EFSA-Q-2021-00153

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Declaration 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.

Acknowledgements: The Panel wishes to thank the following for the support provided to this scientific output (in alphabetical order of the last name): Stefani Fruk, Paola Manini, and the FEEDAP WGs on Microbiology and Toxicology

Suggested citation: EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Bampidis, V., Azimonti, G., Bastos, M. L., Christensen, H., Dusemund, B., Durjava, M., Kouba, M., López-Alonso, M., López Puente, S., Marcon, F., Mayo, B., Pechová, A., Petkova, M., Ramos, F., Sanz, Y., Villa, R. E., Woutersen, R., Tosti, L., … Ortuño, J. (2023). Safety and efficacy of a feed additive consisting of endo-1,4-β-xylanase produced by *Trichoderma citrinoviride* DSM 34663 (Hostazym® X) for use in all poultry species, ornamental birds, all growing *Suidae* and carp (Huvepharma NV). *EFSA Journal, 21*(8), 1–12. https://doi.org/10.2903/j.efsa.2023.8171

ISSN: 1831-4732

The EFSA Journal is a publication of the European Food Safety Authority, a European agency funded by the European Union.

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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 14(1) of that Regulation lays down that an application for renewal shall be sent to the Commission at the latest 1 year before the expiry date of the authorisation; whereas 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 (Huvepharma NV)[2] for the renewal of the authorisation of the additive consisting of endo-1,4-β-xylanase produced by *Trichoderma citrinoviride* DSM 34663[3] (Hostazym® X) when used as a feed additive for chickens for fattening, turkeys for fattening, laying hens, minor poultry species for fattening and laying, weaned piglets and pigs for fattening, chickens and minor poultry species reared for laying, and carp; and an extension of use when used for breeding hens, turkeys reared for breeding, turkeys for breeding purposes, ornamental birds, suckling piglets (for the period in which solid feed is given), minor pig species for fattening, minor poultry species reared for breeding and minor poultry species for breeding (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 14(1) (renewal of the authorisation) 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. The particulars and documents in support of the application were considered valid by EFSA as of 07/07/2021.

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 endo-1,4-β-xylanase produced by *Trichoderma citrinoviride* DSM 34663 (Hostazym® X), when used under the proposed conditions of use (see **Section** 3.1.2).

1.2. Additional information

The subject of the assessment is the feed additive consisting of endo-1,4-β-xylanase produced by *Trichoderma citrinoviride* DSM 34663 (Hostazym® X), intended for use as a zootechnical additive (functional group: digestibility enhancer) for all poultry species, ornamental birds, all growing *Suidae* and carp.

The Panel on Additives and Products or Substances in Animal Feed (FEEDAP) adopted a total of six opinions on the safety and efficacy of this product: two opinions as a feed additive for poultry and pigs (EFSA FEEDAP Panel, 2013a, 2015), another one for its use as a feed additive in chickens reared for laying and minor poultry species reared for laying (EFSA FEEDAP Panel, 2017a), one on its use in feed for carp (EFSA FEEDAP Panel, 2017b), two regarding its use in sows in order to have benefits in piglets (EFSA FEEDAP Panel, 2018a, 2022) and one as a feed additive for rabbits for fattening (EFSA FEEDAP Panel, 2019a).

The additive is currently authorised for use in feed for chickens for fattening, turkeys for fattening, laying hens, minor poultry species for fattening and laying, weaned piglets and pigs for fattening,[4] chickens and minor poultry species reared for laying/breeding[5] and carp.[6]

[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] Huvepharma NV, Uitbreidingstraat 80, 2600 Antwerp (Belgium).
[3] Previously referred as *Trichoderma citrinoviride* Bisset SD135.
[4] Commission Implementing Regulation (EU) 2015/1043 of 30 June 2015. OJ L 167 01.07.2015, p.67.
[5] Commission Implementing Regulation (EU) 2017/1906 of 18 October 2017. OJ L 269 19.10.2017, p.33.
[6] Commission Implementing Regulation (EU) 2018/327 of 5 March 2018. OJ L 63 06.03.2018, p.7.

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[7] in support of the authorisation request for the use of endo-1,4-β-xylanase produced by *Trichoderma citrinoviride* DSM 34663 (Hostazym® X) as a feed additive.

The dossier was received on 31 March 2021 and the general information and supporting documentation are available at https://open.efsa.europa.eu/questions/EFSA-Q-2021-00153.

The FEEDAP Panel used the data provided by the applicant together with data from other sources, such as previous risk assessments by EFSA or other expert bodies and peer-reviewed scientific papers to deliver the present output.

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 endo-1,4-β-xylanase in animal feed are valid and applicable to the current application.[8]

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of endo-1,4-β-xylanase produced by *Trichoderma citrinoviride* DSM 34663 (Hostazym® X) is in line with the principles laid down in Regulation (EC) No 429/2008[9] and the relevant guidance documents: Guidance on studies concerning the safety of use of the additive for users/workers (EFSA FEEDAP Panel, 2012), Guidance on the assessment of the safety of feed additives for the consumer (EFSA FEEDAP Panel, 2017c), Guidance on the identity, characterisation and conditions of use of feed additives (EFSA FEEEDAP Panel, 2017d), Guidance on the assessment of the safety of feed additives for the target species (EFSA FEEDAP Panel, 2017e), Guidance on the assessment of the efficacy of feed additives (EFSA FEEDAP Panel, 2018b), Guidance on the characterisation of microorganisms used as feed additives or as production organisms (EFSA FEEDAP Panel, 2018c), Guidance on the assessment of the safety of feed additives for the environment (EFSA FEEDAP Panel, 2019b), Guidance on the renewal of the authorisation of feed additives (EFSA FEEDAP Panel, 2013b).

3. Assessment

The product Hostazym® X consisting of an endo-1,4-β-xylanase (EC 3.2.1.8) produced by a non-genetically modified strain of *Trichoderma citrinoviride* (DSM 34663) is currently authorised as a zootechnical additive (functional group: digestibility enhancers) for use in feed for chickens for fattening, turkeys for fattening, laying hens, minor poultry species for fattening and laying, chickens and minor poultry species reared for laying, weaned piglets and pigs for fattening and carp. The applicant requested the renewal of the above authorisation. In addition, the applicant requested the extension of its use in feed for all poultry species for breeding and reared for breeding, ornamental birds, suckling piglets and minor porcine species for fattening.

3.1. Characterisation

3.1.1. Characterisation of the additive

The product Hostazym® X contains an endo-1,4-β-xylanase produced by a non-genetically modified strain of *Trichoderma citrinoviride* (DSM 34663).

The applicant declared that no changes in the manufacturing process and composition of the additive had been applied since the authorisation of the product.

[7] FEED dossier reference: FAD-2021-0008.

[8] The full report is available on the EU Science Hub website: https://joint-research-centre.ec.europa.eu/publications/fad-2010-0001_en

[9] 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.

Two solid and two liquid formulations are described by the applicant: Hostazym® X 6000 MG (solid, granulated; moisture content of [redacted]) contains the purified enzyme concentrate ([redacted]), pregelatinised starch ([redacted]) and wheat meal ([redacted]), with a minimum activity of 6,000 EPU[10]/g of product; Hostazym® X 30000 MG (solid, granulated; moisture content of [redacted]) contains the purified enzyme concentrate ([redacted]), pregelatinised starch ([redacted]) and wheat meal ([redacted]), with a minimum activity of 30,000 EPU/g of product; Hostazym® X 6000 L (liquid; relative density of 1,130 kg/m^3) contains the purified enzyme concentrate ([redacted]), sorbitol ([redacted]), propylene glycol ([redacted]), sodium benzoate ([redacted]), potassium sorbate ([redacted]) and water ([redacted]), with a minimum activity of 6,000 EPU/g of product; and Hostazym® X 15000 L (liquid; relative density of 1,130 kg/m^3) contains the purified enzyme concentrate ([redacted]), sorbitol ([redacted]), propylene glycol ([redacted]), sodium benzoate ([redacted]), potassium sorbate ([redacted]) and water ([redacted]), with a minimum activity of 15,000 EPU/g of product.

