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COMMISSION REGULATION (EU) …/…

of XXX

amending Commission Regulation (EU) 2019/1871 as regards the application of reference points for action for nitrofurans and their metabolites

(Text with EEA relevance)

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amending Commission Regulation (EU) 2019/1871 as regards the application of reference points for action for nitrofurans and their metabolites

(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 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council ([1]), and in particular Article 18 thereof,

Whereas:

(1) Nitrofurans and their metabolites are antimicrobial agents which are prohibited for use in food-producing animals in the European Union and therefore they are listed in Table 2 of the Annex to Commission Regulation (EU) No 37/2010 ([2]) for which maximum residue limits cannot be established.

(2) Commission Regulation (EU) 2019/1871 ([3]) established reference points for action (RPAs) for certain non-allowed pharmacologically active substances present in food of animal origin. For nitrofurans and their metabolites, currently 1,0 µg/kg is applied as a reference point of action. As from 28 November 2022, a lower value of 0,5 µg/kg shall be applied.

(3) Based on available information ([4]), semicarbazide ('SEM'), a metabolite of the nitrofuran nitrofurazone, can be present in food either as a metabolite occurring due to

([1]) OJ L 152, 16.6.2009, p. 11.

([2]) Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin (OJ L 15, 20.1.2010, p. 1).

([3]) Commission Regulation (EU) 2019/1871 of 7 November 2019 on reference points for action for non-allowed pharmacologically active substances present in food of animal origin and repealing Decision 2005/34/EC (OJ L 289, 8.11.2019, p. 41).

([4]) EFSA (European Food Safety Authority), O'Keeffe M, Christodoulidou A and Nebbia C, 2021. Scientific report on the presence of nitrofurans and their metabolites in gelatine. *EFSA Journal* 2021;19(10):6881 [22 pp], https://doi.org/10.2903/j.efsa.2021.6881.

illegal treatment with nitrofurazone or as a metabolite produced during food processing, arising from the use of disinfecting agents or from reactions of various food components. Therefore, SEM cannot be considered as an unequivocal marker of the abuse of nitrofurazone in the production of animal products.

(4) Based on data provided by industry and available occurrence data ([5]), higher levels of SEM can be found due to a high temperature processing in gelatine, collagen hydrolysate, whey and milk protein concentrate, caseinates and milk powder although no treatment with nitrofurans has been applied.

(5) Therefore, the exemption from the reference point for action for nitrofurans and their metabolites, if only SEM is present, should be granted for gelatine, collagen hydrolysate, whey and milk protein concentrate, caseinates and milk powder.

(6) Infants and young children are vulnerable group of consumers; their diet consists in particular of milk-powdered food. Therefore, the exemption should not apply to infant formulae and follow-on formulae.

(7) If other nitrofurans or their metabolites are present in exempted processed products, the reference point for action shall apply.

(8) Since the lower reference point of action for nitrofurans and their metabolites applies as from 28 November 2022, the exemption should be applied as from the same date.

(9) 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 Regulation (EU) 2019/1871 is amended in accordance with the Annex to this Regulation.

Article 2

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

It shall apply from 28 November 2022.

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

[5] Richard H. Stadler et al. 2015. Why semicarbazide (SEM) is not an appropriate marker for the usage of nitrofurazone on agricultural animals. Food Additives & Contaminants: Part A, Vol. 32, No. 11, 1842–1850, http://dx.doi.org/10.1080/19440049.2015.1086028.

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Done at Brussels,

For the Commission
The President