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Safety and efficacy of the feed additive consisting of endo-1,4-beta-xylanase produced by *Trichoderma reesei* CBS 143953 (Danisco Xylanase 40000 G/L) for poultry and porcine species (Danisco Animal Nutrition)

EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP), Vasileios Bampidis, Giovanna Azimonti, Maria de Lourdes Bastos, Henrik Christensen, Birgit Dusemund, Mojca Fašmon Durjava, Maryline Kouba, Marta López-Alonso, Secundino López Puente, Francesca Marcon, Baltasar Mayo, Alena Pechová, Mariana Petkova, Fernando Ramos, Yolanda Sanz, Roberto Edoardo Villa, Ruud Woutersen, Boet Glandorf, Montserrat Anguita, Jaume Galobart, Orsolya Holczknecht, Paola Manini, Fabiola Pizzo, Jordi Tarrés-Call and Elisa Pettenati

Abstract

Danisco Xylanase 40000 G/L is the trade name of the feed additive under assessment and contains endo-1,4-beta-xylanase produced by a genetically modified strain of *Trichoderma reesei*. It is authorised for use in chickens for fattening, laying hens, ducks, turkeys for fattening, all minor poultry species, weaned piglets and pigs for fattening. This scientific opinion concerns the request for the renewal of the authorisation of the additive for the species/categories for which there is an authorisation, a reduction of the minimum recommended level in turkeys for fattening and the extension of use to all poultry species (other than ducks) for fattening or reared for laying/breeding and for laying, suckling piglets and minor growing porcine species. The applicant provided evidence that the additive currently in the market complies with the conditions of the authorisation. There is no new evidence that would lead the EFSA Panel on Additives and products or Substances used in Animal Feed (FEEDAP) to reconsider previous conclusions that the additive remains safe for the animal species/categories, the consumer and the environment under the authorised conditions of use. This conclusion applies also to the new target species/categories for which a request of use is made. The additive is not irritant to skin but should be considered as a possible eye irritant and, in common with other proteinaceous substances, respiratory sensitiser. There was no need for assessing the efficacy of the additive in the context of the renewal of the authorisation for chickens for fattening, laying hens, ducks, all minor poultry species, weaned piglets and pigs for fattening. The additive has the potential to be efficacious at 625 U/kg complete feed in all poultry species for fattening (including turkeys) or reared for laying/breeding, and for laying and 2,000 U/kg complete feed in suckling piglets and all minor growing porcine species.

Keywords: Zootechnical additive, digestibility enhancers, xylanase, Danisco Xylanase, poultry, pigs, safety

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Correspondence: feedap@efsa.europa.eu

Panel members: Giovanna Azimonti, Vasileios Bampidis Maria de Lourdes Bastos, Henrik Christensen, Birgit Dusemund, Mojca Fašmon Durjava, Maryline Kouba, Marta López-Alonso, Secundino López Puente, Francesca Marcon, Baltasar Mayo, Alena Pechová, Mariana Petkova, Fernando Ramos, Yolanda Sanz, Roberto Edoardo Villa and Ruud Woutersen.

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1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

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 a feed additive shall submit an application in accordance with Article 7. Also, Article 13(3) of that Regulation lays down that if the holder of an authorisation proposes changing the terms of the authorisation by submitting an application to the Commission, accompanied by the relevant data supporting the request for the change, the Authority shall transmit its opinion on the proposal to the Commission and the Member States. In addition, Article 14(1) of that Regulation lays down that an application for renewal shall be sent to the Commission at the latest one year before the expiry date of the authorisation.

The European Commission received a request from Danisco Animal Nutrition represented in the EU by Genecor International B.V.[2] for the authorisation of a new use, a modification of the current authorisation and renewal of the authorisation of the additive that contains endo-1,4-beta-xylanase produced by *Trichoderma reesei* CBS 143953 (Danisco Xylanase 40000 G/L), when used as a feed additive for ducks, all poultry species (except ducks) for fattening, reared for laying/breeding, for laying, piglets (suckling and weaned), pigs for fattening and all minor growing porcine species (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), under Article 13(3) (modification of the authorisation of a feed additive) and under Article 14(1) (renewal of the authorisation). 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 11 February 2019.

