An Roinn Talmhaíochta,
Bia agus Mara
Department of Agriculture,
Food and the Marine

Information for Compound Mills - Medicated Feed Regulation EU 2019/4

The manufacture, placing on the market and use of medicated feed is now regulated by EU Regulation 2019/4 and in Ireland also SI 36 of 2022. The Department of Agriculture, Food and the Marine (DAFM) wishes to bring a number of areas which will impact you to your attention. You should however familiarise yourself with the detail of the Regulation.

What does the new Regulation mean for your business?

1. Criteria for the approval of feed business operators and their obligations when manufacturing medicated feed are set.
2. Standards to ensure that a veterinary medicinal product is homogeneously dispersed in the medicated feed will be established at an EU level over the coming years.
3. Maximum levels of cross contamination for active substances in non-target feed which will have to be adhered to will be set at an EU level by January 2023.
4. These levels will be established based on a scientific risk assessment carried out by the European Food Safety Authority in conjunction with the European Medicines Agency. Until the completion of this work, and the establishment of these levels, national maximum levels of cross-contamination shall apply. National levels are currently at 3% of the active substance present in non-target feed manufactured after a medicated feed.
5. Prescription Changes
    - A National Veterinary Prescribing System (NVPS) is being developed and rolled out currently. All prescriptions for medicated feed will need to be accessed using this system when operational.
    - A prescription for antimicrobials, this includes coccidiostats and all antibiotics, will be valid for 5 days from the date of issue by the veterinary practitioner. This will be available through the NVPS. There is a responsibility on mills as dispensers of medicated feed to record manufacturing details on the NVPS.
    - A prescription for any non-antimicrobial medicated feed for food producing animals will have a 3-week validity period from the date of issue by the

veterinary practitioner. It must be manufactured and dispensed within 3 weeks and may be administered for the duration of treatment period as specified.

- The length of treatment shall comply with the summary of product characteristics (SPC) for the veterinary medicinal product incorporated into the feed. If the treatment period is not specified in the SPC the treatment period shall not exceed 1 month, or 2 weeks for medicated feed containing antibiotics.
- Medicated feed shall not be used for more than one treatment under the same veterinary prescription.
- Prescriptions shall be recognised throughout the EU.
- Animals must be specifically identified on the prescription.

6. Animals can no longer be treated with antimicrobials in feed as a preventative measure.
7. Mills can manufacture medicated feed in anticipation of receiving a prescription, but it cannot be supplied to the end user without receipt of a valid prescription.
8. Labelling – there are specific requirements for the labelling of medicated feed (contained in annex III of the Regulation). The main changes to this are:-
    - The approval number of the labelling feed business operator;
    - The amount in mg/kg of the added veterinary medicinal product;
    - Any contra-indications of the veterinary medicinal products and adverse events in so far as those particulars are necessary for the use;
    - Where non-food producing animals are concerned a warning that the medicated feed is only for the treatment of animals and that it must be kept out of sight and reach of children;
    - The minimum storage life, which shall take into account the expiry dates of the veterinary medicinal products and shall be expressed as ‘use before…’, followed by the date, and special storage precautions, if appropriate;
    - Information that inappropriate disposal of medicated feed poses serious threats to the environment and may, where relevant, contribute to antimicrobial resistance;
    - Inclusion of the Health Product’s Regulatory Authority (HPRA) website, www.hpra.ie will allow the animal keeper to obtain, in addition to the mandatory details, the package leaflet of each veterinary medicinal product.
9. If you become aware of any suspect/adverse events as a result of the use of medicated feed, you must report it to DAFM and the HPRA.
10. Mills must have a safe system to collect and discard unused or expired medicated feed.

11. Licences given for the manufacture of medicated feed will now be of an indefinite nature. There will be no requirement to renew. All conditions of your licence including any reports required to be submitted and deadlines must be adhered to. Inspections will continue on a risk basis on all premises.

Self - Declaration to continue with your licence under EU 2019/4

You must in advance of July 2022 confirm to DAFM that your premises and manufacturing processes meet the regulatory requirements in relation to:

- Specific operational requirements - Article 4 of EU 2091/4 (summarised below and detailed in Annex 1 of EU 2019/4);
- Composition of the medicated feed - Article 5 EU2019/4;
- Homogeneity of the medicated feed - Article 6 EU2019/4;
- Cross-contamination - Article 7 EU2019/4;
- Anticipated production - Article 8 EU2019/4;
- Labelling, packaging- Article 9,10 EU2019/4;
- Advertising and trade - Article 11,12 EU2019/4;

Failure to do this will result in your licence being revoked and your permission to manufacture medicated feed removed.

Annex I: specific operational requirements (**summarised – please read full detail of annex in EU 2019/4)**

Facilities and Equipment

1. You need to keep your facilities and equipment clean
2. You will need to create a written cleaning plan.
3. Access to your facility should be restricted to authorised personnel

Personnel

1. You need to designate an adequately trained person responsible for the manufacture and quality control of medicated feed.
2. The person responsible for the manufacture should not be the same person responsible for quality control.

Manufacture

1. Feed business operators must ensure that systems of quality assurance and good manufacturing practices are developed, and Hazard Analysis & Critical Control Point (HACCP) principles are applied in line with Feed Hygiene Regulations
2. Medicated feed and intermediate products shall be stored separately from any other feed in order to avoid any cross- contamination.
3. Materials for cleaning the line after manufacture should not affect the safety and quality of the feed
4. Veterinary medicinal products must be stored in a separate secured room

Quality control

1. You need a written quality control plan. It should include regular own checks on the entire manufacturing process from end to end and the measures to be taken in the event of non-compliance.

Storage and transport

1. You need to store medicated feed separately from any other feed
2. Veterinary medicinal products must be stored in a separate secured room
3. You need a designated area for the storage of expired, withdrawn or returned medicated feed intended for disposal

Record-keeping

1. You must keep records for 5 years which include:
    - details of the purchase, manufacturing, storage, and transport of all medicated feed and veterinary medicinal products used
    - your quality control plan and your HACCP documentation

Complaints and product recall

1. You need a system for registering and processing complaints
2. A written system is required for product withdrawals and recalls.

Contact us @ veterinarymedicineswmc@agriculture.gov.ie