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IGFA
The Irish Grain and Feed Association
Feeding the Food Chain

IGFA submission on EU Regulation 2019/4 on the manufacture, placing on the market and use of medicated feed

Introduction

IGFA compound feed manufacturers aim to produce nutritionally balanced feed, meeting the farm animals' nutritional requirements and supporting their performance. This enables us to support safe, efficient and economically viable livestock production.

Key to achieving the above is to ensure that the animal's essential nutrition needs are met in terms of energy, essential amino-acids, trace-elements and minerals. An imbalance in nutrition can adversely affect the animal's performance and in severe cases can have a direct impact on health and welfare. Our nutritionists use their expertise and knowledge of the nutritional value of a large range of feed materials to produce feed that is tailor made for the animal to meet its specific nutritional requirements. The (formulated) feed will also be adapted to the life stage of the animal as, for example, the stages of pre-weaning, post-weaning or post-lactating animals all require specific nutrients. In addition, compound feed manufacturers provide livestock farmers with dietetic feeds for farm animals facing particular stress situations (Directive 2008/38/EC).

The production of medicated feed is a service some IGFA feed manufacturers provide to farmers whose veterinarians determine that a medicated feed is required. Within the IGFA membership, the provision of this service is discussed regularly. Many nutritionists believe that medicated feed can hide underlying situations that could be improved with better animal husbandry or nutrition. It is regrettable that the guidance produced as part of iNAP did not emphasize proper nutrition as a key step in fighting AMR.

Specific Remarks

Is it a feed?

- Regulation 2019/4 amends 183/2005 and clearly places medicated feed within the scope of feed hygiene.
- Preamble (23) states that the feed manufacturer must be approved under 183/2005.
- Article 3.2 (a) defines the product as a feed.
- In Annex 1 Section 3.1 states the FBO must take account of the requirements of relevant quality assurance developed under 183/2005 (feed hygiene).

IGFA Comment - Clearly the intention of the regulators was to set the manufacture of medicated feed within the feed hygiene package and not to treat it as a medicine or pharmaceutical product. We agree that medicated feed should remain within the feed hygiene package.

What is Homogeneity?

- Preamble (14) sets out the need to establish homogeneity criteria and target values.
- The method for determining this is Article 6: The Commission, in agreement with SCoPAFF will determine these criteria.

IGFA Comment - Until SCoPAFF determine the criteria and they are set at EU levels, will the existing standard of coefficient of variation (CV) 10% exist?

What level of cross contamination is permitted?

- Preamble (15 & 16) provide background to the definition and objectives of the Commission. Within this section they accept that within a feed mill there will be transfer of an active substance from one production batch to another. The contamination of a non-target feed should be as low as possible (ALARA).

- Article 7 sets out how these target values will be determined (scientific risk assessment) and EFSA has begun its work. In the meantime, national standards may be applied.

IGFA Comment - During negotiations the EU feed industry and the Parliament put forward the view that a 3% maximum carryover of the active substance in non-target feed is workable in general feed mills. It is our understanding that DAFM officials agree with this position but we need this clarified in writing to avoid confusion. Feed Mills have production processes in place to minimize the risk of carryover into feed for animals directly entering the food chain. We would like clarity on whether there will be an obligation on the feed manufacturer to inform the Department if a feed placed on the market showed, when tested later, a carryover outside the levels agreed upon?

Who is Responsible for Scripts?

- The regulation places the responsibility for the accuracy of the script on the veterinarian or a suitably qualified person as permitted by a member state. Article 16 sets out extensive requirements on how prescriptions should be written and what detail should be included.
- In particular Article 16 (9) states that the veterinarian issuing the prescription shall verify that the medication is justified and is not incompatible with other treatments.
- Regulation 2019/4 does not lay the responsibility for the script on the feed manufacturers except where they premanufacture before receiving the actual prescription.

IGFA Comment - We agree that the veterinarian should be responsible for the accuracy of the script but would call for further training for veterinarians on this issue. The medicines data sheets can be quite complex and require information on animal bodyweight or age and average feed intake per day.

How will unused medicated feed be dealt with?

- Preamble 33 states that member states must decide on who is responsible for disposing of unused or expired medicated feed.
- However, the member state is charged with consulting with industry on how the excess should be handled.
- The system agreed upon must be fit for purpose.

IGFA Comment - Medicated feed is made to order as per the veterinary script and as such unused medicated feed should not be taken back from farms. Responsibility for the disposal of the unused feed should remain with the farmer. Feed manufacturers do not currently accept 'returned' medicated feed from farms as this practise is not permitted within our international feed safety standards. It constitutes a major risk to the FBO's system and also raises serious biosecurity concerns.

General Remarks

Given the volumes of medicated feed coming from businesses in Northern Ireland, can DAFM clarify if feed originating in NI will be produced under the new regulations? If so, how will the production and implementation of the regulation be verified by DAFM? It is important to ensure that Irish livestock farmers have confidence in the standards of medicated feed production across the country and that the same robust standards are in operation.

Finally, our expectation is that any S.I to complement this new regulation should closely reflect the regulation. We expect any additional measures will be proportionate and balanced. In addition, as medicated feed is produced under a licence, the Minister should ensure that the S.I does not grant him powers that interfere with an FBOs right to operate commercially unless he has legitimate reason and proof that there is a breach of the regulations.