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COMMISSION DELEGATED REGULATION (EU) …/...

of XXX

supplementing Regulation (EU) 2019/6 of the European Parliament and of the Council by laying down rules on appropriate measures to ensure the effective and safe use of veterinary medicinal products authorised and prescribed for oral administration via routes other than medicated feed and administered by the animal keeper to food-producing animals

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

Veterinary medicinal products administrated orally by means of mixing in the water for drinking, milk or into the feed and administered by the animal keeper to food-producing animals are associated with increased risk if used improperly, which can lead to effectiveness being impaired, increased risk of adverse events, user safety being jeopardized, spread of antibiotic resistance being promoted, risks for the environment and the quality of the animal food being reduced.

To ensure the proper administration and appropriate dosing of these veterinary medicinal products which are to be administered orally in feed, drinking water or milk to animals and to improve the effective and safe use of these veterinary medicinal products, especially in the case of treatment of groups of animals, rules for veterinarians and animal owners on measures to avoid cross-contamination, good practices on use, administration, preparation and storage, cleaning of the equipment used for administration and disposal of expired/unused products should be set out.

The purpose of this Delegated Regulation is to supplement Regulation (EU) 2019/6 by establishing rules on appropriate measures to ensure the effective and safe use of veterinary medicinal products authorised and prescribed for oral administration via routes other than medicated feed, such as mixing of water for drinking with a veterinary medicinal product or as manual mixing of a veterinary medicinal product into feed and administered by the animal keeper to food-producing animals.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

In accordance with Article 147(5) of Regulation (EU) 2019/6, the Commission has carried out substantial consultation with Member States' experts on veterinary medicines.

This draft Delegated Regulation was also made available to the European Parliament and the Council.

[There were no comments received from the Council.]

[There were no comments received from the European Parliament.]

In addition, stakeholders' comments on the draft Delegated Regulation were collected in the context of the Better Regulation feedback mechanism during the period between […] and […] 2024.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

Article 106(6) of Regulation (EU) 2019/6 empowers the Commission to adopt delegated acts establishing the rules on appropriate measures to ensure the effective and safe use of veterinary medicinal products authorised and prescribed for oral administration via routes other than medicated feed, such as mixing of water for drinking with a veterinary medicinal product or as manual mixing of a veterinary medicinal product into feed and administered by the animal keeper to food-producing animals.

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(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC[1], and in particular Article 106(6) thereof,

Whereas:

(1) Regulation (EU) 2019/6 aims at harmonising the internal market and increasing the availability of veterinary medicinal products, while guaranteeing the highest level of public and animal health and environmental protection. In particular, it aims at containing the spread of antimicrobial resistance with concrete measures to promote a prudent and responsible use of antimicrobials in animals, in line with the 'One Health' approach.

(2) Certain veterinary medicinal products authorised for oral administration via routes other than medicated feed may be associated with risks to public and animal health and to the environment. Their inappropriate administration or dosing can lead to possible reduction of the effectiveness of the treatments, development of antimicrobial or antiparasitic resistance, unintended administration to non-target animals and risks for the target animals, environment and for consumers.

(3) Veterinary medicinal products intended for incorporation into medicated feed in accordance with Regulation (EU) 2019/4 of the European Parliament and of the Council[2] do not fall under the scope of this Regulation.

(4) Pursuant to Article 106(6) of Regulation (EU) 2019/6, the Commission considered the scientific advice on the effective and safe use of veterinary medicinal products authorised and prescribed for oral administration via routes other than medicated feed given by the European Medicines Agency on 28 August 2020[3].

(5) Veterinary medicinal products authorised and prescribed for oral administration via

[1] OJ L 4, 7.1.2019, p. 43, ELI: http://data.europa.eu/eli/reg/2019/6/2022-01-28.

[2] OJ L 4, 7.1.2019, p. 1, ELI: http://data.europa.eu/eli/reg/2019/4/oj.

[3] Advice on implementing measures under Article 106 (6) of Regulation (EU) 2019/6 on veterinary medicinal products – scientific problem analysis and recommendations to ensure a safe and efficient administration of oral veterinary medicinal products via routes other than medicated feed.

routes other than medicated feed and administered by the animal keeper to food-producing animals cover a wide range of products and formulation types. While some veterinary medicinal products, such as tablets or oral solutions via drench application, are directly and individually applied to animals, others require their mixing in drinking water or into feed and may involve the use of equipment. Since the risks associated with the use of veterinary medicinal products administered orally by means of mixing in drinking water or into feed may be higher than other pharmaceutical forms of veterinary medicinal products, measures aiming at ensuring an effective and safe use are necessary.