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 additive that contains endo-1,4-beta-xylanase produced by *T. reesei* CBS 143953 (Danisco Xylanase 40000 G/L), when used under the proposed conditions of use (see Section 3.1.1).

1.2. Additional information

The additive is a preparation of endo-1,4-beta-xylanase which is produced by a genetically modified strain of *T. reesei* (ATCC 5588) and its trade name is Danisco Xylanase 40000 G/L in powder (G) and liquid (L) forms.

EFSA has issued several opinions on the safety and efficacy of Danisco Xylanase 40000 G/L (including the safety of the genetic modification) for different species: chickens for fattening, laying hens, ducks for fattening (EFSA, 2007a, 2008), turkeys for fattening (EFSA, 2007b), weaned piglets and pigs for fattening (EFSA FEEDAP Panel, 2011) and another one regarding the efficacy for laying hens and the safety and efficacy for all minor poultry species (EFSA FEEDAP Panel, 2012).

The additive (4a11) is authorised in the European Union (EU) as a feed additive for chickens for fattening, laying hens, ducks, and turkeys for fattening,[3,4] weaned piglets and pigs for fattening[5] and all minor poultry species.[6]

[1] Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition. OJ L 268, 18.10.2003, p. 29.

[2] Danisco (UK) Ltd. (trading as Danisco Animal Nutrition), PO Box 777 Marlborough Wiltshire SN8 1XN United Kingdom, Represented in the EU by Genecor International B.V., Willem Einthovenstraat 4 2342 BH Oegstgeest The Netherlands.

[3] Commission Regulation (EU) No 9/2010 of 23 December 2009 concerning the authorisation of the endo-1,4-beta-xylanase produced by *Trichoderma reesei* (ATCC PTA 5588) as a feed for chickens for fattening, laying hens, ducks and turkeys for fattening (holder of authorisation Danisco Animal Nutrition, Finnfeeds International Limited). OJ L 3, 7.1.2010, p. 10.

[4] Commission Implementing Regulation (EU) No 1196/2012 of 13 December 2012 amending Regulation (EU) No 9/2010 as regards the minimum content of a preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (ATCC PTA 5588) as a feed additive in feed for laying hens (holder of authorisation Danisco Animal Nutrition). OJ L 342, 14.12.2012, p. 25.

[5] Commission Implementing Regulation (EU) No 528/2011 of 30 May 2011 concerning the authorisation of the endo-1,4-beta-xylanase produced by *Trichoderma reesei* (ATCC PTA 5588) as a feed for weaned piglets and pigs for fattening (holder of authorisation Danisco Animal Nutrition). OJ L 143, 31.05.2011, p. 10.

[6] Commission Implementing Regulation (EU) No 1021/2012 of 6 November 2012 concerning the authorisation of the endo-1,4-beta-xylanase produced by *Trichoderma reesei* (ATCC PTA 5588) as a feed for minor poultry species other than ducks (holder of authorisation Danisco Animal Nutrition). OJ L 307, 7.11.2012, p. 68.

The applicant has requested for the renewal of the authorisation for Danisco Xylanase 40000 G/L for the species/categories for which there is an authorisation, namely chickens and turkeys for fattening, laying hens, ducks, all minor poultry species, weaned piglets and pigs for fattening. Moreover, the applicant has requested for a reduction of the minimum recommended level authorised in turkeys for fattening (from 1,250 U/kg complete feed to 625 U/kg complete feed) and for an extension of use of the additive to all poultry species (other than ducks) for fattening or reared for laying/breeding, and for laying, to suckling piglets, and minor growing porcine species.

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 the product that contains endo-1,4-beta-xylanase produced by *T. reesei* CBS 143953 (Danisco Xylanase 40000 G/L) as a feed additive.

The FEEDAP Panel used the data provided by the applicant together with data from other sources, such as previous risk assessments by EFSA, to deliver the present output.

During the assessment, it was noted that the definition of the xylanase unit activity in the technical dossier was different to the one in the previously evaluated method (Application FAD-2011-0030).[8] The applicant expressed the will to modify the definition of those units according to the method used for the control of the additive evaluated in the context of another application (FAD-2010-0007).[9] The European Union Reference Laboratory (EURL) considered that the conclusions and recommendations reached in that assessment are valid and applicable for the current application.

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of the product that contains endo-1,4-beta-xylanase produced by *T. reesei* CBS 143953 (Danisco Xylanase 40000 G/L) is in line with the principles laid down in Regulation (EC) No 429/2008[10] and the relevant guidance documents: Guidance on the renewal of the authorisation of feed additives (EFSA FEEDAP Panel, 2013), Guidance on the characterisation of microorganisms used as feed additives or as production organisms (EFSA FEEDAP Panel, 2018a), Guidance on the assessment of the safety of feed additives for the target species (EFSA FEEDAP Panel, 2017a) and Guidance on the assessment of the efficacy of feed additives (EFSA FEEDAP Panel, 2018b).

3. Assessment

This assessment regards the renewal of the authorisation of the product that contains endo-1,4-beta-xylanase (EC 3.2.1.8, xylanase) produced by *T. reesei* CBS 143953 (Danisco Xylanase 40000 G/L) when used as a zootechnical additive (functional group of digestibility enhancers) for chickens for fattening, laying hens, ducks, turkeys for fattening, all minor poultry species, weaned piglets and pigs for fattening.

The assessment also regards the request to modify the terms of the authorisation for turkeys for fattening (reduction of the minimum recommended use level) and the request for an extension of use to all poultry species (other than ducks) for fattening or reared for laying/breeding and for laying, suckling piglets and minor growing porcine species. It will be hereafter referred to with its trade name Danisco Xylanase 40000 G/L.

3.1. Characterisation

The additive is authorised in two different formulations, powder (Danisco Xylanase 40000 G) and liquid (Danisco Xylanase 40000 L).

[7] FEED dossier reference: FAD-2018-0087.
[8] The full report is available on the EURL website: https://ec.europa.eu/jrc/sites/jrcsh/files/FinRep-FAD-2011-0030.pdf.
[9] The full report is available on the EURL website: https://ec.europa.eu/jrc/sites/jrcsh/files/FinRep-FAD-2010-0007.pdf.
[10] 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.

The information submitted regarding the manufacturing process [redacted]

The applicant declares that no antibiotics are used during the manufacturing process.[12]

Danisco Xylanase 40000 G contains the [redacted] concentrated product, wheat flour ([redacted]) and calcium propionate ([redacted]).[13]

Danisco Xylanase 40000 L contains the [redacted] concentrated product, sodium chloride ([redacted]), sorbitol ([redacted]), sodium acetate ([redacted]), potassium sorbate ([redacted]) and water ([redacted]).[13]

In the authorisation Regulations, the Units of activity for the xylanase are defined as follows: '1 U is the amount of enzyme which liberates 0.5 μmol of reducing sugar (expressed as xylose equivalents) from a cross-linked oat spelt arabinoxylan substrate at pH 5.3 and 50°C in 1 min'. In the context of the present application, the applicant has proposed a new definition of the xylanase activity: 'one unit of xylanase is the amount of enzyme that releases 0.48 μmol of reducing sugar equivalents (expressed as xylose by the DNS reducing sugar method) from wheat arabinoxylan per min at pH 4.2 and 50°C'. Three recent batches of Danisco Xylanase 40000 G and L were measured with the new method of analysis[14] and showed a mean enzyme activity of 53,602 U/g (range 43,983–59,755 U/g)[15] and 51,325 U/g (range 47,350–53,967 U/g),[16] respectively. These measured enzyme activities showed compliance with the specifications set in the authorisations (minimum guaranteed enzyme activity of 40,000 U/g) and confirmed the correspondence of the new definition/method of analysis with the previous one.

