Cross-contamination of antimicrobial substances in non-target feed

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EU establishes maximum levels of cross-contamination of antimicrobial active substances in non-target feed, and methods of analysis

Commission Delegated Regulation (EU) 2024/1229 of 20 February 2024 supplementing Regulation (EU) 2019/4 of the European Parliament and of the Council by establishing specific maximum levels of cross-contamination of antimicrobial active substances in non-target feed and methods of analysis for these substances in feed

Update

The Regulation supplements the Medicated Feed Regulation (EU) 2019/4. It establishes maximum acceptable levels of cross-contamination for 24 antimicrobial active substances permitted in "non-target feed" (other feed that is not specifically manufactured to contain the active substance/s, but where levels could be present due to cross-contamination).

The maximum level for non-target feed will be 1% of the amount of active substance that is allowed in medicated feed. This maximum level should also apply in non-target feed that is used for flushing to remove left-overs after production of medicated feed.

However, stricter restrictions are needed to avoid:

- cross-contamination between medicated feed produced for fish and feed for other food-producing animals
- residues in milk or eggs
- residues in animals close to the date of slaughter.

The Regulation also provides reference analysis methods for these 24 antimicrobial substances.

Impacted products

feed for food-producing animals

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What is changing?

The rules apply to the 24 active substances listed in Annex II of Regulation 2019/4. In cases where a feed is processed, stored, or transported in the same equipment that was used for a medicated feed containing one of these 24 antimicrobial substances, the European Commission establishes a harmonised acceptable level for cross-contamination, enforceable at a maximum of 1% of the active substance in the medicated feed.

Maximum levels of cross-contamination in non-target feed for milk- or egg-producing animals, and for animals close to the date of slaughter, will apply at the limit of quantification (LOQ, the lowest concentration of a substance that can be measured with certainty using standard tests).

Where the cross-contamination originates from medicated feed intended for fish, the LOQ will apply in non-target feed for all food-producing animals other than fish.

Feed materials used to remove left-overs (flushing) from medicated feed in manufacturing, processing, storage, or transport facilities can be reused in the production of non-target feed if the end product complies either with the maximum of 1% of the active substance in the medicated feed, or with the LOQ if the end product is intended as feed for milk- or egg-producing animals or for animals close to the date of slaughter.

Reference methods of analysis for the quantification of the level of cross-contamination of antimicrobial active substances in feed are recommended in the Annex of the Regulation.

Why?

The new permitted level represents a good balance between the control of antimicrobial resistance and levels that have effects on growth promotion or increased yield, feasibility for the feed industry, and enforceability by competent authorities.

Medicated feed intended for fish often contains substantially higher doses of antimicrobial active substances than medicated feed intended for food-producing animals other than fish. To avoid growth promotion or increased yield in these animals, maximum levels should apply at the LOQ.

Feed materials from flushing can be used in non-target feed, provided that such feed complies with the maximum permitted levels, in order to avoid feed waste.

Timeline

Applies from **20 May 2024**.

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Recommended Actions

Manufacturers, and processing, storage, and transport facilities handling feed for export to the EU should assess and minimise risks of cross-contamination with antimicrobial active substances in non-target feed, if they also handle medicated feed in the same facilities. Cross-contamination should be avoided or kept as low as possible by applying good practices to prevent antimicrobial resistance.

Exporting countries are recommended to use the methods of analysis for antimicrobial active substances referred to in the Annex to this Regulation. Alternative analytical methods may be used if they are validated in accordance with internationally accepted scientific protocols, and only if the LOQ is the same as, or lower than, that referred to in the Annex.

It is also recommended to use official, accredited laboratories with proven competence for such analysis.

Background

In the EU, feeding animals with antimicrobials as a growth promoter and to increase yield is prohibited. It is recognised that these practices can lead to antimicrobial resistance. Antimicrobials can, however, be included in medicated feed when needed. Medicated feed is a mixture of feed and veterinary medicines commonly used to treat animals.

Where medicated feed is manufactured or processed in the same facilities as non-medicated feed ("non-target feed"), there is risk of cross-contamination. In these facilities it is also common practice to remove traces of the medicated feed by flushing the equipment with non-medicated feed, which is then used as a non-target feed (to avoid feed waste).

Regulation (EU) 2019/4 lays down rules for medicated feed. The use of antibiotics (other than coccidiostats or histomonostats) as feed additives has been phased out from 1 January 2006 in accordance with Regulation (EC) 1831/2003.

The European Food Safety Authority (EFSA 2021), in cooperation with the European Medicines Agency, carried out a scientific risk assessment of the growth promotion or increased yield effect that these substances may cause when present in non-target feed.

Resources

EFSA (2021) Maximum levels of cross-contamination for 24 antimicrobial active substances in non-target feed. Part 1: Methodology, general data gaps and uncertainties. EFSA Journal, 19(10): 6852.

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Regulation (EU) 2019/4 Medicated Feed Regulation

Regulation (EC) 1831/2003 on additives for use in animal nutrition

Sources

Delegated Regulation (EU) 2024/1229 establishing specific maximum levels of cross-contamination of antimicrobial active substances in non-target feed and methods of analysis for these substances in feed

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