

Commission Implementing Regulation (EU) 2019/221 of 6 February 2019 amending Regulations (EC) No 785/2007, (EC) No 379/2009, (EC) No 1087/2009, (EU) No 9/2010, (EU) No 337/2011 and Implementing Regulations (EU) No 389/2011, (EU) No 528/2011, (EU) No 840/2012, (EU) No 1021/2012, (EU) 2016/899, (EU) 2016/997, (EU) 2017/440 and (EU) 2017/896 as regards the name of the holder of the authorisation and the representative of the holder of the authorisation for certain feed additives (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2019/221

of 6 February 2019

amending Regulations (EC) No 785/2007, (EC) No 379/2009, (EC) No 1087/2009, (EU) No 9/2010, (EU) No 337/2011 and Implementing Regulations (EU) No 389/2011, (EU) No 528/2011, (EU) No 840/2012, (EU) No 1021/2012, (EU) 2016/899, (EU) 2016/997, (EU) 2017/440 and (EU) 2017/896 as regards the name of the holder of the authorisation and the representative of the holder of the authorisation for certain feed additives

(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 nutrition<sup>(1)</sup> and in particular Article 13(3) thereof,

Whereas:

- (1) In accordance with Regulation (EC) No 1831/2003 of the European Parliament and of the Council, 6-phytase, endo-1,4-beta-xylanase, subtilisin, alpha-amylase, endo-1,3(4)-beta-glucanase, preparation of *Bacillus amyloliquefaciens* (PTA-6507), *Bacillus amyloliquefaciens* (NRRL B-50013) and *Bacillus amyloliquefaciens* (NRRL B-50104) were authorised by Commission Regulations (EC) No 785/2007<sup>(2)</sup>, (EC) No 379/2009<sup>(3)</sup>, (EC) No 1087/2009<sup>(4)</sup>, (EU) No 9/2010<sup>(5)</sup> and (EU) No 337/2011<sup>(6)</sup> and Commission Implementing Regulations (EU) No 389/2011<sup>(7)</sup>, (EU) No 528/2011<sup>(8)</sup>, (EU) No 840/2012<sup>(9)</sup>, (EU) No 1021/2012<sup>(10)</sup>, (EU) 2016/899<sup>(11)</sup>, (EU) 2016/997<sup>(12)</sup>, (EU) 2017/440<sup>(13)</sup> and (EU) 2017/896<sup>(14)</sup>.
- (2) The holder of authorisation, Danisco Animal Nutrition legal entity Danisco (UK) Ltd, has submitted an application in accordance with Article 13(3) of Regulation (EC) No 1831/2003 proposing to add to the authorisations concerned the name of its representative and, for the authorisations granted by Regulations (EC) No 1087/2009 and (EU) No 9/2010, to change of the name of the authorisation holder.
- (3) The holder of authorisation has submitted relevant data supporting the fact that, with effect from 30 March 2019, Genencor International B.V. will act as its representative

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*Changes to legislation: There are currently no known outstanding effects for the  
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for the feed additives concerned. The holder of authorisation also submitted the relevant information to demonstrate that Finnfeeds International Limited changed its name to Danisco (UK) Ltd.

- (4) The proposed change of the terms of the authorisations is purely administrative in nature and does not entail a fresh assessment of the additives concerned. The European Food Safety Authority was informed of the application.
- (5) To allow Genencor International B.V. to act as the representative of the holder of the authorisations, it is necessary to change the terms of the authorisations concerned.
- (6) Regulations (EC) No 785/2007, (EC) No 379/2009, (EC) No 1087/2009, (EU) No 9/2010, (EU) No 337/2011 and Implementing Regulations (EU) No 389/2011, (EU) No 528/2011, (EU) No 840/2012, (EU) No 1021/2012, (EU) 2016/899, (EU) 2016/997, (EU) 2017/440 and (EU) 2017/896 should, therefore, be amended accordingly.
- (7) As the data submitted by the holder of authorisation shows that Genencor International B.V. will act as its representative with effect from 30 March 2019, this Regulation should apply from the same date.
- (8) 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 (EC) No 785/2007**

In the second column of the Annex to Regulation (EC) No 785/2007 the words ‘Danisco Animal Nutrition’ are replaced by the words ‘Danisco (UK) Ltd, trading as Danisco Animal Nutrition and represented by Genencor International B.V.’.

*Article 2*

**Amendment to Regulation (EC) No 379/2009**

1 In the title, the words ‘Danisco Animal Nutrition, legal entity Danisco (UK) Limited’ are replaced by the words ‘Danisco (UK) Ltd, trading as Danisco Animal Nutrition and represented by Genencor International B.V.’.

2 In the second column of the Annex to Regulation (EC) No 379/2009 the words ‘Danisco Animal Nutrition, legal entity Danisco (UK) Limited’ are replaced by the words ‘Danisco (UK) Ltd, trading as Danisco Animal Nutrition and represented by Genencor International B.V.’.