Analytical data to confirm the specifications were provided for five batches of each formulation of the additive,[11] showing the following average values (in EPU/g additive): 8,756 (range 8,100–9,180) for 6000 MG; 43,678 (range 42,700–44,150) for 30000 MG; 7,546 (range 7,210–7,790) for 6000 L; and 21,530 (range 20,600–22,300) for 15000 L.

Three batches of each formulation were analysed for chemical impurities and microbial contamination.[12] The values of lead, arsenic, cadmium and mercury in all batches analysed of the solid and liquid formulations were below the respective limit of detection (LOD).[13] Aflatoxins B1, B2, G1 and G2, deoxynivalenol, ochratoxin A and zearalenone were not detected in any batch of any formulation.[14] Regarding the microbiological contamination, Enterobacteriaceae and *Salmonella* spp. (25 g analysed) were not detected in any formulation. Total yeasts and filamentous fungi showed an average value of 3.6 (range 3.5–3.7) log colony forming units (CFU)/g in 6000 MG and 3.8 (range 3.7–3.9) log CFU/g in 30000 MG and were not detected in the liquid formulations.

The FEEDAP Panel considers that the microbial contamination observed does not raise safety concerns.

No new data have been provided regarding the physico-chemical properties or stability of the additive. No changes have been introduced in the additive or its manufacturing process. Therefore, the data described in previous opinions still apply (EFSA FEEDAP Panel, 2013a, 2017b, 2018a, 2019a).

The xylanase present in the additive is produced by a non-genetically modified strain of *Trichoderma citrinoviride* which is deposited in the German Collection of Microorganisms and Cell Cultures with the accession number DSM 34663 ([redacted] SD 135; formerly deposited at the International Mycological Institute (IMI) with the accession number 356040).[15] [redacted].

The taxonomic identification of the production strain DSM 34663 as *T. citrinoviride* was achieved by analysis of the [redacted] and showed best matches with strains of *Trichoderma citrinoviride*.[16]

The capacity of the production strain to produce antimicrobials was tested in culture supernatants obtained from the fermentation of three industrial-scale batches of the additive, [redacted]. No antimicrobial activity was detected.[17]

Since some *Trichoderma* species are known to be capable of producing potentially toxic compounds, the presence of [redacted] peptaibols was analysed in three batches of the Hostazym® X dry concentrate used to formulate the additive ([redacted]).[18] The results showed that [redacted]

[10] One EPU is the amount of enzyme which releases 0.0083 μmol of reducing sugars (xylose equivalent) per minute from oat spelt xylan at pH 4.5 and 50°C.
[11] Technical dossier/SIn_141022/Annexes RTQ_24, 27, 30 and 33.
[12] Technical dossier/SIn_141022/Annexes RTQ_26, 29, 32 and 35.
[13] LOD (in mg/kg); Arsenic: 0.04; Cadmium: solid 0.05, liquid 0.01; Lead: 0.05; Mercury: 0.005.
[14] LOD (in μg/kg): Aflatoxins B1 (1.0), B2 (1.0), G1 (1.0), G2 (1.0); Ochratoxin A (1.0); Zearalenone (0.5); Deoxynivalenol (100).
[15] Technical dossier/SIn_290623/Safe Deposit_DSMZ_Trichoderma citrinoviride 135.
[16] Technical dossier/SIn_150323/Annex_RTQII_05
[17] Technical dossier/SIn_141022/Annex_RTQ_15
[18] Technical dossier/SIn_141022/Annex_RTQ_11

[redacted] were below their corresponding LOD ([redacted]).[19] No other peptaibols were detected.