Three batches of each formulation were analysed for chemical contamination.[17,18] The analysis included arsenic (< limit of quantification (LOQ)), cadmium (0.03–0.04 mg/kg for the solid and < LOQ for the liquid), lead (< LOQ), mercury (< LOQ), zinc (24–26 mg/kg for the solid and < 0.5 mg/kg in one batch of the liquid formulation analysed). Additional impurities as copper (3.9–4.7 mg/kg), fluoride (< LOQ), nickel (0.2 mg/kg), phosphorus (3,300–3,600 mg/kg), selenium (< LOQ) were analysed only in the solid form, and iron (8.9 mg/kg), aluminium (1.2 mg/kg) only in one batch of the liquid form. Dioxins (polychlorinated dibenzo-*p*-dioxins and dibenzofurans (PCDD/F)) ranged between 0.0633 and 0.0664 ng WHO-PCDD/F-TEQ/kg in the solid and 0.0657–0.153 ng WHO-PCDD/F-TEQ/kg in the liquid form; the sum of dioxins and dioxin-like polychlorinated biphenyls (DL-PCBs) ranged between 0.101 and 0.106 ng WHO-PCDD/F-DL-PCB-TEQ/kg in the solid and 0.105–0.245 ng WHO-PCDD/F-DL-PCB-TEQ/kg in the liquid form; non-dioxin-like PCBs ranged between 0.368 and 0.386 μg/kg in the solid and 0.382–0.890 μg/kg in the liquid form. The following mycotoxins were determined: aflatoxin B1, B2, G1 and G2 (< LOQ in the solid form and < 1 μg/kg in the liquid form), deoxynivalenol (200–280 μg/kg in the solid and < LOQ in the liquid), ochratoxin A (< LOQ in the solid and < 2 μg/kg in the liquid form) and zearalenone (< LOQ in the solid and < 10 μg/kg in the liquid). Additional mycotoxins as HT-2 (< LOQ) and T-2 toxin (< LOQ) were analysed only in the solid form, and fumonisin B1 and B2 (< 20 μg/kg) only in the liquid form. All the observed contaminants are in acceptable ranges. Purity data submitted for the solid formulation included also information on several pesticides which were checked and were not detected. Moreover, three batches of Danisco Xylanase 40000 G and three of Danisco Xylanase 40000 L were analysed for the presence of [redacted][19]

[11] Technical dossier/Section II/Annexes Sect.II/Annex II.20 and Supplementary information February 2021/Reply_FAD-2018-0087_181220.
[12] Technical dossier/Section II/Annexes Sect.II/Annex II.22.
[13] Technical dossier/Supplementary information July 2019/Reply_FAD-2018-0087_180319, reply question 4.
[14] Technical dossier/Supplementary information September 2020/Reply_FAD-2018-0087_290520, reply to question 1.
[15] Technical dossier/Section II/Annexes Sect.II/Annex II.2.
[16] Technical dossier/Section II/Annexes Sect.II/Annex II.3.
[17] Technical dossier/Section II/Annexes Sect.II/Annex II.4 and Annex II.5. LOQ in mg/kg were 0.1 for arsenic; 0.01 for cadmium; 0.1 for copper; 1 for fluoride; 0.05 for lead; 0.005 for mercury; 0.1 for nickel; 3 for phosphorus; 0.2 for selenium; 0.5 for zinc. LOQ in μg/kg were 0.5 for aflatoxin B 1, B2, G1 and G2; 20 for deoxynivalenol and zearalenone; 10 for T-2 and HT-2 toxin; 1 for ochratoxin A.
[18] Technical dossier/Supplementary information February 2021/Reply_FAD-2018-0087_181220. LOQ and LOD for iron and aluminium in mg/kg were 0.2 and 0.5, respectively. LOQ and LOD in μg/kg for fumonisin B1 and B2 were 7 and 20, respectively.
[19] Technical dossier/Supplementary information July 2019/Annex_2_a_Conf and Annex_2b_Conf.

Microbial contamination analysis included *Salmonella* spp. (not detected in 25 g or mL), *Escherichia coli* (not detected in 25 g or mL), Enterobacteriaceae (100, 400 and > 15 × 10^3 Colony forming units (CFU)/g in the solid; and < 1 CFU/g in the liquid form), presumptive *Bacillus cereus* (< 10 CFU/g), moulds (< 10, 28 and 46 CFU/g in the solid form and < 1 CFU/mL in the liquid form) and yeasts (< 10, 28 and 370 CFU/g in the solid form and < 1 CFU/mL in the liquid form). Microbiological quality in the liquid formulation also included total viable counts (7 × 10^5 CFU/mL in one batch and < 10 CFU/mL in two batches) and total coliforms (< 1 CFU/mL).[20] The Panel notes the high counts for Enterobacteriaceae, yeasts and moulds in the solid formulation, as well as the high counts found for total viable cells in the liquid formulation.