### *Article 3*

#### **Amendment to Regulation (EC) No 1087/2009**

1 In the title, the words ‘Danisco Animal Nutrition, legal entity Finnfeeds International Limited’ are replaced by the words ‘Danisco (UK) Ltd, trading as Danisco Animal Nutrition and represented by Genencor International B.V.’.

2 In the second column of the Annex to Regulation (EC) No 1087/2009 the words ‘Danisco Animal Nutrition, legal entity Finnfeeds International Limited’ are replaced by the words ‘Danisco (UK) Ltd, trading as Danisco Animal Nutrition and represented by Genencor International B.V.’.

### *Article 4*

#### **Amendment to Regulation (EU) No 9/2010**

1 In the title, the words ‘Danisco Animal Nutrition, Finnfeeds International Limited’ are replaced by the words ‘Danisco (UK) Ltd, trading as Danisco Animal Nutrition and represented by Genencor International B.V.’.

2 In the second column of the Annex to Regulation (EU) No 9/2010 the words ‘Danisco Animal Nutrition (legal entity: Danisco (UK) Limited)’ are replaced by the words ‘Danisco (UK) Ltd, trading as Danisco Animal Nutrition and represented by Genencor International B.V.’.

### *Article 5*

#### **Amendment to Regulation (EU) No 337/2011**

1 In the title, the words ‘Danisco Animal Nutrition’ are replaced by the words ‘Danisco (UK) Ltd, trading as Danisco Animal Nutrition and represented by Genencor International B.V.’.

2 In the second column of the Annex to Regulation (EU) No 337/2011 the words ‘Danisco Animal Nutrition’ are replaced by the words ‘Danisco (UK) Ltd, trading as Danisco Animal Nutrition and represented by Genencor International B.V.’.

### *Article 6*

#### **Amendment to Implementing Regulation (EU) No 389/2011**

1 In the title, the words ‘Danisco Animal Nutrition’ are replaced by the words ‘Danisco (UK) Ltd, trading as Danisco Animal Nutrition and represented by Genencor International B.V.’.

2 In the second column of the Annex to Implementing Regulation (EU) No 389/2011 the words ‘Danisco Animal Nutrition’ are replaced by the words ‘Danisco (UK) Ltd, trading as Danisco Animal Nutrition and represented by Genencor International B.V.’.

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#### *Article 7*

### **Amendment to Implementing Regulation (EU) No 528/2011**

1 In the title, the words ‘Danisco Animal Nutrition’ are replaced by the words ‘Danisco (UK) Ltd, trading as Danisco Animal Nutrition and represented by Genencor International B.V.’.

2 In the second column of the Annex to Implementing Regulation (EU) No 528/2011 the words ‘Danisco Animal Nutrition’ are replaced by the words ‘Danisco (UK) Ltd, trading as Danisco Animal Nutrition and represented by Genencor International B.V.’.

#### *Article 8*

### **Amendment to Implementing Regulation (EU) No 840/2012**

1 In the title, the words ‘Danisco Animal Nutrition’ are replaced by the words ‘Danisco (UK) Ltd, trading as Danisco Animal Nutrition and represented by Genencor International B.V.’.

2 In the second column of the Annex to Implementing Regulation (EU) No 840/2012 the words ‘Danisco Animal Nutrition (legal entity Danisco (UK) Limited)’ are replaced by the words ‘Danisco (UK) Ltd, trading as Danisco Animal Nutrition and represented by Genencor International B.V.’.

#### *Article 9*

### **Amendment to Implementing Regulation (EU) No 1021/2012**

1 In the title, the words ‘Danisco Animal Nutrition’ are replaced by the words ‘Danisco (UK) Ltd, trading as Danisco Animal Nutrition and represented by Genencor International B.V.’.

2 In the second column of the Annex to Implementing Regulation (EU) No 1021/2012 the words ‘Danisco Animal Nutrition (legal entity: Danisco (UK) Limited)’ are replaced by the words ‘Danisco (UK) Ltd, trading as Danisco Animal Nutrition and represented by Genencor International B.V.’.

#### *Article 10*

### **Amendment to Implementing Regulation (EU) 2016/899**

1 In the title, the words ‘Danisco (UK) Ltd’ are replaced by the words ‘Danisco (UK) Ltd, trading as Danisco Animal Nutrition and represented by Genencor International B.V.’.

2 In the second column of the Annex to Implementing Regulation (EU) 2016/899, the words ‘Danisco (UK) Ltd’ are replaced by the words ‘Danisco (UK) Ltd, trading as Danisco Animal Nutrition and represented by Genencor International B.V.’.

#### *Article 11*

##### **Amendment to Implementing Regulation (EU) 2016/997**

1 In the title, the words ‘Danisco (UK) Ltd’ are replaced by the words ‘Danisco (UK) Ltd, trading as Danisco Animal Nutrition and represented by Genencor International B.V.’.

2 In the second column of the Annex to Implementing Regulation (EU) 2016/997 the words ‘Danisco (UK) Ltd’ are replaced by the words ‘Danisco (UK) Ltd, trading as Danisco Animal Nutrition and represented by Genencor International B.V.’.