The presence of viable cells of the production strain was investigated in three batches of Hostazym® X dry concentrate ([redacted]) tested in triplicate.[20] [redacted], no viable cells of the production strain were found.

3.1.2. Conditions of use

The additive is currently authorised for use in feed as a zootechnical additive for chickens for fattening, chickens and minor poultry species reared for laying, laying hens, weaned piglets and pigs for fattening at a proposed minimum level of 1,500 EPU/kg complete feed; and for turkeys for fattening, minor poultry species for fattening and carp at a proposed minimum level of 1,050 EPU/kg complete feed. The applicant has not asked to modify these conditions of use.

Other provisions as stated in the authorisation:

Pigs:

1) In the directions for use of the additive and premixture, indicate the storage conditions and stability to pelleting.
2) For use in feed rich in starch and non-starch polysaccharides (mainly beta-arabinoxylans).
3) For safety: breathing protection, glasses and gloves shall be used during handling.
4) For use in weaned piglets until approximately 35 kg.

Poultry/Carp:

1) In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated.
2) For users of the additive and premixtures, feed business operators shall establish operational procedures and additional measures to address potential risks resulting from their use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including skin, eyes and breathing protections.

The applicant requests the extension of use for breeding hens and minor poultry species for breeding and chickens and minor poultry species reared for breeding, ornamental birds, suckling piglets and minor porcine species for fattening at a proposed minimum level of 1,500 EPU/kg complete feed, and for turkeys for breeding and reared for breeding at a proposed minimum level of 1,050 EPU/kg complete feed.

3.2. Safety

The safety of Hostazym X® for the target species, consumers, users and the environment, including the safety of the production strain, has been evaluated in previous opinions (EFSA FEEDAP Panel 2013a, 2015, 2017a,b, 2018a, 2019a). The Panel concluded that the additive is safe for the target species tested, and the use of the product as a feed additive would be of no concern for the consumers of products derived from animals fed with the additive, or for the environment. Regarding the safety for the user, no specific studies were provided. Therefore, the product was considered a potential skin and eye irritant and a potential skin and respiratory sensitiser.

For the present dossier, the applicant (i) states that no adverse events in any of the target animal species, consumers and users have been reported to Huvepharma since the market authorisation of Hostazym® X, (ii) performed a literature search in order to provide evidence that in the light of the current knowledge the additive remains safe under the approved conditions for target species, consumers, users and the environment, (iii) submitted an *in vitro* micronucleus test and (iv) provided

[19] [redacted]

[20] Technical dossier/SIn_141022/Annex_RTQ_16 and Annex_RTQ_17

new tests to support the safety for the users. The Panel assessed all these data and addressed the safety aspects for the new target species for which the applicant requested the authorisation.

3.2.1. Literature search

The literature search was conducted in CAB Abstracts® and FSTA® covering from 2010 to 2021 and considered studies in the target species (including those for which an extension of use has been requested in the current application), consumers, users/workers, the environment and the production strain, with no limitations in the search.[21] The number of hits identified after duplicate removal was 414. Titles and abstracts were further screened against the inclusion criteria concerning potentially harmful effects of xylanases produced by the production organism and the production microorganism itself on humans and/or the target animals, resulting in 61 hits. These publications were full-text screened, and 10 were considered relevant for the present assessment. Eight of these publications were EFSA opinions on the same additive (EFSA FEEDAP Panel, 2013a, 2015, 2017a,b, 2018a, 2019a) or on another multi-enzyme product containing endo-1,4-β-xylanase produced by *T. citrinoviride* (EFSA FEEDAP Panel, 2017f, 2019c). The other two publications assessed the effects of supplementation of the diets of laying hens with an additive combining Hostazym® X and an endo-1,4-glucanase also produced by *T. citrinoviride* on the zootechnical performance and mortality of laying hens (Prytkov et al., 2020, 2021). These studies showed limitations to be supportive of the safety for the target species due to (i) the length of the trials (4 weeks in Prytkov et al., 2020); (ii) the limited number of endpoints considered; (iii) the lack of statistical analysis reported; and (iv) the lack of information about the enzyme activity in feed. Despite that, none of the studies showed a negative effect on the birds' performance and mortality.