No antimicrobial activity was detected [redacted][21]

Physico-chemical properties, stability and homogeneity of both forms of the additive were addressed in previous opinions. The applicant provided new data on the physico-chemical properties of both forms of the additive in recent batches.

Danisco Xylanase 40000 G is a light brown, fine granular powder with a bulk density of 652 kg/m^3.[22] Three batches of the solid form were analysed for particle size distribution by laser diffraction and showed a mean particle size of about 383–425 μm (the fractions below 100 and 10 μm of diameter represented up to 13.2 and 2.14%, respectively).[23] The dusting potential (Stauber–Heubach method) measured in three batches was on average 15 mg/m^3 (range 10–25 mg/m^3).[24]

Danisco Xylanase 40000 L is a transparent light brown liquid preparation with a viscosity of 3.7–4.1 mPa·s at 20°C.[25]

The xylanase present in the additive is produced by a genetically modified strain of *T. reesei*, which is deposited at the Westerdijk Fungal Biodiversity Institute with the accession number CBS 143953.[26] The strain was formerly deposited at the American Type Culture Collection with the accession number ATCC 5588.

The taxonomic identification of the recipient strain [redacted] as *T. reesei* was confirmed [redacted][27] The Panel notes that taxonomic identification performed with the production strain (*T. reesei* CBS 143953) would be preferred for the assessment. *T. reesei* CBS 143953 was developed from [redacted] The assessment of the genetic modification of the production strain was performed in a previous evaluation (EFSA, 2007a) and the Panel concluded that the genetic modification of the xylanase production strain does not raise any safety concern. The production strain has not been subject to any further genetic modification.

Since some *Trichoderma* species are known to be capable of producing various mycotoxins and antifungal metabolites, [redacted]

[20] Technical dossier/Section II/Annexes Sect.II/Annex II.4 and Annex II.5. LOQ in mg/kg were 0.1 for arsenic; 0.01 for cadmium; 0.1 for copper; 1 for fluoride; 0.05 for lead; 0.005 for mercury; 0.1 for nickel; 3 for phosphorus; 0.2 for selenium; 0.5 for zinc. LOQ in μg/kg were 0.5 for aflatoxin B 1, B2, G1 and G2; 20 for deoxynivalenol and zearalenone; 10 for T-2 and HT-2 toxin; 1 for ochratoxin A.
[21] Technical dossier/Section II/Annexes Sect.II/Annex II.17.
[22] Technical dossier/Section II/Annexes Sect.II/Annex II.11.
[23] Technical dossier/Section II/Annexes Sect.II/Annex II.9.
[24] Technical dossier/Section II/Annexes Sect.II/Annex II.10.
[25] Technical dossier/Section II/Annexes Sect.II/Annex II.12.
[26] Technical dossier/Section II/Annexes Sect.II/Annex II.14.Conf.
[27] Technical dossier/Supplementary information July 2019/Annex_1a.

[redacted][28,29] The Panel notes that the test with the production strain would have been preferred.

The presence of viable cells of the production strain was investigated [redacted][30] No cells were detected.

The presence of DNA from the production strain was analysed [redacted][31] [32] The analysis showed no amplification in the samples [redacted]

3.1.1. Conditions of use

The additive is currently authorised for use in feed as a zootechnical additive for chickens for fattening, laying hens, ducks, all minor poultry species other than ducks at a minimum recommended level of 625 U/kg complete feed, for turkeys for fattening at a minimum recommended level of 1,250 U/kg complete feed and for weaned piglets, pigs for fattening at a minimum recommended level of 2,000 U/kg complete feed. The applicant has not asked to modify these conditions of use except for turkeys for fattening, for which has asked to reduce the minimum recommended level to 625 U/kg complete feed.

In addition, the applicant proposed the extension of use to all poultry species (other than ducks), for fattening or reared for laying/breeding, and for laying[33] at a minimum recommended level of 625 U/kg complete feed and to suckling piglets and minor growing porcine species at a minimum recommended level of 2,000 U/kg complete feed, respectively.

