Medicated feed legislation - establishment of maximum limits of cross contamination of antimicrobials in non-target feed

IGFA Briefing to update members on current situation

24 March 2023

Introduction

Medicated feed is one of the oral routes to administer veterinary medicines to animals and is generally used to treat diseases in large groups of animals. Regulation (EU) 2019/4 outlines EU harmonised standards for manufacturing, storing and transporting medicated feed, applicable since 28 January 2022. Article 7(3) of this regulation required the European Commission to adopt, by 28 January 2023, delegated acts establishing maximum levels of cross-contamination for the 24 antimicrobials identified in Annex II of the regulation in non-target feed and methods of analysis for these active substances. Until these maximum levels of cross-contamination are established at EU level, Member States are allowed apply national maximum levels of cross-contamination. The current acceptable limits of cross-contamination across Europe vary between 1 and 3%. The level advised by DAFM in Ireland is 3%.

What is meant by cross contamination and non-target feed?

Regulation (EU) 2019/4

- ✓ *(15) The manufacture of different types of feed after each other in the same production line may result in the presence of traces of an active substance in the line, which ends up in the beginning of the production of another feed. That transfer of traces of an active substance from one production batch to another is called 'cross-contamination'*
- ✓ *Article 3 (d) 'cross-contamination' means contamination of a non-target feed with an active substance originating from the previous use of the facilities or equipment*
- ✓ *Article 3 (c) 'non-target feed' means feed, whether medicated or not, which is not intended to contain a specific active substance*

Discussions establishing maximum levels of cross-contamination - current state of play

The EU Expert Animal Nutrition Group held its second meeting on 21 February 2023 (previous meeting 15 December 2021), to discuss the delegated regulation establishing maximum levels of cross-contamination. This group is composed of members from SCoPAFF – Animal Nutrition which includes DAFM Staff members and 5 industry stakeholders (FEFAC, FEFANA, FEDIAF, Animal Health Europe and Copa-Cogeca). The group was set up to advise the EU Commission for the drafting of delegated acts related to the feed legislation. FEFAC also set up a medicated feed task force in 2021 to mirror the discussion. IGFA contributes to the discissions on behalf of members.

At the meeting in February the Commission presented a background paper. This paper makes two key points
(a) the importance of medicated feed as a safe means to deliver antimicrobials to large groups of animals
(b) the fact that cross-contamination is unavoidable
They noted that the legal deadline for setting the delegated act had not been met because they lacked the scientific opinion from EFSA on the growth promoting effects of anti-microbials, the official method of analysis and the limit of quantification for each active substance.

Three possible options were tabled by the Commission

- Option 1: Establishing cross-contamination maximum levels at the LOQ for each substance (i.e. the lowest concentration at which the analyte can be detected).
- Option 2: Establishing cross-contamination maximum levels taking into account the lowest levels with growth promotion/yield increase effects.
- Option 3: Establishing cross-contamination maximum levels based on 1% of the dose in the non-target feed.

FEFAC responded highlighting that production of medicated feed is primarily a service to farmers and added that medicated feed is a compound feed with medicinal products added, not a pharmaceutical product. They pointed to the European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) data, showing the amount of antibiotics sold in the form of medicated premixtures decreased by 66% between 2015 and 2020. In addition, a further reduction has occurred since the entry into application of the ban on prophylactic use of antibiotics (-25 to -50% based on feedback from members including IGFA).

The medicated feed industry stated that options 1&2 above are unrealistic. Industry considers option 3 a potential starting point for further discussion. The Commission was reminded that achieving 1% is already demanding and would require flushing after a batch of medicated feed as not all operators can or will wish to dedicate a separate production line.

What happens if the maximum limits of cross contamination of antimicrobials in non-target feed are set too low?
It was acknowledged that the lower the limits are set, the more difficult it would be for small and medium size enterprises, who may be forced to cease the production of medicated feed. The economic investment and logistic costs necessary to limit cross contamination would be extremely high and onerous to implement. Such a scenario would lead to a reduction in the production of medicated feed, which is considered a safe route of administration of antimicrobials in large groups of food-producing animals. Furthermore, it may also have implications for imports of feed from third countries, which also would have to comply with the maximum levels of cross contamination in non-target feed set in the delegated act/s.

It is to be expected that a reduction in the production of medicated feed by professional operators will most likely result in a switching to the provision of medications via drinking water and top dressing.

However, the advice issued by the European Medicines Agency (EMA) is that top dressing of oral powders and granules administrated to terrestrial animals on feed, should be restricted to individual animals only. This will restrict the ability of veterinary professionals to treat large groups of animals safely.

In addition, due to the physical characteristics of some of the antimicrobials, homogeneity can best be achieved as a medicated feed and not as top dressings. Furthermore, not all antimicrobials can be used in water due to a low solubility or bad palatability.

Following this meeting IGFA held discussions with DAFM. We made it clear that anything below the current 3% carryover would prove challenging for IGFA medicated feed members due to the necessary significant investment. Considering medicated feed is already a small percentage of overall feed produced and the market is shrinking, significant investment would hardly be feasible.

Next Steps
The Commission asked Member States and stakeholders to provide data on the number of operators approved for production of medicated feed (industrial and on farm mixers), structures of the feed mills (number of production lines, proportion of medicated feed produced, number of substances handled during a year) as well as information on those veterinary medicinal products authorized nationally for use in medicated feed including the authorised dosages. Member States were also requested to report on present tolerances on carry-over, control modalities and legal requirements regarding the destination of flushing materials. Below is a summary of the situation in Ireland based on current information

- Licences issued by DAFM for medicated feed manufacturing - 14 mills and 32 home mixers (pigs).
- Flushing sizes ranges from 250-500kg which are flushed forward with the medicated feed and delivered on farm.
- There are no resources available to designate separate production lines for medicated feed.
- In 2021 the % of total feed produced as medicated feed ranged from 4 - 9.5% and in 2022 it was 1.5 - 5.5%.

Based on feedback from Members States, the Commission will proceed to the drafting of the delegated act which will be presented for another round of discussions at Expert Group level within the next few months. At that stage IGFA will again consult with medicated feed members.

Ends