

COMMISSION IMPLEMENTING REGULATION (EU) 2018/1567**of 18 October 2018****correcting Implementing Regulation (EU) 2018/249 concerning the authorisation of taurine, beta-alanine, L-alanine, L-arginine, L-aspartic acid, L-histidine, D,L-isoleucine, L-leucine, L-phenylalanine, L-proline, D,L-serine, L-tyrosine, L-methionine, L-valine, L-cysteine, glycine, monosodium glutamate and L-glutamic acid as feed additives for all animal species and L-cysteine hydrochloride monohydrate for all species except cats and dogs****(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 9(2) thereof,

Whereas:

- (1) Commission Implementing Regulation (EU) 2018/249 ⁽²⁾ authorises certain feed additives as flavourings, including glycine, L-cysteine and L-cysteine hydrochloride monohydrate.
- (2) An error appears in the Annex to Implementing Regulation (EU) 2018/249 in the entry for glycine where, in the column 'Other provisions', it is stated that the label of this additive is to indicate that recommended maximum content of the active substance of complete feedingstuff, with a moisture content of 12 % for other categories and species, is 25 g/kg. In accordance with the opinion of the European Food Safety Authority ⁽³⁾ issued for the authorisation of this feed additive, the correct amount is 25 mg/kg.
- (3) Errors appear in the Annex to Implementing Regulation (EU) 2018/249, in the entries for L-cysteine and L-cysteine hydrochloride monohydrate regarding the manufacturing process of the active substance. In particular, while it is indicated in the column 'Composition, chemical formula, description analytical method' that the active substance is produced by chemical synthesis or protein hydrolysis. In this part, it is omitted to indicate that the protein hydrolysis is made with animal or vegetal proteins, so the use of human hair that could be used as a source for hydrolysis to produce this specific additive is not allowed.
- (4) The erroneous provisions have given rise to confusion for the feed business operators as regards the actual provisions for placing on the market 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 of glycine, L-cysteine and L-cysteine hydrochloride monohydrate. The corrections to Implementing Regulation (EU) 2018/249 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.
- (5) 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

The Annex to Implementing Regulation (EU) 2018/249 is corrected in accordance with Annex to this Regulation.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.⁽²⁾ Commission Implementing Regulation (EU) 2018/249 of 15 February 2018 concerning the authorisation of taurine, beta-alanine, L-alanine, L-arginine, L-aspartic acid, L-histidine, D,L-isoleucine, L-leucine, L-phenylalanine, L-proline, D,L-serine, L-tyrosine, L-methionine, L-valine, L-cysteine, glycine, monosodium glutamate and L-glutamic acid as feed additives for all animal species and L-cysteine hydrochloride monohydrate for all species except cats and dogs (OJ L 53, 23.2.2018, p. 134).⁽³⁾ EFSA Journal 2014; 12(5):3670

*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 15 March 2018.

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

Done at Brussels, 18 October 2018.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Annex to Implementing Regulation (EU) 2018/249 is corrected as follows:

(1) in the entry concerning substance 2b17034 glycine, the column 'Other provisions' is corrected as follows:

(a) point 3 is replaced by the following:

'3. On the label of the additive the following shall be indicated: "Recommended maximum content of the active substance of complete feeding stuff with a moisture content of 12 %:

— 20 g/kg for cats and dogs;

— 25 mg/kg for other species and categories.'";

(b) point 5 is replaced by the following:

'5. The functional group, the identification number, the name and the added amount of the active substance shall be indicated in the labelling of feed materials and compound feedingstuffs where the content of the active substance in the complete feeding stuff with a moisture content of 12 % exceeds:

— 20 g/kg for cats and dogs;

— 25 mg/kg for other species and categories.';

(2) in the entry concerning substance 2b17033 L-cysteine, in the column 'Composition, chemical formula, description, analytical method', the text 'Produced by chemical synthesis or protein hydrolysis' is replaced by the text 'Produced by chemical synthesis or hydrolysis of animal or vegetal protein';

(3) in the entry concerning substance 2b920 L-cysteine hydrochloride monohydrate, in the column 'Composition, chemical formula, description, analytical method', the text 'Produced by chemical synthesis or protein hydrolysis' is replaced by the text 'Produced by chemical synthesis or hydrolysis of animal or vegetal proteins'.