The authorisations under other provisions foresee:

- In the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting.
- For use in feed rich in starch and non-starch polysaccharides.
- For piglets (weaned) up to 35 kg.

3.2. Safety

The safety of Danisco Xylanase 40000 G and L for the target species, consumers, users and the environment, including the safety of the production strain, has been evaluated in previous opinions (EFSA, 2007a,b, 2008; EFSA FEEDAP Panel, 2011, 2012). The Panel concluded that the genetic modification of the production strain is of no concern, that the additive is safe for the target species evaluated 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. The Panel also concluded that the additive is not irritant to the skin but should be considered as a possible eye irritant and, in common with other proteinaceous substances, a respiratory sensitiser.

The data newly provided to confirm the identification of the production strain *T. reesei* CBS 143953 allow to unambiguously identify the recipient strain as *T. reesei*. The production strain has not been subject to any further genetic modification and neither viable cells nor DNA of the production strain were detected in a liquid concentrate representative of both final formulations.

In line with the requirements established in the EFSA guidance on the renewal (EFSA FEEDAP Panel, 2013), the applicant 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. The applicant searched in a total of three relevant databases (CAB Abstracts, Veterinary Science Database and Medline).[34,35] The search covered the period 2009–

[28] Technical dossier/Section II/Annexes Sect.II/Annex II.18.Conf.
[29] Technical dossier/Supplementary information May 2020/Annex_4.
[30] Technical dossier/Supplementary information May 2020/Annex_1 and Supplementary information February 2021/Annex_1.
[31] Technical dossier/Supplementary information May 2020/Annex_2.
[32] Technical dossier/Supplementary information July 2019/Annex_5b.
[33] The Panel notes that this extension of use considers the species for which the additive is already authorised.
[34] Technical dossier/Section III/Bibliography Sect.III/RCVS 2017.
[35] Technical dossier/Section III/Bibliography Sect.III/RCVS 2018.

2017 for poultry and 2011–2018 for swine species, was restricted to publications in English language only and the search terms and search strategy were provided. The main search term was 'xylanase' and included terms relevant for target species safety and for toxicological aspects.

The literature search for poultry and for swine species retrieved 347 and 363 publications, respectively. Most of the publications were excluded from the assessment because the product was not the one under assessment (77 for poultry and 109 for swine species) or the safety of the product was not assessed (262 for poultry and 250 for swine species). The other publications found did not report any safety issues. Therefore, the FEEDAP Panel concludes that there is no new evidence that would lead the Panel to reconsider its previous conclusions on the safety of the product for the target species evaluated, consumers and the environment under the authorised conditions of use. Regarding the safety for the user, the additive is not irritant to the skin but should be considered as a possible eye irritant and, in common with other proteinaceous substances, respiratory sensitiser.

The applicant stated that no adverse events have been detected under its global monitoring plan.[36]

The current application requests for an extension of the use of the additive to all poultry species for fattening or reared for laying/breeding, and for laying, to suckling piglets and minor growing porcine species. In the past, the FEEDAP Panel evaluated tolerance trials which showed that the additive is safe for chickens for fattening, laying hens and ducks for fattening (EFSA, 2007a), for turkeys for fattening (EFSA, 2007b), for weaned piglets and pigs for fattening (EFSA FEEDAP Panel, 2011) and for all minor poultry species (EFSA FEEDAP Panel, 2012). Therefore, the Panel considers that the conclusions from chickens and turkeys for fattening and laying hens can be extended/extrapolated to all poultry species for fattening or reared for laying/breeding, and for laying. Similarly, the conclusions reached in weaned piglets can be extended to suckling piglets and extrapolated to minor porcine species in the suckling/growing phase. Consequently, the additive is safe for all poultry species for fattening or reared for laying/breeding, and for laying at the recommended level of 625 U/kg complete feed and for suckling piglets and minor growing porcine species at the recommended level of 2,000 U/kg complete feed.

3.3. Efficacy

The efficacy of Danisco Xylanase 40000 G/L was previously established in chickens for fattening and ducks for fattening at a minimum recommended level of 625 U/kg complete feed (EFSA, 2007a), in weaned piglets and pigs for fattening at a minimum recommended level of 2,000 U/kg complete feed (EFSA FEEDAP Panel, 2011) and in laying hens and all minor poultry species at a minimum recommended level of 625 U/kg complete feed (EFSA FEEDAP Panel, 2012). The conditions of use for these target species have not been modified and therefore no further assessment is needed for the renewal of the authorisation.

