

DECISION OF THE EEA JOINT COMMITTEE

No 37/2012

of 30 March 2012

amending Annex I (Veterinary and phytosanitary matters) to the EEA Agreement

THE EEA JOINT COMMITTEE,

Having regard to the Agreement on the European Economic Area, as amended by the Protocol adjusting the Agreement on the European Economic Area, hereinafter referred to as 'the Agreement', and in particular Article 98 thereof,

Whereas:

- (1) Annex I to the Agreement was amended by Decision of the EEA Joint Committee No 5/2012 of 10 February 2012 ⁽¹⁾.
- (2) Commission Regulation (EU) No 170/2011 of 23 February 2011 concerning the authorisation of *Saccharomyces cerevisiae* MUCL 39885 as a feed additive for piglets (weaned) and amending Regulation (EC) No 1200/2005 (holder of authorisation Prosol SpA) ⁽²⁾ is to be incorporated into the Agreement.
- (3) Commission Regulation (EU) No 171/2011 of 23 February 2011 concerning the authorisation of 6-phytase (EC 3.1.3.26) produced by *Aspergillus oryzae* DSM 14223 as a feed additive for poultry and for porcine species and amending Regulation (EC) No 255/2005 (holder of authorisation DSM Nutritional Products Ltd represented by DSM Nutritional products Sp. z o.o) ⁽³⁾ is to be incorporated into the Agreement.
- (4) Commission Regulation (EU) No 184/2011 of 25 February 2011 concerning the authorisation of *Bacillus subtilis* C-3102 (DSM 15544) as a feed additive for chickens reared for laying, turkeys, minor avian species and other ornamental and game birds (holder of authorisation Calpis Co. Ltd Japan, represented by Calpis Co. Ltd Europe Representative Office) ⁽⁴⁾ is to be incorporated into the Agreement.
- (5) Commission Regulation (EU) No 212/2011 of 3 March 2011 concerning the authorisation of *Pediococcus acidilactici* CNCM MA 18/5M as a feed additive for laying hens (holder of authorisation Lallemand SAS) ⁽⁵⁾ is to be incorporated into the Agreement.
- (6) Commission Regulation (EU) No 221/2011 of 4 March 2011 concerning the authorisation of 6-phytase (EC 3.1.3.26) produced by *Aspergillus oryzae* DSM 14223 as a feed additive for salmonids (holder of authorisation DSM Nutritional Products Ltd represented by DSM Nutritional products Sp. Z o.o) ⁽⁶⁾ is to be incorporated into the Agreement.
- (7) Commission Regulation (EU) No 335/2011 of 7 April 2011 amending Regulation (EC) No 1091/2009 as regards the minimum content of the enzyme preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (MUCL 49755) and endo-1,3(4)-beta-glucanase produced by *Trichoderma reesei* (MUCL 49754) as a feed additive in feed for chickens for fattening ⁽⁷⁾ is to be incorporated into the Agreement.
- (8) Commission Regulation (EU) No 336/2011 of 7 April 2011 amending Regulation (EC) No 1292/2008 as regards the use of the feed additive *Bacillus amyloliquefaciens* CECT 5940 in feed containing diclazuril, monensin sodium and nicarbazin ⁽⁸⁾ is to be incorporated into the Agreement.
- (9) 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) ⁽⁹⁾ is to be incorporated into the Agreement.
- (10) Commission Implementing Regulation (EU) No 361/2011 of 13 April 2011 concerning the authorisation of *Enterococcus faecium* NCIMB 10415 as a feed additive for chickens for fattening (holder of authorisation DSM Nutritional products Ltd represented by DSM Nutritional Products Sp. z o.o) and amending Regulation (EC) No 943/2005 ⁽¹⁰⁾ is to be incorporated into the Agreement.

⁽¹⁾ OJ L 161, 21.6.2012, p. 8.

⁽²⁾ OJ L 49, 24.2.2011, p. 8.

⁽³⁾ OJ L 49, 24.2.2011, p. 11.

⁽⁴⁾ OJ L 53, 26.2.2011, p. 33.

⁽⁵⁾ OJ L 59, 4.3.2011, p. 1.

⁽⁶⁾ OJ L 60, 5.3.2011, p. 3.

⁽⁷⁾ OJ L 94, 8.4.2011, p. 14.

⁽⁸⁾ OJ L 94, 8.4.2011, p. 17.

⁽⁹⁾ OJ L 94, 8.4.2011, p. 19.

⁽¹⁰⁾ OJ L 100, 14.4.2011, p. 22.

