Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018 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 (Text with EEA relevance)

REGULATION (EU) 2019/4 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 11 December 2018

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(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 43(2) and point (b) of Article 168(4) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee[(1)],

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure[(2)],

Whereas:

(1) Council Directive 90/167/EEC[(3)] constitutes the Union's regulatory framework for the preparation, placing on the market and use of medicated feed.

(2) Livestock production occupies a very important place in the agriculture of the Union. The rules concerning medicated feed have a significant influence on the keeping and on the rearing of animals, including non-food-producing animals, and on the production of products of animal origin.

(3) The pursuit of a high level of protection of human health is one of the fundamental objectives of Union food law, as laid down in Regulation (EC) No 178/2002 of the European Parliament and of the Council[(4)], and the general principles laid down in that Regulation should apply to the placing on the market and use of feed without prejudice to more specific Union legislation. In addition, the protection of animal health constitutes one of the general objectives of Union food law.

(4) Prevention of disease is better than cure. Medicinal treatments, especially with antimicrobials, should never replace good husbandry, bio-security and management practices.

(5) Experience with the application of Directive 90/167/EEC has shown that further measures should be taken to strengthen the effective functioning of the internal market and to explicitly give and improve the possibility to treat non-food-producing animals with medicated feed.

(6) Medicated feed is one of the routes for the oral administration of veterinary medicinal products. Medicated feed is a homogeneous mixture of feed and veterinary medicinal products. Other routes for oral administration, such as mixing of water for drinking with a veterinary medicinal product or manual mixing of a veterinary medicinal product into feed should not fall within the scope of this Regulation. The authorisation for use in feed, the manufacture, distribution, advertising and supervision of those veterinary medicinal products are governed by Regulation (EU) 2019/6 of the European Parliament and of the Council[(5)].

(7) Regulation (EU) 2019/6 applies to veterinary medicinal products, including those products which Directive 90/167/EEC referred to as 'pre-mixes', until such time as those products are included in medicated feed or intermediate products, after which this Regulation applies to the exclusion of Regulation (EU) 2019/6.

(8) As a type of feed, medicated feed and intermediate products fall within the scope of Regulations (EC) No 183/2005[(6)], (EC) No 767/2009[(7)], (EC) No 1831/2003[(8)] and Directive 2002/32/EC[(9)] of the European Parliament and of the Council. Thus, whenever medicated feed is manufactured with a compound feed all relevant Union legislation on compound feed applies and whenever medicated feed is manufactured from a feed material, all relevant Union legislation on feed material applies. This applies to feed business operators, whether they operate in a feed mill, with a specially equipped vehicle or on-farm, as well as to feed business operators storing, transporting or placing on the market medicated feed and intermediate products.

(9) Specific provisions for medicated feed and intermediate products should be established concerning facilities and equipment, personnel, manufacture, quality control, storage, transport, record-keeping, complaints, product recalls and labelling.

(10) Medicated feed imported into the Union must satisfy the general obligations laid down in Article 11 of Regulation (EC) No 178/2002 and the import conditions laid down in Regulation (EC) No 183/2005 and in Regulation (EU) 2017/625 of the European Parliament and of the Council[(10)]. Within that framework, medicated feed imported into the Union should be considered as falling within the scope of this Regulation.

(11) Without prejudice to the general obligations laid down in Article 12 of Regulation (EC) No 178/2002 concerning exports of feed to third countries, this Regulation should apply to medicated feed and intermediate products which are manufactured, stored, transported or placed on the market within the Union with the intention to be exported. However, the specific requirements concerning labelling, prescription and use of medicated feed and intermediate products, laid down in this Regulation, should not apply to products intended to be exported.

(12) While veterinary medicinal products and the supply thereof are covered by Regulation (EU) 2019/6, intermediate products are not and should therefore be specifically covered by this Regulation in a corresponding way.

(13) Medicated feed should be manufactured only with veterinary medicinal products authorised for the purpose of the manufacture of medicated feed and the compatibility of all compounds used should be ensured for the purpose of safety and efficacy of the product. Additional specific requirements or instructions for the inclusion of the veterinary medicinal products into feed should be provided for to ensure safe and efficient treatment of the animals.

(14) Homogeneous dispersion of the veterinary medicinal product into the feed is also crucial for the manufacture of a safe and efficient medicated feed. Therefore, the possibility to establish criteria, such as target values, for the homogeneity of the medicated feed should be provided for.

(15) Feed business operators may manufacture within one establishment a broad range of feeds for different target animals and containing different types of compounds such as feed additives or veterinary medicinal products. 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’.

(16) 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. For the purposes of this Regulation, the concept of cross-contamination is used specifically to designate the transfer of traces of an active substance contained in a medicated feed to a non-target feed. Contamination of non-target feed with active substances contained in medicated feed should be avoided or kept as low as possible.

(17) In order to protect animal health, human health and the environment, maximum levels of cross-contamination for active substances in non-target feed should be established, based on a scientific risk assessment performed by the European Food Safety Authority (EFSA) and in cooperation with the European Medicines Agency, as well as taking into account the application of good manufacturing practice and the ‘as low as reasonably achievable’ (‘ALARA’) principle. Until the completion of that scientific risk assessment, national maximum levels of cross-contamination for active substances in non-target feed, regardless of its origin, should apply, taking into account the unavoidable cross-contamination and the risk caused by the active substances concerned.

