



EUROPEAN
COMMISSION

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COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

**correcting Commission 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)

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(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 nutrition¹, and in particular Article 9(2) thereof,

Whereas:

- (1) Commission Implementing Regulation (EU) 2018/249² 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 Authority³ 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.

¹ OJ L268 18.10.2003? P.29

² Commission 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 O J L 53, 23.2.2018, p. 134.

³ EFSA Journal 2014 ; 12(5) :3670

- (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. 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.

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,

For the Commission

The President

Jean- Claude JUNCKER