Medicated feed: manufacture, placing on the market and use

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The Committee on Agriculture and Rural Development adopted a report by Clara Eugenia AGUILERA GARCÍA (S&D, ES) on the proposal for a regulation of the European Parliament and of the Council on the manufacture, placing on the market and use of medicated feed and repealing Council Directive 90/167 /EEC.

The committee recommended that the European Parliament's position adopted at first reading following the ordinary legislative procedure should amend the Commission proposal as follows:

Legal basis: the proposal should be based on **Article 43(2)** whereby the ordinary legislative procedure is used for legislation necessary for the pursuit of the objectives of the common agricultural policy.

Scope: this Regulation shall apply to:

- the manufacture, storage and transport of medicated feed and intermediate products intended for both food-producing and non-food producing animals;
- the placing on the market, including import from third countries, and use of medicated feed and intermediate products intended for both food-producing and non-food producing animals.

This Regulation shall not apply to finished veterinary medicinal products to be orally administered that have been approved for **use via feed as oral powders (via 'top dressing') or in drinking water**. The Commission shall, by 12 months after the date of entry into force of this Regulation, propose a specific legislative proposal on the administration of veterinary medicinal products for use via feed or in drinking water.

Definitions: the report proposes:

- to amend the definition of ´**premix for medicated feedingstuffs**´, as the medicated premix is the veterinary medicinal product, which is an appropriate pharmaceutical form primarily authorised to be used incorporated in medicated feedingstuffs in conditions fully in compliance with the conditions of the marketing authorisation;
- to introduce the definitions of **'antimicrobials'and 'antibiotics' / 'antibacterials'**, as well as the definitions of 'preventive treatment (prophylaxis), 'control treatment (metaphylaxis) and 'curative (therapeutic) treatment' as laid down in the Veterinary Medicinal Products proposal;
- to define '**non-target feed'** as an ordinary feed containing no veterinary medicinal products;
- to define '**mobile mixer**' and 'on-farm mixer';
- to define **'cross-contamination'** to mean a contamination resulting from a carry-over or from the transfer in feed of any unintended substance.

General obligations: Members added a provisions stipulating that distributors who supply medicated feed **solely for non-food producing animals**, which is manufactured and distributed in sealed bags and supplied under prescription directly to the animal holders, shall be exempt from the obligations of feed business operators.

Justification

The exemption proposed facilitates wholesale and retail (veterinary and pharmacist) distribution solely of medicated feed for pets without imposing unnecessary administrative burdens.

Composition: the feed used for the production of medicated feed shall comply with all relevant provisions of Union legislation concerning animal feedingstuffs.

Homogeneous distribution: it is stated that feed business operators manufacturing medicated feed shall ensure the homogeneous distribution (instead of homogeneous incorporation) of the veterinary medicinal product or the intermediate product in the feed.

Carry-over: according to the amended text, feed business operators shall manufacture, store, transport and place on the market medicated feed and intermediate products shall apply measures to **avoid carry-over** in accordance with the ALARA (As Low As Reasonably Achievable) principle, in order to avoid risk for animal health, human health or the environment.

The Commission proposes to establish a general 1% carry-over limit for all active substances containing antimicrobials, until such time as specific limits are set for each active substance individually. Members proposed that a **3% general limit for all active substances is more appropriate until specific limits** - established by the European Feed and Safety Authority (EFSA) and based on scientific evidence - **are fixed for each active substance**.

The Commission shall, by means of implementing acts, establish a **detailed schedule listing, in order of priority, the different active substances** for which specific carry-over limits must be adopted. EFSA and the European Medicines Agency (EMA) shall be consulted as the list is being compiled. By two years after the date of entry into force of this Regulation, the Commission shall submit a **report** to the European Parliament and to the Council **indicating the specific carry-over limits adopted**.

Packaging: medicated feed and intermediate products shall be placed on the market only in properly labelled and sealed packages, including sack packaging, or containers. Appropriate derogations should be provided for those instances where the application of that requirement is not necessary to protect human or animal health or consumer interests, and would represent an excessive administrative and technical burden.

Trade with third countries: Members proposed that imports, from third countries, of food producing animals which have been administered medicated feed containing antimicrobial veterinary medicinal products in order to prevent disease shall be prohibited. Similarly, imports of foodstuffs derived from those animals shall be prohibited.

Prescriptions: the supply of medicated feed to animal holders shall be subject to the presentation and, in case of manufacturing by on-farm mixers, the possession of a **veterinary prescription issued by a veterinarian or another professional person qualified to do** so in accordance with applicable national law, following a proper assessment of the health status of the animals concerned.

Members called for prescriptions for medicated feed containing veterinary medicinal products which have anabolic, anti-inflammatory, anti-infectious (other than anthelmintic), anti-cancer, hormonal or psychotropic properties or substances only to be issued by a veterinarian after a clinical examination and diagnosis.

For medicated feed containing **antibiotics**, a physical examination and diagnosis shall be carried out for every prescription issued.

The duration of the treatment shall follow the valid summary of product characteristics (SPC) of the authorised veterinary medicinal product incorporated into the medicated feed and should **not exceed three**

weeks in the case of medicated feed with incorporated veterinary medicinal products containing active substances with the potential to select resistance.

Significant and imminent health risks may be grounds for the **limited and non-routine prophylactic use of vaccines and anti-parasitical treatments**.

Use in food-producing animals: the Commission proposal sets limits for the quantities of medicated feed that suppliers are allowed to provide to farmers (one month's supply or 2 weeks for antimicrobials).

Members considered that setting time limits of this type in an EU regulation is inappropriate. They suggested the **quantities required for a treatment shall be determined in accordance with the summary of product characteristics** included in the marketing authorisation of the veterinary medicinal product included in the prescription.

Use of medicated feed containing antimicrobials: Members stated that the prophylactic use of medicated feed containing antibiotics **shall not be allowed** unless such use is permitted under the veterinary medicinal products. The use of antibiotics to **enhance the performance** of food-producing animals shall be prohibited.

Prophylaxis with antibiotics shall not be applied routinely nor to compensate for poor hygiene or for inadequate husbandry conditions. However, such prophylaxis may be permitted in very exceptional cases before a disease is diagnosed or clinical signs of disease are present on the basis of the epidemiological and clinical knowledge of the veterinarian.

Annexes: in annex IV, the report proposes changes to the permitted tolerances of deviations from the amount of an active substance indicated on the label, in order to adapt them to the proportions used in the manufacture of medicated feed.