- (11) Commission Implementing Regulation (EU) No 371/2011 of 15 April 2011 concerning the authorisation of dimethylglycine sodium salt as feed additive for chickens for fattening (holder of the authorisation Taminco N.V.)⁽¹⁾ is to be incorporated into the Agreement.
- (12) Commission Implementing Regulation (EU) No 373/2011 of 15 April 2011 concerning the authorisation of the preparation of *Clostridium butyricum* FERM-BP 2789 as a feed additive for minor avian species except laying birds, weaned piglets and minor porcine species (weaned) and amending Regulation (EC) No 903/2009 (holder of authorisation Miyarisan Pharmaceutical Co. Ltd, represented by Miyarisan Pharmaceutical Europe S.L.U.)⁽²⁾ is to be incorporated into the Agreement.
- (13) Commission Implementing Regulation (EU) No 388/2011 of 19 April 2011 concerning the authorisation of maduramicin ammonium alpha as a feed additive for chickens for fattening (holder of authorisation Alpharma (Belgium) BVBA) and amending Regulation (EC) No 2430/1999⁽³⁾ is to be incorporated into the Agreement.
- (14) 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)⁽⁴⁾ is to be incorporated into the Agreement.
- (15) Commission Implementing Regulation (EU) No 406/2011 of 27 April 2011 amending Regulation (EC) No 2380/2001 as regards the composition of the feed additive maduramicin ammonium alpha⁽⁵⁾ is to be incorporated into the Agreement.
- (16) Commission Implementing Regulation (EU) No 495/2011 of 20 May 2011 amending Regulation (EC) No 109/2007 as regards the composition of the feed additive monensin sodium⁽⁶⁾ is to be incorporated into the Agreement.
- (17) Commission Implementing Regulation (EU) No 496/2011 of 20 May 2011 concerning the authorisation of sodium benzoate as a feed additive for weaned piglets (holder of the authorisation Kemira Oyj)⁽⁷⁾ is to be incorporated into the Agreement.
- (18) Commission Implementing Regulation (EU) No 515/2011 of 25 May 2011 concerning the authorisation of vitamin B 6 as a feed additive for all animal species⁽⁸⁾ is to be incorporated into the Agreement.
- (19) Commission Implementing Regulation (EU) No 516/2011 of 25 May 2011 amending Regulation (EC) No 600/2005 as regards the use of the preparation of *Bacillus licheniformis* DSM 5749 and *Bacillus subtilis* DSM 5750 in feed containing formic acid⁽⁹⁾ is to be incorporated into the Agreement.
- (20) Commission Implementing Regulation (EU) No 527/2011 of 30 May 2011 concerning the authorisation of a preparation of endo-1,4- β -xylanase produced by *Trichoderma reesei* (MUCL 49755), endo-1,3(4)- β -glucanase produced by *Trichoderma reesei* (MUCL 49754) and polygalacturonase produced by *Aspergillus aculeatus* (CBS 589.94) as feed additive for weaned piglets (holder of the authorisation Aveve NV)⁽¹⁰⁾ is to be incorporated into the Agreement.
- (21) Commission Implementing Regulation (EU) No 528/2011 of 30 May 2011 concerning the authorisation of endo-1,4- β -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)⁽¹¹⁾ is to be incorporated into the Agreement.
- (22) Commission Implementing Regulation (EU) No 532/2011 of 31 May 2011 concerning the authorisation of robenidine hydrochloride as a feed additive for rabbits for breeding and rabbits for fattening (holder of authorisation Alpharma Belgium BVBA) and amending Regulations (EC) No 2430/1999 and (EC) No 1800/2004⁽¹²⁾ is to be incorporated into the Agreement.

⁽¹⁾ OJ L 102, 16.4.2011, p. 6.

⁽²⁾ OJ L 102, 16.4.2011, p. 10.

⁽³⁾ OJ L 104, 20.4.2011, p. 3.

⁽⁴⁾ OJ L 104, 20.4.2011, p. 7.

⁽⁵⁾ OJ L 108, 28.4.2011, p. 11.

⁽⁶⁾ OJ L 134, 21.5.2011, p. 6.

⁽⁷⁾ OJ L 134, 21.5.2011, p. 9.

⁽⁸⁾ OJ L 138, 26.5.2011, p. 40.

⁽⁹⁾ OJ L 138, 26.5.2011, p. 43.

⁽¹⁰⁾ OJ L 143, 31.5.2011, p. 6.

⁽¹¹⁾ OJ L 143, 31.5.2011, p. 10.

