



Brussels, **XXX**
SANTE/1678826/2024 CIS
(POOL/G5/2024/1678826/1678826 CIS-
EN.doc)
[...](2024) **XXX** draft

COMMISSION IMPLEMENTING REGULATION (EU) .../...

of XXX

amending Implementing Regulations (EU) No 389/2011, (EU) 2016/899, (EU) 2017/440, (EU) 2017/896, (EU) 2020/164, (EU) 2020/166, (EU) 2021/2051, (EU) 2021/2096, (EU) 2023/1167, (EU) 2023/1703 and (EU) 2023/1713 as regards the name of the holder of the authorisation for feed additives

(Text with EEA relevance)

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(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition¹ and in particular Article 13(3) thereof,

Whereas:

- (1) A preparation of endo-1,4-beta-xylanase, subtilisin and alpha-amylase, 6-phytase produced by *Trichoderma reesei* (ATCC SD-6528), a preparation of *Bacillus amyloliquefaciens* (PTA-6507), *Bacillus amyloliquefaciens* (NRRL B-50013) and *Bacillus amyloliquefaciens* (NRRL B-50104), a preparation of 6-phytase produced by *Trichoderma reesei* (ATCC SD-6528), 6-phytase produced by *Schizosaccharomyces pombe* (ATCC 5233), a preparation of *Bacillus velezensis* PTA-6507, *Bacillus velezensis* NRRL B-50013 and *Bacillus velezensis* NRRL B-50104, endo-1,4-beta-xylanase produced by *Trichoderma reesei* CBS 143953, a preparation of 6-phytase produced by *Trichoderma reesei* CBS 146250, a preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* CBS 143953 and endo-1,3(4)-beta-glucanase produced by *Trichoderma reesei* CBS 143945, a preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* ATCC PTA-5588, protease produced by *Bacillus subtilis* CBS 148232 and alpha-amylase produced by *Bacillus licheniformis* ATCC SD-6525 were authorised as feed additives ('feed additives concerned') by Commission Implementing Regulations (EU) No 389/2011², (EU) 2016/899³, (EU) 2017/440⁴, (EU) 2017/896⁵, (EU) 2020/164⁶, (EU) 2020/166⁷, (EU)

¹ OJ L 268, 18.10.2003, p. 29, ELI: <http://data.europa.eu/eli/reg/2003/1831/oj>

² Commission Implementing Regulation (EU) No 389/2011 of 19 April 2011 concerning the authorisation of an enzyme preparation of endo-1,4-beta-xylanase, subtilisin and alpha-amylase as feed additive for laying hens (holder of authorisation Danisco Animal Nutrition) (OJ L 104, 20.4.2011, p. 7, ELI: http://data.europa.eu/eli/reg_impl/2011/389/oj)

³ Commission Implementing Regulation (EU) 2016/899 of 8 June 2016 concerning the authorisation of a 6-phytase produced by *Trichoderma reesei* (ATCC SD-6528) as a feed additive for all poultry species and all porcine species (other than suckling piglets) (holder of authorisation Danisco (UK) Ltd) (OJ L 152, 09.06.2016, p. 15, ELI: http://data.europa.eu/eli/reg_impl/2016/899/oj)

⁴ Commission Implementing Regulation (EU) 2017/440 of 13 March 2017 concerning the authorisation of the preparation of *Bacillus amyloliquefaciens* (PTA-6507), *Bacillus amyloliquefaciens* (NRRL B-50013) and *Bacillus amyloliquefaciens* (NRRL B-50104) as a feed additive for chickens for fattening, chickens reared for laying, minor poultry species for fattening and minor poultry species reared for laying (holder of authorisation

2021/2051⁸, (EU) 2021/2096⁹, (EU) 2023/1167¹⁰, (EU) 2023/1703¹¹, and (EU) 2023/1713¹², respectively.

- (2) The holder of the authorisations for the feed additives concerned, Danisco (UK) Ltd (operating also as Danisco Animal Nutrition), has submitted an application in accordance with Article 13(3) of Regulation (EC) No 1831/2003 proposing to change the name of the holder of the authorisations for the feed additives concerned to Genencor International B.V.
- (3) The proposed change of the terms of the authorisations is purely administrative in nature and does not entail a fresh assessment of the feed additives concerned. The European Food Safety Authority was informed of the application.

