



Brussels, **XXX**
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[...] (2024) **XXX** draft

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 in collagen**

(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 in collagen

(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) Commission Regulation (EU) 2019/1871 ⁽²⁾ 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. For semicarbazide (SEM), a metabolite of the nitrofurans nitrofurazone, the exemption of application of RPA is granted for certain processed products of animal origin unless other nitrofurans or their metabolites are found together with SEM in those processed products.
- (2) Based on 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 provided by food business operators and other interested parties, a higher level of SEM can be found also in collagen as the consequence of processing and not related to the illegal use of nitrofurans. Therefore, collagen should be added to the exempted processed products of animal origin as regards the enforcement of RPA for SEM.
- (3) Since food business operators and other interested parties have provided requested data and information satisfactory by the deadline mentioned in footnote 2 in the Annex to Regulation (EU) 2019/1871, this requirement should be deleted.
- (4) Regulation (EU) 2019/1871 should be amended accordingly.
- (5) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

⁽¹⁾ OJ L 152, 16.6.2009, p. 11.

⁽²⁾ 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).

HAS ADOPTED THIS REGULATION:

Article 1

Footnote ⁽²⁾ under the table in the Annex to Regulation (EU) 2019/1871 is amended as follows:

‘⁽²⁾ Due to the occurrence of SEM at levels above the RPA as the consequence of processing in gelatine, collagen, 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, 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 nitrofurans metabolites has been detected.’

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*.

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

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN