COMMISSION REGULATION (EC) No 1519/2007

of 19 December 2007

amending Regulations (EC) No 2430/1999, (EC) No 418/2001 and (EC) No 162/2003 as regards the terms of the authorisation of certain additives in feedingstuffs belonging to the group of coccidiostats and other medicinal substances

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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) Article 13(3) of Regulation (EC) No 1831/2003 provides for the possibility of changing the terms of authorisation of an additive further to an application from the holder of the authorisation.

(2) The use of the additive diclazuril 0,5 g/100 g (Clinacox 0,5 % Premix), diclazuril 0,2 g/100 g (Clinacox 0,2 % Premix), belonging to the group of 'Coccidiostats and other medicinal substances' was authorised for 10 years for chickens for fattening by Commission Regulation (EC) No 2430/1999 [2]. The authorisation was linked to the person responsible for putting the additive into circulation.

(3) The use of the additive diclazuril 0,5 g/100 g (Clinacox 0,5 % Premix), diclazuril 0,2 g/100 g (Clinacox 0,2 % Premix) belonging to the group of 'Coccidiostats and other medicinal substances' was authorised for 10 years for turkeys for fattening by Commission Regulation (EC) No 418/2001 [3]. The authorisation was linked to the person responsible for putting the additive into circulation.

(4) The use of the additive diclazuril 0,5 g/100 g (Clinacox 0,5 % Premix), diclazuril 0,2 g/100 g (Clinacox 0,2 % Premix) belonging to the group of 'Coccidiostats and other medicinal substances' was authorised for 10 years for chickens reared for laying by Commission Regulation (EC) No 162/2003 [4]. The authorisation was linked to the person responsible for putting the additive into circulation.

(5) The holder of the authorisations, Janssen Animal Health BVBA, has submitted an application under Article 13(3) of Regulation (EC) No 1831/2003 proposing to change the name of the person responsible for putting into circulation the additives referred to in recitals 2 to 4 of this Regulation. With the application they have submitted data showing that the marketing rights for those additives have been transferred to Janssen Pharmaceutica NV, its Belgian parent company, with effect from 2 July 2007.

(6) Assigning the authorisation of an additive linked to a person responsible for putting it into circulation to another person is based on a purely administrative procedure and did not entail a fresh assessment of the additives. The European Food Safety Authority was informed of the application.

(7) To allow Janssen Pharmaceutica NV to exploit its ownership rights from 2 July 2007 on, it is necessary to change the name of the person responsible for putting the additives into circulation, with effect from 2 July 2007. Therefore, it is necessary for this Regulation to apply retroactively.

(8) Regulations (EC) No 2430/1999, (EC) No 418/2001 and (EC) No 162/2003 should therefore be amended accordingly.

(9) It is appropriate to provide for a transitional period during which existing stocks may be used up.

(10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

[1] OJ L 268, 18.10.2003, p. 29. Regulation as amended by Commission Regulation (EC) No 378/2005 (OJ L 59, 5.3.2005, p. 8).
[2] OJ L 296, 17.11.1999, p. 3. Regulation as amended by Regulation (EC) No 249/2006 (OJ L 42, 14.2.2006, p. 22).
[3] OJ L 62, 2.3.2001, p. 3.
[4] OJ L 26, 31.1.2003, p. 3.

HAS ADOPTED THIS REGULATION:

Article 1

1. In Annex I to Regulation (EC) No 2430/1999, in column 2 of the entry for E 771, the words 'Janssen Animal Health BVBA' are replaced by the words 'Janssen Pharmaceutica NV'.

2. In Annex III to Regulation (EC) No 418/2001, in column 2 of the entry for E 771, the words 'Janssen Animal Health BVBA' are replaced by the words 'Janssen Pharmaceutica NV'.

3. In the Annex to Regulation (EC) No 162/2003, in column 2 of the entry for E 771, the words 'Janssen Animal Health BVBA' are replaced by the words 'Janssen Pharmaceutica NV'.

Article 2

Existing stocks which are in conformity with the provisions applicable before the entry into force of this Regulation may continue to be placed on the market and used until 30 April 2008.

Article 3

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

It shall apply from 2 July 2007.

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

Done at Brussels, 19 December 2007.

For the Commission
Markos KYPRIANOU
Member of the Commission