Danisco (UK) Ltd, trading as Danisco Animal Nutrition) (OJ L 67, 14.3.2017, p. 74, ELI: http://data.europa.eu/eli/reg_impl/2017/440/oj)

⁵ Commission Implementing Regulation (EU) 2017/896 of 24 May 2017 concerning the authorisation of a preparation of 6-phytase, produced by *Trichoderma reesei* (ATCC SD-6528) as a feed additive in solid form for all poultry species and all porcine species (other than suckling piglets) (holder of the authorisation Danisco (UK) Ltd) (OJ L 138, 25.5.2017, p. 123, ELI: http://data.europa.eu/eli/reg_impl/2017/896/oj)

⁶ Commission Implementing Regulation (EU) 2020/164 of 5 February 2020 concerning the authorisation of 6-phytase produced by *Schizosaccharomyces pombe* (ATCC 5233) as a feed additive for all avian species and all swine species and repealing Regulation (EC) No 379/2009 (holder of authorisation Danisco (UK) Ltd, trading as Danisco Animal Nutrition and represented by Genencor International B.V.) (OJ L 34, 06.02.2020, p. 37, ELI: http://data.europa.eu/eli/reg_impl/2020/164/oj)

⁷ Commission Implementing Regulation (EU) 2020/166 of 5 February 2020 concerning the renewal of the authorisation of 6-phytase produced by *Schizosaccharomyces pombe* (ATCC 5233) as a feed additive for chickens for fattening, laying hens, turkeys for fattening, ducks for fattening, weaned piglets, pigs for fattening and sows and repealing Regulation (EC) No 785/2007 (holder of authorisation Danisco (UK) Ltd, trading as Danisco Animal Nutrition and represented by Genencor International B.V.) (OJ L 34, 06.02.2020, p. 43, ELI: http://data.europa.eu/eli/reg_impl/2020/166/oj)

⁸ Commission Implementing Regulation (EU) 2021/2051 of 24 November 2021 concerning the authorisation of a preparation of *Bacillus velezensis* PTA-6507, *Bacillus velezensis* NRRL B-50013 and *Bacillus velezensis* NRRL B-50104 as a feed additive for turkeys for fattening (holder of authorisation: Danisco Animal Nutrition represented by Genencor International B.V.) (OJ L 420, 25.11.2021, p. 19, ELI: http://data.europa.eu/eli/reg_impl/2021/2051/oj)

⁹ Commission Implementing Regulation (EU) 2021/2096 of 29 November 2021 concerning the authorisation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* CBS 143953 as a feed additive for all poultry species, pigs for fattening, piglets and all minor porcine species (holder of the authorisation: Danisco (UK) Ltd, represented in the Union by Genencor International B.V.) (OJ L 427, 20.11.2021, p. 187, ELI: http://data.europa.eu/eli/reg_impl/2021/2096/oj)

¹⁰ Commission Implementing Regulation (EU) 2023/1167 of 15 June 2023 concerning the authorisation of a preparation of 6-phytase produced by *Trichoderma reesei* CBS 146250 as a feed additive for all poultry species and all pigs (holder of authorisation: Danisco (UK) Ltd, trading as Danisco Animal Nutrition and represented by Genencor International B.V.) (OJ L 155, 16.6.2023, p. 6, ELI: http://data.europa.eu/eli/reg_impl/2023/1167/oj)

¹¹ Commission Implementing Regulation (EU) 2023/1703 of 7 September 2023 concerning the renewal of the authorisation of a preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* CBS 143953 and endo-1,3(4)-beta-glucanase produced by *Trichoderma reesei* CBS 143945 as a feed additive for poultry species, weaned piglets, pigs for fattening, lactating sows and minor porcine species (weaned piglets, pigs for fattening and lactating sows), the authorisation of that preparation for suckling piglets and minor porcine species (suckling piglets) (holder of authorisation: Danisco (UK) Ltd, trading as Danisco Animal Nutrition and represented by Genencor International B.V.) and repealing Regulation (EU) No 337/2011 and Implementing Regulation (EU) 2016/997 (OJ L 221, 8.9.2023, p. 3, ELI: http://data.europa.eu/eli/reg_impl/2023/1703/oj)

¹² Commission Implementing Regulation (EU) 2023/1713 of 7 September 2023 concerning the authorisation of a preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* ATCC PTA-5588, protease produced by *Bacillus subtilis* CBS 148232 and alpha-amylase produced by *Bacillus licheniformis* ATCC SD-6525 for chickens for fattening, chickens reared for laying and minor poultry species (holder of authorisation: Danisco (UK) Ltd represented in the Union by Genencor international B.V.) (OJ L 221, 8.9.2023, p. 51, ELI: http://data.europa.eu/eli/reg_impl/2023/1713/oj)

- (4) To allow Genencor International B.V. to exploit its marketing rights, it is necessary to change the terms of the authorisations concerned.
- (5) Commission Implementing Regulations (EU) No 389/2011, (EU) 2016/899, (EU) 2017/440, (EU) 2017/896, (EU) 2020/164, (EU) 2020/166, (EU) 2021/2051, (EU) 2021/2096, (EU) 2023/1167, (EU) 2023/1703 and (EU) 2023/1713 should therefore, be amended accordingly.
- (6) Since safety reasons do not require the immediate application of the amendments made by this Regulation, it is appropriate to allow a transitional period during which existing stocks may be used up.
- (7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

Amendment to Regulation (EU) No 389/2011

Regulation (EU) No 389/2011 is amended as follows:

- (1) in the title, the words "Danisco Animal Nutrition" are replaced by the words "Genencor International B.V.";
- (2) in the second column of the Annex to Regulation (EU) No 389/2011, the words "Danisco Animal Nutrition" are replaced by the words " Genencor International B.V."