The applicant has now requested to reduce the recommended level to 625 U/kg complete feed in turkeys for fattening, which was previously established at 1,250 U/kg complete feed (EFSA, 2007b).

In addition, the applicant proposed the extension of use to all poultry species for fattening or reared for laying/breeding, and for laying at a minimum recommended level of 625 U/kg complete feed and to suckling piglets and minor growing porcine species at a minimum recommended level of 2,000 U/kg complete feed.

Considering that efficacy has been demonstrated in chickens and ducks for fattening and in laying hens at the level of 625 U/kg complete feed and the fact that the mode of action of the enzyme present in the additive can be reasonably assumed to be the same in the different poultry species, the conclusions from the efficacy studies previously evaluated can be extended/extrapolated to all poultry species for fattening (including turkeys) or reared for laying/breeding, and for laying. In a similar way, the conclusions from the efficacy in weaned piglets and pigs for fattening can be extended to suckling piglets and extrapolated to minor growing porcine species at a level of 2,000 U/kg complete feed. Therefore, the Panel considers that the additive has the potential to be efficacious in these species at the proposed conditions of use.

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[37] and Good Manufacturing Practice.

[36] Technical dossier/Section III/AnnexIII.1.

[37] 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

The additive currently in the market complies with the conditions of authorisation.

There is no new evidence that would lead the FEEDAP Panel to reconsider its previous conclusions that Danisco Xylanase 40000 G/L is safe for chickens for fattening, laying hens, ducks, turkeys for fattening, all minor poultry species, weaned piglets and pigs for fattening the consumer and the environment under the authorised conditions of use. This conclusion applies also to the new target species/categories for which a request for an extension of use is made.

The additive is not irritant to skin but should be considered as a possible eye irritant and, in common with other proteinaceous substances, respiratory sensitiser.

There is no need for assessing the efficacy of the additive in the context of the renewal of the authorisation for chickens for fattening, laying hens, ducks, all minor poultry species, weaned piglets and pigs for fattening. The Panel concludes that the additive has the potential to be efficacious in all poultry species for fattening, or reared for laying/breeding, and laying at 625 U/kg complete feed and in suckling piglets and all minor growing porcine species at 2,000 U/kg complete feed.

5. Documentation as provided to EFSA/Chronology

Date	Event
05/12/2018	Dossier received by EFSA. Danisco Xylanase 40000 G/Danisco Xylanase 40000 L (endo-1,4-beta-xylanase) for all ducks, all other poultry species (except breeders), piglets (weaned, suckling), pigs for fattening and minor growing porcine species. Submitted by Danisco Animal Nutrition represented in the EU by Genecor International B.V.
19/12/2018	Reception mandate from the European Commission
11/02/2019	Application validated by EFSA – Start of the scientific assessment
18/03/2019	Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. *Issues: characterisation, safety*
13/05/2019	Comments received from Member States
02/07/2019	Reception of supplementary information from the applicant - Scientific assessment re-started
08/10/2019	Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. *Issues: characterisation*
23/10/2019	Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. *Issues: characterisation*
06/03/2020	Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. *Issues: characterisation*
04/05/2020	Reception of supplementary information from the applicant - Scientific assessment re-started
29/05/2020	Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. *Issues: characterisation, safety*
15/12/2020	Reception of supplementary information from the applicant - Scientific assessment re-started
18/12/2020	Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. *Issues: characterisation*
01/02/2021	Reception of supplementary information from the applicant - Scientific assessment re-started
17/03/2021	Opinion adopted by the FEEDAP Panel. End of the Scientific assessment

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Abbreviations

CFU	colony forming unit
DL-PCB	dioxin-like polychlorinated biphenyl
EURL	European Union Reference Laboratory
FEEDAP	EFSA Panel on Additives and products or Substances used in Animal Feed
LOQ	limit of quantification
PCDD/F	polychlorinated dibenzo-*p*-dioxins and dibenzofurans
TEQ	toxic equivalent
WHO	World Health Organization