COMMISSION IMPLEMENTING REGULATION (EU) No 118/2012

of 10 February 2012

amending Regulations (EC) No 2380/2001, (EC) No 1289/2004, (EC) No 1455/2004, (EC) No 1800/2004, (EC) No 600/2005, (EU) No 874/2010, Implementing Regulations (EU) No 388/2011, (EU) No 532/2011 and (EU) No 900/2011 as regards the name of the holder of the authorisation of certain additives in animal feed and correcting Implementing Regulation (EU) No 532/2011

(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 [1] and in particular Article 13(3) thereof,

Whereas:

(1) Alpharma BVBA and Pfizer Ltd have submitted an application under Article 13(3) of Regulation (EC) No 1831/2003 proposing to change the name of the holder of the authorisations as regards Commission Regulations (EC) No 2380/2001 of 5 December 2001 concerning the 10-year authorisation of an additive in feedingstuffs [2], (EC) No 1289/2004 of 14 July 2004 concerning the authorisation for 10 years of the additive Deccox® in feedingstuffs, belonging to the group of coccidiostats and other medicinal substances [3], (EC) No 1455/2004 of 16 August 2004 concerning the authorisation for 10 years of the additive 'Avatec 15 %' in feedingstuffs, belonging to the group of coccidiostats and other medicinal substances [4], (EC) No 1800/2004 of 15 October 2004 concerning the authorisation for 10 years of the additive Cycostat 66G in feedingstuffs, belonging to the group of coccidiostats and other medicinal substances [5], (EC) No 600/2005 of 18 April 2005 concerning a new authorisation for 10 years of a coccidiostat as an additive in feedingstuffs, the provisional authorisation of an additive and the permanent authorisation of certain additives in feedingstuffs [6], (EU) No 874/2010 of 5 October 2010 concerning the authorisation of lasalocid A sodium as a feed additive for turkeys up to 16 weeks (holder of authorisation Alpharma (Belgium) BVBA) and amending Regulation (EC) No 2430/1999 [7], Commission Implementing Regulations (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 [8], (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 [9] and as regards (EU) No 900/2011 of 7 September 2011 concerning the authorisation of lasalocid A sodium as a feed additive for pheasants, guinea fowl, quails and partridges other than laying birds (holder of authorisation Alpharma (Belgium) BVBA) [10].

(2) The applicants claim that, with effect from 1 March 2011 as a result of the acquisition of Alpharma BVBA by Pfizer Ltd, the latter owns the marketing rights for the additives decoquinate, lasalocid A sodium, maduramicin ammonium alpha, robenidine hydrochloride and salinomycin.

(3) 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.

(4) To allow the applicant to exploit its marketing rights under the name of Pfizer Ltd it is necessary to change the terms of the authorisations.

(5) Regulations (EC) No 2380/2001, (EC) No 1289/2004, (EC) No 1455/2004, (EC) No 1800/2004, (EC) No 600/2005, (EU) No 874/2010, Implementing Regulations (EU) No 388/2011, (EU) No 532/2011 and (EU) No 900/2011 should therefore be amended accordingly.

(6) Since the modifications to the conditions of the authorisations are not related to safety reasons, it is appropriate to provide for a transitional period during which existing stocks may be used up.

[1] OJ L 268, 18.10.2003, p. 29.
[2] OJ L 321, 6.12.2001, p. 18.
[3] OJ L 243, 15.7.2004, p. 15.
[4] OJ L 269, 17.8.2004, p. 14.
[5] OJ L 317, 16.10.2004, p. 37.
[6] OJ L 99, 19.4.2005, p. 5.
[7] OJ L 263, 6.10.2010, p. 1.
[8] OJ L 104, 20.4.2011, p. 3.
[9] OJ L 146, 1.6.2011, p. 7.
[10] OJ L 231, 8.9.2011, p. 15.

(7) The maximum residue limits (MRLs) for turkeys and chickens for fattening introduced into the Annex to Regulation (EC) No 1800/2004 by Commission Regulation (EC) No 101/2009 [1] and the trade name 'Robenz 66 G' for turkeys and chickens for fattening introduced into the Annex to Regulation (EC) No 1800/2004 by Commission Regulation (EC) No 214/2009 [2] were, by error, omitted in the Annex to Regulation (EC) No 1800/2004 as amended by Implementing Regulation (EU) No 532/2011. It is therefore necessary to reintroduce these MRLs and the trade name.

(8) Therefore, the Annex to Implementing Regulation (EU) No 532/2011 should be corrected accordingly.

(9) 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 2380/2001

In column 2 of the Annex to Regulation (EC) No 2380/2001, the words 'Alpharma Belgium BVBA' are replaced by 'Pfizer Ltd'.

Article 2

Amendment to Regulation (EC) No 1289/2004

In column 2 of the Annex to Regulation (EC) No 1289/2004, the words 'Alpharma (Belgium) BVBA' are replaced by 'Pfizer Ltd'.

Article 3

Amendment to Regulation (EC) No 1455/2004

In column 2 of the Annex to Regulation (EC) No 1455/2004, the words 'Alpharma (Belgium) BVBA' are replaced by 'Pfizer Ltd'.

Article 4

Amendment to Regulation (EC) No 1800/2004

In column 2 of the Annex to Regulation (EC) No 1800/2004, the words 'Alpharma (Belgium) BVBA' are replaced by 'Pfizer Ltd'.

Article 5

Amendment to Regulation (EC) No 600/2005

In column 2 of Annex I to Regulation (EC) No 600/2005, the words 'Alpharma (Belgium) BVBA' are replaced by 'Pfizer Ltd'.

Article 6

Amendment to Regulation (EU) No 874/2010

In column 2 of the Annex to Regulation (EU) No 874/2010, the words 'Alpharma (Belgium) BVBA' are replaced by 'Pfizer Ltd'.

Article 7

Amendment to Implementing Regulation (EU) No 388/2011

In column 2 of the Annex to Implementing Regulation (EU) No 388/2011, the words 'Alpharma (Belgium) BVBA' are replaced by 'Pfizer Ltd'.

Article 8

Amendment to Implementing Regulation (EU) No 532/2011

In column 2 of Annex I to Implementing Regulation (EU) No 532/2011 the words 'Alpharma Belgium BVBA' are replaced by 'Pfizer Ltd'.

Article 9

Amendment to Implementing Regulation (EU) No 900/2011

In column 2 of the Annex to Implementing Regulation (EU) No 900/2011, the words 'Alpharma (Belgium) BVBA' are replaced by 'Pfizer Ltd'.

Article 10

Correction to Implementing Regulation (EU) No 532/2011

Annex II to Implementing Regulation (EU) No 532/2011 is corrected in accordance with the Annex to this Regulation.

Article 11

Transitional measures

Existing stocks which are in conformity with the provisions applying before the date of entry into force of this Regulation may continue to be placed on the market and used until 2 September 2012.

Article 12

Entry into force

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

Article 10 and the Annex shall, however, apply from 21 June 2011.

[1] OJ L 34, 4.2.2009, p. 5.
[2] OJ L 73, 19.3.2009, p. 12.

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

Done at Brussels, 10 February 2012.

For the Commission
The President
José Manuel BARROSO

ANNEX

In Annex II to Implementing Regulation (EU) No 532/2011, the Annex to Regulation (EC) No 1800/2004 as amended by Implementing Regulation (EU) No 532/2011 is corrected as follows:

(1) in column 3 the words '(Cycostat 66G)' are replaced by '(Robenz 66 G)';

(2) A new column is added:

'Maximum residue limits (MRLs) in the relevant foodstuffs of animal origin
800 µg robenidine hydrochloride/kg of wet liver. 350 µg robenidine hydrochloride/kg of wet kidney. 200 µg robenidine hydrochloride/kg of wet muscle. 1 300 µg robenidine hydrochloride/kg of wet skin/fat.
400 µg robenidine hydrochloride/kg of skin/fat. 400 µg robenidine hydrochloride/kg of wet liver. 200 µg robenidine hydrochloride/kg of wet kidney. 200 µg robenidine hydrochloride/kg of wet muscle.'