3.2.2. Toxicological studies

3.2.2.1. *In vitro* micronucleus test

The toxicological studies submitted in the previous dossiers aimed at assessing the genotoxic potential of the additive did not allow to properly assess the potential numerical chromosome aberrations induced by the test item (EFSA FEEDAP Panel, 2013a, 2015). In the current application, the applicant submitted an *in vitro* micronucleus test to evaluate the potential of the intermediate enzyme concentrate ( ) to induce chromosomal damage.[22] The Panel concludes that Hostazym® X concentrate did not induce structural and numerical chromosome aberrations under the experimental conditions applied in this study.

3.2.3. Safety for the user

The applicant provided new tests to study the skin corrosion, eye irritation and skin sensitisation potential for the most concentrated forms of the solid (Hostazym® X 30000) and liquid (Hostazym® X 15000) formulations. No studies investigating the skin irritation potential of the additive were submitted.

The skin corrosion potential of Hostazym® X 30000MG and 15000 L was investigated in an *in vitro* skin corrosion study according to OECD TG 431. The results of the test indicated that both forms of the additive tested can be categorised according to the UN GHS classification as 'Non-corrosive'.

The eye irritation potential of Hostazym® X 30000 MG and 15000 L was investigated *in vivo* using New Zealand white rabbits. The irritating effect was scored according to the Draize method. The study was performed according to OECD TG 405. The results of the studies showed that the formulations are irritant to the eye.

[21] Technical dossier/SIn_141022/Annex RTQ_05.
[22] Technical dossier/SIn_141022/Annex RTQ_36.

The skin sensitisation potential of Hostazym® X 30000 MG and 15000 L was assessed using the Local Lymph Node Assay in mice following OECD TG 429. The results of the studies indicated that the formulations are not skin sensitisers.

3.2.3.1. Conclusions on user safety

The Panel considers that the conclusions reached in the tests conducted with Hostazym® X 30000 MG and 15000 L also apply to 6000 MG and 6000 L, respectively. Therefore, the formulations of the additive are neither skin corrosive nor skin sensitisers but are irritant to the eyes. The Panel cannot conclude on the potential of the formulations of the additive to be skin irritant. Due to the proteinaceous nature of the active substance, the additive is considered a respiratory sensitiser.

3.2.4. Safety aspects related to the new use of the additive

The current application requests an extension of the use of the additive to hens, turkeys and minor poultry species for breeding and reared for breeding, ornamental birds, suckling piglets and minor porcine species for fattening.

Regarding the safety for the target species, the FEEDAP Panel evaluated in the past tolerance trials which showed that chickens and turkeys for fattening, laying hens, weaned piglets and carp tolerated well 300,000 EPU/kg feed. The Panel considers that the conclusions reached in chickens for fattening and laying hens can be extrapolated to ornamental birds and all poultry species reared for breeding and for breeding purposes. The conclusions reached in weaned piglets can be extended to suckling piglets and extrapolated to minor porcine species for fattening at the proposed use levels. Therefore, the Panel concludes that the additive is safe for all poultry species for breeding and reared for breeding, ornamental birds, suckling piglets and minor porcine species for fattening at the recommended levels.

The proposed extension of use to the new species/categories would not introduce risks not already identified in the previous opinions; the Panel considers that the conclusions of the previous assessments regarding the safety for the consumers and environment still apply to the present assessment. Therefore, the use of the additive in the new species/categories is considered safe for the consumers and the environment.