#### *Article 12*

##### **Amendment to Implementing Regulation (EU) 2017/440**

1 In the title, the words ‘Danisco (UK) Ltd, trading as Danisco Animal Nutrition’ are replaced by the words ‘Danisco (UK) Ltd, trading as Danisco Animal Nutrition and represented by Genencor International B.V.’.

2 In the second column of the Annex to Implementing Regulation (EU) 2017/440 the words ‘Danisco (UK) Ltd, trading as Danisco Animal Nutrition’ are replaced by the words ‘Danisco (UK) Ltd, trading as Danisco Animal Nutrition and represented by Genencor International B.V.’.

#### *Article 13*

##### **Amendment to Implementing Regulation (EU) 2017/896**

1 In the title, the words ‘Danisco (UK) Ltd’ are replaced by the words ‘Danisco (UK) Ltd, trading as Danisco Animal Nutrition and represented by Genencor International B.V.’.

2 In the second column of the Annex to Implementing Regulation (EU) 2017/896 the words ‘Danisco (UK) Ltd’ are replaced by the words ‘Danisco (UK) Ltd, trading as Danisco Animal Nutrition and represented by Genencor International B.V.’.

#### *Article 14*

##### **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*.

It shall apply from 30 March 2019.

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

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**Changes to legislation:** There are currently no known outstanding effects for the  
Commission Implementing Regulation (EU) 2019/221. (See end of Document for details)

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Done at Brussels, 6 February 2019.

*For the Commission*

*The President*

Jean-Claude JUNCKER

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- (1) [OJ L 268, 18.10.2003, p. 29.](#)
- (2) Commission Regulation (EC) No 785/2007 of 4 July 2007 concerning the authorisation of 6-phytase EC 3.1.3.26 (Phyzyme XP 5000G Phyzyme XP 5000L) as a feed additive ([OJ L 175, 5.7.2007, p. 5.](#))
- (3) Commission Regulation (EC) No 379/2009 of 8 May 2009 concerning the authorisation of a new use of 6-phytase EC 3.1.3.26 as a feed additive for chickens for fattening, turkeys for fattening, laying hens, ducks for fattening, piglets (weaned), pigs for fattening and sows (holder of the authorisation Danisco Animal Nutrition, legal entity Danisco (UK) Limited ([OJ L 116, 9.5.2009, p. 6.](#)).
- (4) Commission Regulation (EC) No 1087/2009 of 12 November 2009 concerning the authorisation of an enzyme preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (ATCC PTA 5588), subtilisin produced by *Bacillus subtilis* (ATCC 2107) and alpha-amylase produced by *Bacillus amyloliquefaciens* (ATCC 3978) as a feed additive for chickens for fattening, for ducks and for turkeys for fattening (holder of authorisation Danisco Animal Nutrition, legal entity Finnfeeds International Limited) ([OJ L 297, 13.11.2009, p. 4.](#))
- (5) 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 additive 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.](#))
- (6) Commission Regulation (EU) No 337/2011 of 7 April 2011 concerning the authorisation of an enzyme preparation of endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase as feed additive for poultry, weaned piglets and pigs for fattening (holder of the authorisation Danisco Animal Nutrition) ([OJ L 94, 8.4.2011, p. 19.](#))
- (7) 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.](#))
- (8) Commission Implementing Regulation (EU) No 528/2011 of 30 May 2011 concerning the authorisation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (ATCC PTA 5588) as a feed additive for weaned piglets and pigs for fattening (holder of authorisation Danisco Animal Nutrition) ([OJ L 143, 31.5.2011, p. 10.](#))
- (9) Commission Implementing Regulation (EU) No 840/2012 of 18 September 2012 concerning the authorisation of 6-phytase (EC 3.1.3.26) produced by *Schizosaccharomyces pombe* (ATCC 5233) as a feed additive for all avian species for fattening other than chickens for fattening, turkeys for fattening and ducks for fattening and all avian species for laying other than laying hens (holder of authorisation Danisco Animal Nutrition) ([OJ L 252, 19.9.2012, p. 14.](#))
- (10) Commission Implementing Regulation (EU) No 1021/2012 of 6 November 2012 concerning the authorisation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (ATCC PTA 5588) as a feed additive for minor poultry species other than ducks (holder of authorisation Danisco Animal Nutrition) ([OJ L 307, 7.11.2012, p. 68.](#))
- (11) 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, 9.6.2016, p. 15.](#))
- (12) Commission Implementing Regulation (EU) 2016/997 of 21 June 2016 concerning the authorisation of endo-1,4-beta-xylanase EC 3.2.1.8 produced by *Trichoderma reesei* (ATCC PTA 5588) and endo-1,3(4)-beta-glucanase EC 3.2.1.6 produced by *Trichoderma reesei* (ATCC SD 2106) as a feed additive for lactating sows and minor porcine species (holder of authorisation Danisco (UK) Ltd) ([OJ L 164, 22.6.2016, p. 4.](#))
- (13) 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 Danisco (UK) Ltd, trading as Danisco Animal Nutrition) ([OJ L 67, 14.3.2017, p. 74.](#))

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- (14) 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](#)).

**Changes to legislation:**

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