⁽¹²⁾ OJ L 146, 1.6.2011, p. 7.

- (23) Commission Regulation (EU) No 574/2011 of 16 June 2011 amending Annex I to Directive 2002/32/EC of the European Parliament and of the Council as regards maximum levels for nitrite, melamine, *Ambrosia* spp. and carry-over of certain coccidiostats and histomonostats and consolidating Annexes I and II thereto ⁽¹⁾ is to be incorporated into the Agreement.
- (24) Commission Regulation (EU) No 575/2011 of 16 June 2011 on the Catalogue of feed materials ⁽²⁾ is to be incorporated into the Agreement.
- (25) Commission Implementing Regulation (EU) No 868/2011 of 31 August 2011 concerning the authorisation of a preparation of *Lactobacillus plantarum* (DSM 21762) and of a preparation of *Lactobacillus buchneri* (DSM 22963) as feed additives for all animal species ⁽³⁾ is to be incorporated into the Agreement.
- (26) Regulation (EU) No 171/2011 repeals Commission Regulation (EC) No 1500/2007 ⁽⁴⁾ which is incorporated in the Agreement and is therefore to be repealed under the Agreement.
- (27) Regulation (EU) No 575/2011 repeals Commission Regulation (EU) No 242/2010 ⁽⁵⁾ which is incorporated in the Agreement and is therefore to be repealed under the Agreement.
- (28) This Decision concerns legislation regarding feedingstuffs. Legislation regarding feedingstuffs shall not apply to Liechtenstein as long as the application of the Agreement between the European Community and the Swiss Confederation on trade in agricultural products is extended to Liechtenstein, as specified in the sectoral adaptations to Annex I to the Agreement. This Decision is therefore not to apply to Liechtenstein.
- **32011 R 0532**: Commission Implementing Regulation (EU) No 532/2011 of 31 May 2011 (OJ L 146, 1.6.2011, p. 7).;
- (2) the following indent shall be added in point 1y (Commission Regulation (EC) No 2380/2001):
- **32011 R 0406**: Commission Implementing Regulation (EU) No 406/2011 of 27 April 2011 (OJ L 108, 28.4.2011, p. 11).;
- (3) the following indent shall be added in point 1zzd (Commission Regulation (EC) No 1800/2004):
- **32011 R 0532**: Commission Implementing Regulation (EU) No 532/2011 of 31 May 2011 (OJ L 146, 1.6.2011, p. 7).;
- (4) the following shall be added in point 1zzf (Commission Regulation (EC) No 255/2005):
- ‘, as amended by:
- **32011 R 0171**: Commission Regulation (EU) No 171/2011 of 23 February 2011 (OJ L 49, 24.2.2011, p. 11).;
- (5) the following indent shall be added in point 1zzi (Commission Regulation (EC) No 521/2005):
- **32011 R 0221**: Commission Regulation (EU) No 221/2011 of 4 March 2011 (OJ L 60, 5.3.2011, p. 3).;

HAS ADOPTED THIS DECISION:

Article 1

Chapter II of Annex I to the Agreement shall be amended as follows:

- (1) the following indents shall be added in point 1k (Commission Regulation (EC) No 2430/1999):
- **32011 R 0388**: Commission Implementing Regulation (EU) No 388/2011 of 19 April 2011 (OJ L 104, 20.4.2011, p. 3),

- (6) the following indent shall be added in point 1zzj (Commission Regulation (EC) No 600/2005):
- **32011 R 0516**: Commission Implementing Regulation (EU) No 516/2011 of 25 May 2011 (OJ L 138, 26.5.2011, p. 43).;
- (7) the following indent shall be added in point 1zzl (Commission Regulation (EC) No 943/2005):
- ‘, as amended by:

⁽¹⁾ OJ L 159, 17.6.2011, p. 7.

⁽²⁾ OJ L 159, 17.6.2011, p. 25.

⁽³⁾ OJ L 226, 1.9.2011, p. 2.

⁽⁴⁾ OJ L 333, 19.12.2007, p. 54.

⁽⁵⁾ OJ L 77, 24.3.2010, p. 17.

— **32011 R 0361**: Commission Implementing Regulation (EU) No 361/2011 of 13 April 2011 (OJ L 100, 14.4.2011, p. 22).;

- (8) the following indent shall be added in point 1zzm (Commission Regulation (EC) No 1200/2005):
- **32011 R 0170**: Commission Regulation (EU) No 170/2011 of 23 February 2011 (OJ L 49, 24.2.2011, p. 8).;
- (9) the following indent shall be added in point 1zzzg (Commission Regulation (EC) No 109/2007):
- **32011 R 0495**: Commission Implementing Regulation (EU) No 495/2011 of 20 May 2011 (OJ L 134, 21.5.2011, p. 6).;
- (10) the text of point 1zzzzf (Commission Regulation (EC) No 1500/2007) shall be deleted;
- (11) the following shall be added in point 1zzzzze (Commission Regulation (EC) No 1292/2008):
- ‘, as amended by:
- **32011 R 0336**: Commission Regulation (EU) No 336/2011 of 7 April 2011 (OJ L 94, 8.4.2011, p. 17).;
- (12) the following shall be added in point 1zzzzzn (Commission Regulation (EC) No 903/2009):
- ‘, as amended by:
- **32011 R 0373**: Commission Regulation (EU) No 373/2011 of 15 April 2011 (OJ L 102, 16.4.2011, p. 10).;
- (13) the following shall be added in point 1zzzzzt (Commission Regulation (EC) No 1091/2009):
- ‘, as amended by:
- **32011 R 0335**: Commission Regulation (EU) No 335/2011 of 7 April 2011 (OJ L 94, 8.4.2011, p. 14).;
- (14) the following points shall be inserted after point 2s (Commission Regulation (EU) No 1120/2010):
- ‘2t. **32011 R 0170**: Commission Regulation (EU) No 170/2011 of 23 February 2011 concerning the authorisation of *Saccharomyces cerevisiae* MUCL 39885 as a feed additive for piglets (weaned) and amending Regulation (EC) No 1200/2005 (holder of authorisation Prosol SpA) (OJ L 49, 24.2.2011, p. 8).
- 2u. **32011 R 0171**: Commission Regulation (EU) No 171/2011 of 23 February 2011 concerning the authorisation of 6-phytase (EC 3.1.3.26) produced by *Aspergillus oryzae* DSM 14223 as a feed additive for poultry and for porcine species and amending Regulation (EC) No 255/2005 (holder of authorisation DSM Nutritional Products Ltd represented by DSM Nutritional products Sp. z o.o) (OJ L 49, 24.2.2011, p. 11).
- 2v. **32011 R 0184**: Commission Regulation (EU) No 184/2011 of 25 February 2011 concerning the authorisation of *Bacillus subtilis* C-3102 (DSM 15544) as a feed additive for chickens reared for laying, turkeys, minor avian species and other ornamental and game birds (holder of authorisation Calpis Co. Ltd Japan, represented by Calpis Co. Ltd Europe Representative Office) (OJ L 53, 26.2.2011, p. 33).
- 2w. **32011 R 0212**: Commission Regulation (EU) No 212/2011 of 3 March 2011 concerning the authorisation of *Pediococcus acidilactici* CNCM MA 18/5M as a feed additive for laying hens (holder of authorisation Lallemand SAS) (OJ L 59, 4.3.2011, p. 1).
- 2x. **32011 R 0221**: Commission Regulation (EU) No 221/2011 of 4 March 2011 concerning the authorisation of 6-phytase (EC 3.1.3.26) produced by *Aspergillus oryzae* DSM 14223 as a feed additive for salmonids (holder of authorisation DSM Nutritional Products Ltd represented by DSM Nutritional products Sp. Z o.o) (OJ L 60, 5.3.2011, p. 3).
- 2y. **32011 R 0337**: 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).
- 2z. **32011 R 0361**: Commission Implementing Regulation (EU) No 361/2011 of 13 April 2011 concerning the authorisation of *Enterococcus faecium* NCIMB 10415 as a feed additive for chickens for fattening (holder of authorisation DSM Nutritional products Ltd represented by DSM Nutritional Products Sp. z o.o) and amending Regulation (EC) No 943/2005 (OJ L 100, 14.4.2011, p. 22).

- 2za. **32011 R 0371**: Commission Implementing Regulation (EU) No 371/2011 of 15 April 2011 concerning the authorisation of dimethylglycine sodium salt as feed additive for chickens for fattening (holder of the authorisation Taminco N.V.) (OJ L 102, 16.4.2011, p. 6).
- 2zb. **32011 R 0373**: Commission Implementing Regulation (EU) No 373/2011 of 15 April 2011 concerning the authorisation of the preparation of *Clostridium butyricum* FERM-BP 2789 as a feed additive for minor avian species except laying birds, weaned piglets and minor porcine species (weaned) and amending Regulation (EC) No 903/2009 (holder of authorisation Miyarisan Pharmaceutical Co. Ltd, represented by Miyarisan Pharmaceutical Europe S.L.U.) (OJ L 102, 16.4.2011, p. 10).
- 2zc. **32011 R 0388**: Commission Implementing Regulation (EU) No 388/2011 of 19 April 2011 concerning the authorisation of maduramicin ammonium alpha as a feed additive for chickens for fattening (holder of authorisation Alpharma (Belgium) BVBA) and amending Regulation (EC) No 2430/1999 (OJ L 104, 20.4.2011, p. 3).
- 2zd. **32011 R 0389**: 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).
- 2ze. **32011 R 0496**: Commission Implementing Regulation (EU) No 496/2011 of 20 May 2011 concerning the authorisation of sodium benzoate as a feed additive for weaned piglets (holder of the authorisation Kemira Oyj) (OJ L 134, 21.5.2011, p. 9).
- 2zf. **32011 R 0515**: Commission Implementing Regulation (EU) No 515/2011 of 25 May 2011 concerning the authorisation of vitamin B 6 as a feed additive for all animal species (OJ L 138, 26.5.2011, p. 40).
- 2zg. **32011 R 0527**: Commission Implementing Regulation (EU) No 527/2011 of 30 May 2011 concerning the authorisation of a preparation of endo-1,4-β-xylanase produced by *Trichoderma reesei* (MUCL 49755), endo-1,3(4)-β-glucanase produced by *Trichoderma reesei* (MUCL 49754) and polygalacturonase produced by *Aspergillus aculeatus* (CBS 589.94) as feed additive for weaned piglets (holder of the authorisation Aveve NV) (OJ L 143, 31.5.2011, p. 6).
- 2zh. **32011 R 0528**: Commission Implementing Regulation (EU) No 528/2011 of 30 May 2011 concerning the authorisation of endo-1,4-β-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).
- 2zi. **32011 R 0532**: Commission Implementing Regulation (EU) No 532/2011 of 31 May 2011 concerning the authorisation of robenidine hydrochloride as a feed additive for rabbits for breeding and rabbits for fattening (holder of authorisation Alpharma Belgium BVBA) and amending Regulations (EC) No 2430/1999 and (EC) No 1800/2004 (OJ L 146, 1.6.2011, p. 7).
- 2zj. **32011 R 0868**: Commission Implementing Regulation (EU) No 868/2011 of 31 August 2011 concerning the authorisation of a preparation of *Lactobacillus plantarum* (DSM 21762) and of a preparation of *Lactobacillus buchneri* (DSM 22963) as feed additives for all animal species (OJ L 226, 1.9.2011, p. 2).;
- (15) the following indent shall be added in point 33 (Directive 2002/32/EC of the European Parliament and of the Council):
- ‘— **32011 R 0574**: Commission Regulation (EU) No 574/2011 of 16 June 2011 (OJ L 159, 17.6.2011, p. 7).’;
- (16) the text of point 49 (Commission Regulation (EU) No 242/2010) shall be deleted;
- (17) the following point shall be inserted after point 50 (Commission Regulation (EU) No 454/2010):
- ‘51. **32011 R 0575**: Commission Regulation (EU) No 575/2011 of 16 June 2011 on the Catalogue of feed materials (OJ L 159, 17.6.2011, p. 25).’.

Article 2

The texts of Regulations (EU) No 170/2011, (EU) No 171/2011, (EU) No 184/2011, (EU) No 212/2011, (EU) No 221/2011, (EU) No 335/2011, (EU) No 336/2011, (EU) No 337/2011, Implementing Regulations (EU) No 361/2011, (EU) No 371/2011, (EU) No 373/2011, (EU) No 388/2011, (EU) No

389/2011, (EU) No 406/2011, (EU) No 495/2011, (EU) No 496/2011, (EU) No 515/2011, (EU) No 516/2011, (EU) No 527/2011, (EU) No 528/2011, (EU) No 532/2011, Regulations (EU) No 574/2011, (EU) No 575/2011 and Implementing Regulation (EU) No 868/2011 in the Icelandic and Norwegian languages, to be published in the EEA Supplement to the *Official Journal of the European Union*, shall be authentic.

Article 3

This Decision shall enter into force on 1 May 2012, provided that all the notifications under Article 103(1) of the Agreement have been made to the EEA Joint Committee (*).

Article 4

This Decision shall be published in the EEA Section of, and in the EEA Supplement to, the *Official Journal of the European Union*.

Done at Brussels, 30 March 2012.

For the EEA Joint Committee

The Acting President

Gianluca GRIPPA

(*) No constitutional requirements indicated.