3.2.5. Conclusions on the safety

Based on the information provided by the applicant and the fact that the manufacturing and composition of the additive have not been modified, the FEEDAP Panel concludes that there is no evidence to reconsider the conclusions reached in the previous opinions on the safety of the additive for all poultry species for fattening and reared for laying, laying hens, weaned piglets, pigs for fattening and carp. Therefore, the Panel concludes that the additive remains safe under the approved conditions for those target species, consumers and the environment.

The Panel concludes that the additive is safe for all poultry species for breeding and reared for breeding, ornamental birds, suckling piglets and minor porcine species for fattening at the recommended levels. The use of the additive in these target species is considered safe for the consumer and the environment.

The additive is not a skin sensitiser, but it should be considered an eye irritant and respiratory sensitiser. No conclusion can be drawn on the skin irritancy potential of the additive.

3.3. Efficacy

The present application for renewal of the authorisation does not include a proposal for amending or supplementing the conditions of use for those species/categories for which there is an authorisation. Therefore, there is no need to assess the efficacy of the additive in the context of the renewal of the authorisation.

The current application includes the extension of use to hens and minor poultry species for breeding, chickens and minor poultry species reared for breeding, ornamental birds, suckling piglets and minor porcine species for fattening at 1,500 EPU/kg complete feed, and in turkeys for breeding and reared for breeding at 1,050 EPU/kg. The FEEDAP Panel has concluded in previous opinions that the additive is efficacious in chickens for fattening, laying hens, minor poultry species for laying and reared for laying, weaned piglets and pigs for fattening at 1,500 EPU/kg feed (EFSA FEEDAP Panel, 2013a, 2017a) and in turkeys for fattening, minor growing poultry species and carp at 1,050

EPU/kg feed (EFSA FEEDAP Panel, 2013a, 2017b). The Panel considers that the conclusions reached in chickens for fattening and laying hens can be extrapolated to chickens and minor poultry species reared for breeding, all poultry for breeding and ornamental birds; those reached in turkeys for fattening can be extended to turkeys reared for breeding; and those in weaned piglets and pigs for fattening can be extended to suckling piglets (for which solid feed is given) and extrapolated to minor porcine species for fattening. Therefore, the Panel concludes that the additive has the potential to be efficacious in all poultry species for breeding and minor poultry species reared for breeding, ornamental birds, suckling piglets (for the period in which solid feed is given) and minor porcine species for fattening at a proposed minimum concentration of 1,500 EPU/kg complete feed, and for turkeys reared for breeding at a proposed minimum concentration of 1,050 EPU/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[23] and Good Manufacturing Practice.

4. Conclusions

The applicant provided evidence that the additive currently in the market complies with the conditions of the authorisation.

The Panel concludes that the additive remains safe for all poultry species for fattening and reared for laying, laying hens, weaned piglets, pigs for fattening and carp at the authorised conditions of use. These conclusions can be extended to all poultry species for breeding and reared for breeding, ornamental birds, suckling piglets and minor porcine species for fattening at the proposed conditions of use.

The use of the feed additive in animal nutrition is safe for the proposed conditions of use for consumers and the environment.

The additive is not a skin corrosive or skin sensitiser, but it should be considered an eye irritant and a respiratory sensitiser. No conclusion can be reached for the skin irritancy of the additive.

The additive has the potential to be efficacious in chickens for fattening and reared for laying/breeding, minor poultry species reared for laying/breeding, all poultry species for laying/breeding and all growing pigs at a proposed minimum level of 1,500 EPU/kg complete feed; and for turkeys for fattening, turkeys reared for breeding, minor poultry species for fattening and carp at a proposed minimum level of 1,050 EPU/kg complete feed.

References

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2012. Guidance on studies concerning the safety of use of the additive for users/workers. EFSA Journal 2012;10(1):2539, 5 pp. https://doi.org/10.2903/j.efsa.2012.2539

EFSA FEEDAP Panel (Panel on Additives and Products or Substances used in Animal Feed), 2013a Scientific Opinion on the safety and efficacy of Hostazym® X (endo-1,4-beta-xylanase) as feed additive for poultry, piglets and pigs for fattening. EFSA Journal 2013;11(2):3105, 23 pp. https://doi.org/10.2903/j.efsa.2013.3105.

