Collagen exempted from semicarbazide reference point for action

Published by AGRINFO on 21 Nov 2024

Collagen added to list of products for which semicarbazide reference point for action does not apply

Commission Regulation (EU) 2024/2858 of 12 November 2024 amending Regulation (EU) 2019/1871 as regards the application of reference points for action for nitrofurans and their metabolites in collagen

Update

For certain non-allowed pharmacologically active substances, reference points for action (RPA) – the lowest level that can be analytically achieved – are set. Animal products containing residues at or above the RPA are considered not to comply with the EU law and may not be placed on the market.

Semicarbazide (SEM), a metabolite of the nitrofuran nitrofurazone, has an RPA of 0.5 µg/kg. However, in some processed animal products, higher levels of SEM can occur as a result of processing rather than the illegal use of nitrofurazone. The RPA of 0.5 µg/kg does not apply to such products unless illegal use of nitrofurazone is established.

This Regulation adds collagen to the list of exempted products to which the RPA does not apply.

Impacted products

collagen

What is changing?

Regulation 2019/1871 (Annex) establishes an RPA of 0.5 µg/kg for SEM, and footnote 2 lists processed animal products (e.g. gelatine, whey, and milk protein concentrates) with SEM levels above the RPA that can occur as a result of processing, rather than the illegal use of nitrofurazone or SEM. For these products, the RPA applies only if illegal use has been established.

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This Regulation adds **collagen** to this list of processed animal products. The RPA of 0.5 µg/kg for SEM therefore only applies to collagen if illegal use of nitrofurazone or SEM has been established, meaning where at least one of the other nitrofuran metabolites has been detected.

Why?

On the basis of new data and information collected, it is recognised that the processing of collagen can result in the production of SEM at levels higher than the RPA without any illegal use of nitrofurans having taken place.

Timeline

The exemption of collagen will apply from **3 December 2024**.

What are the major implications for exporting countries?

In collagen, SEM levels higher than 0.5 µg/kg are permitted as long as no other nitrofurans are present.

Background

RPAs in foods of animal origin are set in Regulation 2019/1871 for non-allowed pharmacologically active substances chloramphenicol, malachite green, and nitrofurans (and their metabolites such as SEM). During controls, foods found to have a level of these substances at or above the RPA must not be put on the EU market. Where these substances are present below the RPA, competent authorities of the Member State where the food was controlled must investigate whether there has been illegal treatment with a prohibited or non-allowed pharmacologically active substance.

Resources

EFSA (2013) Guidance on methodological principles and scientific methods to be taken into account when establishing Reference Points for Action (RPAs) for non-allowed pharmacologically active substances present in food of animal origin. EFSA Journal, 11(4): 3195.

European Commission (2024) Guidelines on EU requirements for entry of animals and products of animal origin: Control plans for residues of veterinary medicines, pesticides and contaminants.

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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

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

Sources

Commission Regulation (EU) 2024/2858 as regards the application of reference points for action for nitrofurans and their metabolites in collagen

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