COMMISSION REGULATION (EU) 2023/411

of 23 February 2023

amending 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 of animal origin in the Union and therefore nitrofurans are listed in Table 2 of the Annex to Commission Regulation (EU) No 37/2010 ([2]) on prohibited substances, for which maximum residue limits cannot be established.

(2) Commission Regulation (EU) 2019/1871 ([3]) established reference points for action ('RPA') for certain non-allowed pharmacologically active substances present in food of animal origin, for which no maximum residue limits have been laid down. From 28 November 2022, a reference point of action of 0,5 µg/kg shall be applied for nitrofurans and their metabolites.

(3) Based on the opinion of the European Food Safety Authority ([4]), semicarbazide ('SEM'), a metabolite of the nitrofuran nitrofurazone, can be present in food either as a metabolite occurring due to 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, the presence of SEM cannot be considered as an unequivocal marker of abuse of nitrofurazone during animal products production.

(4) Based on data provided by industry and available occurrence data ([5]), higher levels of SEM can be found in gelatine, collagen hydrolysate, hydrolysed cartilage products, spray dried blood products, whey and milk protein concentrates, caseinates and milk powder as a result of high temperature processing, even when no treatment with nitrofurans has been applied to those processed products.

(5) Therefore, as an exception, the RPA for SEM should not be applied for gelatine, collagen hydrolysate, hydrolysed cartilage products, spray dried blood products, whey and milk protein concentrates, caseinates and milk powder unless other nitrofurans or their metabolites are found together with SEM in those processed products.

([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.

([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, p. 1842–1850, http://dx.doi.org/10.1080/19440049.2015.1086028

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

(7) In order to enable the Commission to establish specific regulatory measures as regards the presence of SEM in gelatine, collagen hydrolysate, hydrolysed cartilage products, spray dried blood products, whey and milk protein concentrates, caseinates and milk powder, food business operators and other interested parties should provide within a defined time period necessary data and information on investigations on the parameters and factors in the processing steps resulting in the formation of SEM during processing in those processed products. Food business operators should also take measures to reduce the presence of SEM in these products at levels as low as reasonably achievable. In the absence of those data and information, the exemption can no longer be maintained.

(8) Regulation (EU) 2019/1871 should be amended accordingly.

(9) The reference point of action at level 0,5 µg/kg for nitrofurans and their metabolites applies as from 28 November 2022. In order to avoid unnecessary withdrawals from the market of the processed products concerned with SEM content at the level above the RPA because of wrong assumption of illegal use of nitrofurans, it is necessary to apply the exemption retroactively from the same date.

(10) 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.

Done at Brussels, 23 February 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

The Annex to Regulation (EU) 2019/1871 is replaced by the following:

'*ANNEX*

Reference points for action (RPA)

Substance	RPA (µg/kg)	Other provisions
Chloramphenicol	0,15	
Malachite green	0,5	0,5 µg/kg for the sum of malachite green and leucomalachite green
Nitrofurans and their metabolites	0,5 ([1]) ([2])	0,5 µg/kg for each of the metabolites of furazolidone (AOZ or 3-amino-2-oxazolidinone), furaltadone (AMOZ or 3-amino-5-methylmorpholino-2-oxazolidinone), nitrofurantoin (AHD or 1-aminohydantoin), nitrofurazone (SEM or semicarbazide) and nifursol (DNSH or 3,5-dinitrosalicylic acid hydrazide)

([1]) Due to the natural occurrence of SEM in crayfish at levels above the RPA, only levels of AOZ, AMOZ, AHD and DNSH above the RPA are a clear indication of the illegal use of nitrofurans and their metabolites. The RPA of 0,5 µg/kg for SEM in crayfish shall only be applied when the illegal use of nitrofurazone or SEM on crayfish has been established, i.e. at least one of the other nitrofuran metabolites has been detected.

([2]) Due to the occurrence of SEM at levels above the RPA as the consequence of processing in gelatine, collagen hydrolysate, hydrolysed cartilage products, spray dried blood products, whey and milk protein concentrates, caseinates and milk powder (excluding infant formulae and follow-on formulae) only levels of AOZ, AMOZ, AHD and DNSH above the RPA are a clear indication of the illegal use of nitrofurans and their metabolites. The RPA of 0,5 µg/kg for SEM in gelatine, collagen hydrolysate, hydrolysed cartilage products, spray dried blood products, whey and milk protein concentrates, caseinates and milk powder (excluding infant formulae and follow-on formulae) shall only be applied, when the illegal use of nitrofurazone or SEM has been established, i.e. at least one of the other nitrofuran metabolites has been detected.

Food business operators and other interested parties shall communicate by 1 March 2024 to the Commission the results of investigations on the parameters and factors in the processing steps resulting in the formation of SEM in gelatine, collagen hydrolysate, hydrolysed cartilage products, spray dried blood products, whey and milk protein concentrates, caseinates and milk powder (excluding infant formulae and follow-on formulae) during processing. They shall also communicate the measures taken to ensure that the levels of SEM in these products are kept as low as reasonably achievable. In the absence of satisfactory data and information, measures shall be taken to end this exemption.'