Medicated feed: manufacture, placing on the market and use

2014/0255(COD) - 11/12/2018 - Final act

PURPOSE: adopt new rules on medicated feed with a view to ensuring a high level of protection for human and animal health, providing adequate information for users and strengthening the effective functioning of the internal market.

LEGISLATIVE ACT: Regulation (EU) 2019/4 of the European Parliament and of the Council on the manufacture, placing on the market and use of medicated feed, amending Regulation (EC) No 183/2005 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC.

CONTENT: the Regulation establishes new rules on more responsible ways to produce, sell and use medicated feeds for animals in order to combat the spread of antimicrobial resistance. It will apply to (i) the manufacture, storage and transport of medicated feed and intermediate products; (ii) the placing on the market, including import from third countries, and the use of medicated feed; (iii) the export to third countries of medicated feed.

The new rules clarify, in particular, the following points:

Approval of establishments

Feed business operators manufacturing, storing, transporting or placing on the market medicated feed or intermediate products shall ensure that establishments under their control are approved by the competent authority.

The competent authority shall approve establishments only where an on-site visit, prior to start-up of the relevant activity, has demonstrated that the system put in place for the manufacture, storage, transport or placing on the market of medicated feed or intermediate products meets the specific requirements of the Regulation.

Feed business operators dealing with some lower risk activities, such as certain types of transport, storage and retail, will be exempted from the approval obligation, but this does not exempt them from the registration obligation.

Cross-contamination

Cross-contamination may occur during manufacture, processing, storage or transport of feed where the same production and processing equipment, including for mobile mixing, storage facilities or means of transport are used for feed with different components.

The Regulation sets out harmonised requirements to prevent cross-contamination of non-target feed with active substances. The Commission may establish, by means of delegated acts, specific maximum levels of cross-contamination for active substances in non-target feed on the basis of a scientific risk assessment performed by the European Food Safety Authority (EFSA) and in cooperation with the European Medicines Agency.

Prescription and use

The new rules specify how to prescribe and use medicated feed containing antimicrobial agents for food producing animals.

The supply of medicated feed to animal keepers shall be subject to the presentation and, in case of manufacturing by on-farm mixers, the possession of a veterinary prescription for medicated feed. A veterinary prescription for medicated feed shall be issued only after a clinical examination or any other proper assessment of the health status of the animal or group of animals by a veterinarian and only for a diagnosed disease.

Prophylaxis or use of medicated feed to enhance the performance of animals will not be allowed, except, in certain cases, as regards medicated feed containing antiparasitics and immunological veterinary medicinal products.

The use of medicated feed containing antimicrobials for metaphylaxis will only be allowed when the risk of spread of an infection or of an infectious disease is high. The use of medicated feed containing some antiparasitics should be based on the knowledge of the parasite infestation status in the animal or group of animals.

Advertising

The advertising of medicated feed and intermediate products is prohibited. That prohibition shall not apply to advertising made exclusively to veterinarians. The advertising shall not include information in any form that could be misleading or lead to incorrect use of the medicated feed. Medicated feed shall not be distributed for promotional purposes except for small quantities of samples.

ENTRY INTO FORCE: 27.1.2019.

APPLICATION: from 28.1.2022.