(18) Labelling of medicated feed should comply with the general principles laid down in Regulation (EC) No 767/2009 and should be subject to specific labelling requirements in order to provide the user with the information necessary to correctly administer the medicated feed. Similarly, limits for the deviations of the labelled content of medicated feed from the actual content should be established.

Changes to legislation: *There are currently no known outstanding effects for the Regulation (EU) 2019/4 of the European Parliament and of the Council. (See end of Document for details)*

(19) Medicated feed and intermediate products should be marketed in sealed packages or containers for safety reasons and to protect users' interests. This should not apply to mobile mixers that supply medicated feed directly to the animal keeper.

(20) The advertising of medicated feed could affect public and animal health and distort competition. Therefore, advertising of medicated feed should satisfy certain criteria. Veterinarians can properly evaluate the information available in advertising because of their knowledge and experience in animal health. The advertising of medicated feed to persons who cannot properly appreciate the risk associated with their use may lead to medicine misuse or overconsumption which is liable to harm public or animal health, or the environment.

(21) For intra-Union trade and import of medicated feed, it should be ensured that the veterinary medicinal products contained therein are allowed for use in the destination Member State in accordance with Regulation (EU) 2019/6.

(22) It is important to take into consideration the international dimension of the development of antimicrobial resistance. Antimicrobial resistant organisms can spread to humans and animals in the Union and third countries through consumption of products of animal origin, from direct contact with animals or humans or by other means. This has been recognised in Article 118 of Regulation 2019/6 which provides that operators in third countries are to respect certain conditions relating to antimicrobial resistance for animals and products of animal origin exported from such third countries to the Union. This is to be taken into consideration also in respect of the use of antimicrobial medicinal products concerned if they are administered via medicated feed. Furthermore, in the context of international cooperation and in line with the activities and policies of international organisations such as the World Health Organization (WHO) Global Action Plan and the Strategy on Antimicrobial Resistance and the Prudent use of Antimicrobials of the World Organisation for Animal Health, steps restricting the use of medicated feed containing antimicrobials in order to prevent a disease should be considered worldwide for animals and products of animal origin exported from third countries to the Union.

(23) Feed business operators manufacturing – whether they operate in a feed mill, with a specially equipped vehicle or on-farm – storing, transporting or placing on the market medicated feed and intermediate products, should be approved by the competent authority, in accordance with the approval system laid down in Regulation (EC) No 183/2005, in order to ensure both feed safety and product traceability. Feed business operators dealing with some lower risk activities, such as certain types of transport, storage and retail, should be exempted from the approval obligation, however this should not exempt them from the registration obligation under the registration system laid down in Regulation (EC) No 183/2005. To ensure appropriate use and full traceability for medicated feed, retailers of medicated feed for pets and keepers of fur animals feeding animals with medicated feed, which are not subject to the approval obligations, should provide information to competent authorities. Provision should be made for a transition procedure concerning establishments already approved under Directive 90/167/EEC.

(24) Care should be taken to ensure that the medicated-feed-handling requirements laid down in this Regulation and in the delegated and implementing acts adopted pursuant to this Regulation concerning feed business operators, in particular on-farm mixers, are feasible and practical.

(25) In order to ensure the safe use of medicated feed, its supply and use should be subject to presentation of a valid veterinary prescription for medicated feed which has been issued by a veterinarian after examination or any other proper assessment of the health status of the animals to be treated. However, the possibility to manufacture medicated feed before a veterinary prescription for medicated feed is presented to the manufacturer should not be excluded. Where medicated feed has been prescribed in a Member State by a veterinarian, it should as a general rule be possible for that veterinary prescription for medicated feed to be recognised and for the medicated feed to be dispensed in another Member State. By way of derogation, a Member State could allow a prescription for medicated feed to be issued by a professional person qualified to do so, other than a veterinarian, in accordance with applicable national law at the time of entry into force of this Regulation. Such a prescription for medicated feed issued by such a professional person, other than a veterinarian, should be valid only in that Member State and should exclude the prescription of medicated feed containing antimicrobial veterinary medicinal products and of any other veterinary medicinal products where a diagnosis by a veterinarian is necessary.

(26) In order to ensure prudent use – which means appropriate use of medicines in accordance with the veterinary prescription for medicated feed and the summary of product characteristics – of medicated feed for food-producing animals and fur animals and therefore provide the basis for the assurance of a high level of protection of animal health and public health, specific conditions concerning the use and the validity of the veterinary prescription for medicated feed, compliance with the withdrawal period and record-keeping by the animal keeper, where appropriate, should be provided for.

(27) Taking into account the serious public health risk posed by antimicrobial resistance, it is appropriate to limit the use of medicated feed containing antimicrobials for animals. Prophylaxis or use of medicated feed to enhance the performance of animals should 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 should only be allowed when the risk of spread of an infection or of an infectious disease is high, in accordance with Regulation 2019/6.

(28) 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. Despite the measures that farmers take to ensure good hygiene and biosecurity, animals may suffer from diseases which need to be prevented by medicated feed for reasons of both animal health and welfare. Animal diseases which are transmissible to humans may also have a significant impact on public health. Therefore the use of medicated feed containing immunological veterinary medicinal products or some antiparasitics should be allowed in the absence of a diagnosed disease.