EFSA FEEDAP Panel (Panel on Additives and Products or Substances used in Animal Feed), 2013b. Guidance on the renewal of the authorisation of feed additives. EFSA Journal 2013;11(10):3431, 8 pp. https://doi.org/10.2903/j.efsa.2013.3431

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2015. Scientific Opinion on the safety of Hostazym X as a feed additive for poultry and pigs. EFSA Journal 2015;13(1):3969, 10 pp. https://doi.org/10.2903/j.efsa.2015.3969

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2017a. Scientific Opinion on the safety and efficacy of Hostazym X (endo-1,4-beta-xylanase) as a feed additive for chickens reared for laying and minor poultry species reared for laying. EFSA Journal 2017;15(2):4708, 6 pp. https://doi.org/10.2903/j.efsa.2017.4708

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2017b. Scientific Opinion on the safety and efficacy of Hostazym X (endo-1,4-beta-xylanase) as a feed additive for carps. EFSA Journal 2017;15(7):4942, 9 pp. https://doi.org/10.2903/j.efsa.2017.4942

[23] 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.

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Rychen G, Aquilina G, Azimonti G, Bampidis V, Bastos ML, Bories G, Chesson A, Cocconcelli PS, Flachowsky G, Gropp J, Kolar B, Kouba M, Lopez-Alonso M, Lopez Puente S, Mantovani A, Mayo B, Ramos F, Saarela M, Villa RE, Wallace RJ, Wester P, Anguita M, Dujardin B, Galobart J and Innocenti ML, 2017c. Guidance on the assessment of the safety of feed additives for the consumer. EFSA Journal 2017;15(10):5022, 17 pp. https://doi.org/10.2903/j.efsa.2017.5022

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Rychen G, Aquilina G, Azimonti G, Bampidis V, Bastos ML, Bories G, Chesson A, Cocconcelli PS, Flachowsky G, Gropp J, Kolar B, Kouba M, Lopez-Alonso M, Lopez Puente S, Mantovani A, Mayo B, Ramos F, Saarela M, Villa RE, Wallace RJ, Wester P, Anguita M, Galobart J and Innocenti ML, 2017d. Guidance on the identity, characterisation and conditions of use of feed additives. EFSA Journal 2017;15(10):5023, 12 pp. https://doi.org/10.2903/j.efsa.2017.5023

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Rychen G, Aquilina G, Azimonti G, Bampidis V, Bastos ML, Bories G, Chesson A, Cocconcelli PS, Flachowsky G, Gropp J, Kolar B, Kouba M, Lopez-Alonso M, Lopez Puente S, Mantovani A, Mayo B, Ramos F, Saarela M, Villa RE, Wallace RJ, Wester P, Anguita M, Galobart J, Innocenti ML and Martino L, 2017e. Guidance on the assessment of the safety of feed additives for the target species. EFSA Journal 2017;15(10):5021, 19 pp. https://doi.org/10.2903/j.efsa.2017.5021

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2017f. Safety and efficacy of FRA(®) Octazyme C Dry (α-galactosidase, α-amylase, endo-1,3(4)-β-glucanase, endo-1,4-β-glucanase, mannan-endo-1,4-β-mannosidase, pectinase, protease, endo-1,4-β-xylanase) for chickens for fattening and weaned piglets. EFSA Journal 2017;15(8):4943, 20 pp. https://doi.org/10.2903/j.efsa.2017.4943

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2018a. Scientific Opinion on the safety and efficacy of Hostazym X (endo-1,4-beta-xylanase) as a feed additive for sows in order to have benefits in piglets. EFSA Journal 2018;16(10):5456, 8 pp. https://doi.org/10.2903/j.efsa.2018.5456