Article 2

Amendment to Regulation (EU) 2016/899

Regulation (EU) 2016/899 is amended as follows:

- (1) in the title, the words "Danisco (UK) Ltd" are replaced by the words "Genencor International B.V.";
- (2) in the second column of the Annex to Regulation (EU) 2016/899, the words "Danisco (UK) Ltd" are replaced by the words "Genencor International B.V. ".

Article 3

Amendment to Regulation (EU) 2017/440

Regulation (EU) 2017/440 is amended as follows:

- (1) in the title, the words "Danisco (UK) Ltd, trading as Danisco Animal Nutrition" are replaced by the words "Genencor International B.V.";
- (2) in the second column of the Annex to Regulation (EU) 2017/440, the words "Danisco (UK) Ltd, trading as Danisco Animal Nutrition" are replaced by the words "Genencor International B.V. ".

Article 4

Amendment to Regulation (EU) 2017/896

Regulation (EU) 2017/896 is amended as follows:

- (1) in the title, the words "Danisco (UK) Ltd." are replaced by the words "Genencor International B.V.";
- (2) in the second column of the Annex to Regulation (EU) 2017/896, the words "Danisco (UK) Ltd" are replaced by the words "Genencor International B.V.".

Article 5

Amendment to Regulation (EU) 2020/164

Regulation (EU) 2020/164 is amended as follows:

- (1) in the title, the words "Danisco (UK) Ltd., trading as Danisco Animal Nutrition and represented by Genencor International B.V." are replaced by the words "Genencor International B.V.";
- (2) in the second column of the Annex to Regulation (EU) 2020/164, the words "Danisco (UK) Ltd, trading as Danisco Animal Nutrition and represented by Genencor International B.V." are replaced by the words "Genencor International B.V.".

Article 6

Amendment to Regulation (EU) 2020/166

Regulation (EU) 2020/166 is amended as follows:

- (1) in the title, the words "Danisco (UK) Ltd., trading as Danisco Animal Nutrition and represented by Genencor International B.V." are replaced by the words "Genencor International B.V.";
- (2) in the second column of the Annex to Regulation (EU) 2020/166, the words "Danisco (UK) Ltd, trading as Danisco Animal Nutrition and represented by Genencor International B.V." are replaced by the words "Genencor International B.V.".

Article 7

Amendment to Regulation (EU) 2021/2051

Regulation (EU) 2021/2051 is amended as follows:

- (1) in the title, the words "Danisco Animal Nutrition represented by Genencor International B.V." are replaced by the words "Genencor International B.V.";
- (2) in the second column of the Annex to Regulation (EU) 2021/2051, the words "Danisco Animal Nutrition represented by Genencor International B.V." are replaced by the words "Genencor International B.V.".

Article 8

Amendment to Regulation (EU) 2021/2096

Regulation (EU) 2021/2096 is amended as follows:

- (1) in the title, the words "Danisco (UK) Ltd., represented in the Union by Genencor International B.V." are replaced by the words "Genencor International B.V.";
- (2) in the second column of the Annex to Regulation (EU) 2021/2096, the words "Danisco (UK) Ltd., represented in the Union by Genencor International B.V." are replaced by the words "Genencor International B.V.".

Article 9

Amendment to Regulation (EU) 2023/1167

Regulation (EU) 2023/1167 is amended as follows:

- (1) in the title, the words "Danisco (UK) Ltd, trading as Danisco Animal Nutrition and represented by Genencor International B.V." are replaced by the words "Genencor International B.V.";
- (2) in the second column of the Annex to Regulation (EU) 2023/1167, the words "Danisco (UK) Ltd, trading as Danisco Animal Nutrition and represented by Genencor International B.V." are replaced by the words "Genencor International B.V.".

Article 10

Amendment to Regulation (EU) 2023/1703

Regulation (EU) 2023/1703 is amended as follows:

- (1) in the title, the words "Danisco (UK) Ltd, trading as Danisco Animal Nutrition and represented by Genencor International B.V." are replaced by the words "Genencor International B.V.";
- (2) in the second column of the Annex to Regulation (EU) 2023/1703, the words "Danisco (UK) Ltd, trading as Danisco Animal Nutrition and represented by Genencor International B.V." are replaced by the words "Genencor International B.V.".

Article 11

Amendment to Regulation (EU) 2023/1713

Regulation (EU) 2023/1713 is amended as follows:

- (1) in the title, the words "Danisco (UK) Ltd represented in the Union by Genencor International B.V." are replaced by the words "Genencor International B.V.";
- (2) in the second column of the Annex to Regulation (EU) 2023/1713, the words "Danisco (UK) Ltd represented in the Union by Genencor International B.V." are replaced by the words "Genencor International B.V.".

Article 12

Transitional measure

The feed additives concerned, produced and labelled before the date of entry into force of this Regulation in accordance with the rules applicable before that date, may continue to be placed on the market and used until stocks are exhausted.

Article 13

Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN