COMMISSION IMPLEMENTING REGULATION (EU) 2018/353

of 9 March 2018

correcting Implementing Regulation (EU) 2017/1145 on the withdrawal from the market of certain feed additives authorised pursuant to Council Directives 70/524/EEC and 82/471/EEC and repealing the obsolete provisions authorising those 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 ([1]), and in particular Article 10(5) thereof,

Whereas:

(1) Commission Implementing Regulation (EU) 2017/1145 ([2]) requires the withdrawal from the market of feed additives which were placed on the market and entered in the Community Register of Feed Additives as existing products in accordance with Article 10(1) of Regulation (EC) No 1831/2003, and for which no applications in accordance with Article 10(2) and (7) of that Regulation were submitted before the deadline provided for in those provisions, or for which an application was submitted but subsequently withdrawn. Implementing Regulation (EU) 2017/1145 also repeals the regulations or deletes the provisions authorising those additives.

(2) By mistake, Annex II to Implementing Regulation (EU) 2017/1145 setting out the list of additives to be withdrawn from the market in respect of certain animal species included the feed additive coccidiostat authorised by Commission Regulation (EC) No 1463/2004 ([3]), although an application was submitted in due time in accordance with Article 10(2) of Regulation (EC) No 1831/2003. That Regulation was therefore repealed by mistake by Article 3 of Implementing Regulation (EU) 2017/1145. By mistake, Commission Regulation (EC) No 833/2005 ([4]) was mentioned in recital 3 of Implementing Regulation (EU) 2017/1145, both as to be amended and as to be repealed. It should be corrected to indicate that Regulation (EC) No 833/2005 should be only repealed. By mistake, Commission Regulation (EC) No 1459/2005 ([5]) was not repealed by Article 3 of Implementing Regulation (EU) 2017/1145, while it authorises certain iodine compounds that are to be withdrawn from the market in accordance with Implementing Regulation (EU) 2017/1145. Commission Regulation (EC) No 1443/2006 ([6]) was erroneously repealed by Article 3 of Implementing Regulation (EU) 2017/1145. Only Article 1 of and Annex I to that Regulation should be deleted as only those provisions concern certain enzymes that are to be withdrawn in accordance with Implementing Regulation (EU) 2017/1145. Those errors should be corrected.

(3) By mistake, the provisions of Commission Regulation (EC) No 1334/2003 ([7]) authorising some iron compounds, to be withdrawn from the market in accordance with Implementing Regulation (EU) 2017/1145, were not deleted by Article 8 of that Regulation amending Regulation (EC) No 1334/2003. That Article should be corrected.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) Commission Implementing Regulation (EU) 2017/1145 of 8 June 2017 on the withdrawal from the market of certain feed additives authorised pursuant to Council Directives 70/524/EEC and 82/471/EEC and repealing the obsolete provisions authorising those feed additives (OJ L 166, 29.6.2017, p. 1).
([3]) Commission Regulation (EC) No 1463/2004 of 17 August 2004 concerning the authorisation for 10 years of the additive 'Sacox 120 microGranulate' in feedingstuffs, belonging to the group of coccidiostats and other medicinal substances. (OJ L 270, 18.8.2004, p. 5).
([4]) Commission Regulation (EC) No 833/2005 of 31 May 2005 concerning the permanent authorisation of additives in feedingstuffs (OJ L 138, 1.6.2005, p. 5).
([5]) Commission Regulation (EC) No 1459/2005 of 8 September 2005 amending the conditions for authorisation of a number of feed additives belonging to the group of trace elements. (OJ L 233, 9.9.2005, p. 8).
([6]) Commission Regulation (EC) No 1443/2006 of 29 September 2006 concerning the permanent authorisations of certain additives in feedingstuffs and an authorisation for 10 years for a coccidiostat. (OJ L 271, 30.9.2006, p. 12).
([7]) Commission Regulation (EC) No 1334/2003 of 25 July 2003 amending the conditions for authorisation of a number of additives in feedingstuffs belonging to the group of trace elements (OJ L 187, 26.7.2003, p. 11).

(4) In Part A of Annex I to Implementing Regulation (EU) 2017/1145 setting out the feed additives to be withdrawn for all species and categories of animals, in the table concerning vitamins, the L form of the vitamin menadione sodium bisulphite is included. This should be corrected as no reference to this L form was made in the authorisation.

(5) Parts A and B of Annex I to Implementing Regulation (EU) 2017/1145 should be corrected as regards some colourants as the species and categories of animals for which those colourants are required to be withdrawn from the market and the functions of those colourants were not indicated correctly. The requirement to withdraw the additive from the market for some of them applies only for certain species and the use as colourant is restricted to certain functions.

(6) Implementing Regulation (EU) 2017/1145 should therefore be corrected accordingly.

(7) The erroneous provisions have given rise to confusion for the feed business operators as regards the actual regulatory status of the additives concerned. That situation has created legal uncertainty as to the applicable regulatory framework. Those errors have therefore resulted in some market disturbance linked to the questioned authorisation to place on the market and use certain additives. The corrections to Implementing Regulation (EU) 2017/1145 should therefore apply retroactively on the day of entry into force of that Implementing Regulation, in order to restore legal certainty in relation to the regulatory status of the additives subject to the errors, to avoid any detrimental consequences for the operators concerned and consequently to bring stability back to the market.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Implementing Regulation (EU) 2017/1145 is corrected as follows:

(1) Recital 3 is corrected as follows:

(a) the reference to Regulation (EC) No 1463/2004 is deleted with the corresponding footnote;

(b) the reference to Regulation (EC) No 833/2005 is deleted with the corresponding footnote from the list of Regulations to be amended. The corresponding footnote is inserted after the words '(EC) No 833/2005' in the list of Regulations to be repealed;

(c) the reference to Regulation (EC) No 1459/2005 is inserted between the words '(EC) No 833/2005' and '(EC) No 492/2006' in the list of Regulations to be repealed together with a footnote referring to its full title and reference of publication;

(d) the reference to Regulation (EC) No 1443/2006 is deleted with the corresponding footnote from the list of Regulations to be repealed and inserted with the corresponding footnote between the words '(EC) No 1284/2006' and 'and (EU) No 1270/2009' in the list of Regulations to be amended.

(2) Article 3 is replaced by the following:

'*Article 3*

Repeals

Regulations (EC) No 937/2001, (EC) No 871/2003, (EC) No 277/2004, (EC) No 278/2004, (EC) No 1332/2004, (EC) No 1465/2004, (EC) No 833/2005, (EC) No 1459/2005, (EC) No 492/2006, (EC) No 1743/2006, (EC) No 757/2007, and (EC) No 828/2007 are repealed.'

(3) In Article 8 the following points are inserted after the words 'The Annex to Regulation (EC) No 1334/2003, is amended as follows:' and the existing points are renumbered accordingly:

'(1) in entry E 1 Iron — Fe, the words "Ferrous chloride, tetrahydrate" and all content relating only to Ferrous chloride, tetrahydrate are deleted.

(2) in entry E 1 Iron — Fe, the words "Ferrous citrate, hexahydrate" and all content relating only to Ferrous citrate, hexahydrate are deleted.

(3) in entry E 1 Iron — Fe, the words "Ferrous lactate, trihydrate" and all content relating only to Ferrous lactate, trihydrate are deleted.'

(4) The following Article 25a is inserted:

'*Article 25a*

Amendment to Regulation (EC) No 1443/2006

Article 1 of and Annex I to Regulation (EC) No 1443/2006 are deleted.'

(5) Annex I is corrected in accordance with the Annex to this Regulation.

Article 2

Entry into force

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

It shall apply from 19 July 2017.

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

Done at Brussels, 9 March 2018.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Annex I is corrected as follows:

(1) Part A is corrected as follows:

(a) under the heading 'Vitamins, provitamins and chemically well-defined substances having similar effect', in the entry referring to the additive Vitamin K, the words 'L-menadione sodium bisulphite' are replaced by 'menadione sodium bisulphite';

(b) under the heading 'Other colourants' the entry of the table referring to colouring agents authorised for colouring foodstuffs by Community rules is replaced by the following:

'Relevant number	Colouring agents authorised for colouring foodstuffs by Community rules, with the exception of: E150b, E150c and E150d Caramel colours; E 141 Chlorophyllin Copper Complex; E 172 Iron Oxide Red, Black & Yellow; E 171 Titanium dioxide (anatase & rutile structure); E 153 Carbon black	All species'

(2) Part B is corrected as follows:

(a) under the heading 'Carotenoids and xanthophylls', the entry for the additive E161j Astaxanthin is replaced by the following:

'E161j	Astaxanthin	All species with the exception of: — Fish and crustaceans for uses belonging to the functional group 2(a) (ii) — Ornamental fish for uses belonging to the functional group 2(a) (iii)'

(b) under the heading 'Other colourants' the table referring to the entries for the additives E155, E104, E122 and E160b is replaced by the following:

'E 155	Brown HT	Dogs and cats
E 104	Quinoline yellow	All species except non-food producing animals for uses belonging to the functional group 2(a) (i)
E 122	Azorubine (carmoisine)	All species with the exception of dogs and cats for uses belonging to the functional group 2(a) (i)
Relevant number	Colouring agents authorised for colouring foodstuffs by Community rules, with the exception of:	
	E102 Tartrazine.	All species except except dogs and cats
	E 160b Bixin.	All species except except dogs and cats.
	E 110 Sunset yellow FCF	All species except except dogs and cats.
	E 120 Carmine (Carmine Lake WSP 50 %)	All species except except dogs and cats
	E 124 Ponceau 4 R	All species except except dogs and cats

	E 127 Erythrosine	All species except except dogs, cats and reptiles
	E 129 Allura red	All species except except dogs and cats
	E 132 Indigotine	All species except except dogs and cats
	E 133 Brilliant blue	All species except except dogs and cats
E 160 b	Bixin as a colouring agent	Ornamental fish
E102	Tartrazine as a colouring agent	All species except ornamental fish, grain-eating ornamental birds and small rodents
E131	Patent Blue V as a colouring agent	All species except non-food producing animals for uses belonging to the functional group 2(a) (i)
E 124	Ponceau 4 R as a colouring agent	All species except ornamental fish
E127	Erythrosine as a colouring agent	All species except ornamental fish.
E132	Indigotine as a colouring agent	All species except ornamental fish
E 141	Chlorophyllin copper complex as a colouring agent	All species except ornamental fish, grain-eating ornamental birds and small rodents
E110	Sunset yellow FCF as a colouring agent	All species except ornamental fish, grain-eating ornamental birds and small rodents
E 153	Carbon black as a colouring agent	All species except ornamental fish'