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Rychen G, Aquilina G, Azimonti G, Bampidis V, Bastos ML, Bories G, Chesson A, Cocconcelli PS, Flachowsky G, Gropp J, Kolar B, Kouba M, Lopez-Alonso M, Lopez Puente S, Mantovani A, Mayo B, Ramos F, Saarela M, Villa RE, Wallace RJ, Wester P, Anguita M, Galobart J, Innocenti ML and Martino L, 2018b. Guidance on the assessment of the efficacy of feed additives. EFSA Journal 2018;16(5):5274, 25 pp. https://doi.org/10.2903/j.efsa.2018.5274

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Rychen G, Aquilina G, Azimonti G, Bampidis V, Bastos ML, Bories G, Chesson A, Cocconcelli PS, Flachowsky G, Gropp J, Kolar B, Kouba M, Lopez-Alonso M, Lopez Puente S, Mantovani A, Mayo B, Ramos F, Saarela M, Villa RE, Wallace RJ, Wester P, Glandorf B, Herman L, Karenlampi S, Aguilera J, Anguita M, Brozzi R and Galobart J, 2018c. Guidance on the characterisation of microorganisms used as feed additives or as production organisms. EFSA Journal 2018;16(3):5206, 24 pp. https://doi.org/10.2903/j.efsa.2018.5206

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2019a. Scientific Opinion on the safety and efficacy of Hostazym X (endo-1,4-beta-xylanase) as a feed additive for rabbits for fattening. EFSA Journal 2019;17(1):5529, 8 pp. https://doi.org/10.2903/j.efsa.2019.5529

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Bampidis V, Bastos M, Christensen H, Dusemund B, Kouba M, Kos Durjava M, Lopez-Alonso M, Lopez Puente S, Marcon F, Mayo B, Pechova A, Petkova M, Ramos F, Sanz Y, Villa RE, Woutersen R, Brock T, de Knecht J, Kolar B, van Beelen P, Padovani L, Tarres-Call J, Vettori MV and Azimonti G, 2019b. Guidance on the assessment of the safety of feed additives for the environment. EFSA Journal 2019;17(4):5648, 78 pp. https://doi.org/10.2903/j.efsa.2019.5648

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2019c. Safety and efficacy of FRA®Octazyme C Dry (endo-1,4-b-xylanase, mannan-endo-1,4-b-mannosidase,a-amylase,endo-1,3(4)-b-glucanase, pectinase, endo-1,4-b-glucanase,protease,a-galactosidase) as a feed additive for weaned piglets and chickens for fattening. EFSA Journal 2019;17(6):5730, 10 pp. https://doi.org/10.2903/j.efsa.2019.5730

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2022. Scientific Opinion on the Efficacy of a feed additive consisting of endo-1,4-beta-xylanase produced by *Trichoderma citrinoviride* (IMI SD 135) (HOSTAZYM®X) for sows in order to have benefits in piglets. EFSA Journal 2022;20(3):7154, 9 pp. https://doi.org/10.2903/j.efsa.2022.7154

Prytkov YN, Ageev BV, Kiseleva KV, Bochkareva EV and Alieva EN, 2020. The effects of multienzyme Hostazym Combi on the productive performance in laying hens fed freshly harvested wheat. Ptitsevodstvo, 103,43–45.

Prytkov YN, Ageev BV, Bochkareva EV, Kiseleva KV and Alieva EN, 2021. The use of the enzymic preparation Hostazym Combi at the poultry factory of LLC "avangard". Zootekhniya, 30–32.

Abbreviations

CABI-IMI	Centre for Agriculture and Bioscience International-International Mycological Institute
CFU	colony-forming unit
EURL	European Union Reference Laboratory
FEEDAP	EFSA Scientific Panel on Additives and Products or Substances used in Animal Feed
LOD	limit of detection
OECD	Organisation for Economic Co-operation and Development