(6) Therefore, this Regulation should apply to veterinary medicinal products administered orally by means of mixing into or addition onto feed and to the mixing of veterinary medicinal products in drinking water or in liquid feed by the animal keeper. It should not apply to the mixing of a veterinary medicinal product into feed-by-feed business operators irrespectively of whether they operate in a feed mill, with a mobile mixer or an on-farm mixer, which is covered by Regulation (EU) 2019/4.

(7) Most veterinary medicinal products authorised for food-producing animals are subject to veterinary prescription. Veterinarians should prescribe the most appropriate route of administration. When considering an oral route of administration, the veterinarians should take into account, on a case-by-case basis, the individual circumstances of the animals to be treated, the facilities, equipment and expertise of the person responsible for the administration of the veterinary medicinal product that are relevant to ensuring the safe and effective use of veterinary medicinal products for each treatment.

(8) Inappropriate administration or disposal of veterinary medicinal products and feed or drinking water containing veterinary medicinal products could pose risks to the environment and may contribute to the development, selection and spread of antimicrobial or antiparasitic resistance. Therefore, veterinarians should provide animal keepers with information and instructions in accordance with the product information of the veterinary medicinal product aiming at minimising those risks.

(9) The oral administration of veterinary medicinal products by applying them onto the surface or by mixing them into solid feed immediately prior to feeding groups of animals competing for the same feed raises a risk of both underdosage and overdosage. In particular, for veterinary medicinal products containing antimicrobials and antiparasitics, this may contribute to the development and spread of antimicrobial and antiparasitic resistance. Therefore, the prescription and oral administration of an antimicrobial or antiparasitic veterinary medicinal product by means of mixing into solid feed or administration on the surface of solid feed immediately prior to feeding should only be allowed when the animals are fed individually or when the intake of the veterinary medicinal product by individual animals can be effectively controlled in a small group of animals.

(10) The availability of veterinary medicinal products, the access to medicated feed produced in accordance with Regulation (EU) 2019/4, the need for small group treatments due to local husbandry and farming practices as well as the national policy on prudent use of veterinary medicinal products may vary across the Union. Therefore, Member States should be allowed to further restrict within their territory the prescription and oral administration of antimicrobial or antiparasitic veterinary medicinal products that are mixed into solid feed or administered on the surface of solid feed immediately prior to feeding, to individually fed animals only. Such restriction should not have a negative impact on the animal health or welfare.

(11) As indicated in the scientific advice given by the European Medicines Agency, individual treatments via solid feed in aquaculture are not possible. Oral treatment via drinking water, which is an alternative oral treatment option for other animal species, is not suitable for treatments in aquaculture either. The aquaculture sector is very diverse across the Union, with large differences in terms of animal species, farming practices and size of the farms. In some Member States, there is a limited number of compound feed producers for aquaculture and immediate access to medicated feed produced in accordance with Regulation (EU) 2019/4 for group treatment may not be feasible.

(12) Where medicated feed produced in accordance with Regulation (EU) 2019/4 is not available or where animal treatment should be started before the delivery of the medicated feed, a prohibition to prescribe antimicrobial and antiparasitic veterinary medicinal products to be mixed into solid feed for group treatment in food producing aquatic species would create animal health and welfare issues. Therefore, in those situations such group treatments should be allowed.

(13) Since the combined use of several antimicrobial veterinary medicinal products may represent a particular risk with respect to the development of antimicrobial resistance, oral administration of several antimicrobial veterinary medicinal products at the same time, via routes other than via medicated feed should be restricted.

(14) In order to ensure the effective and safe use of veterinary medicinal products prescribed for oral administration via routes other than medicated feed, animal keepers should use the veterinary medicinal products only in accordance with the veterinary prescription, which is based in particular upon a diagnosis, the target species and the number of animals to be treated.

(15) Animal keepers should have the relevant expertise and skills to ensure the effective and safe use of veterinary medicinal products authorised and prescribed for oral administration by means of mixing in drinking water or into different types of feed.

(16) The equipment used for the oral administration of veterinary medicinal products and its maintenance should be such as to ensure the effective and safe use of the prescribed veterinary medicinal products in the target animals and reduce the risks of contamination of the animals surrounding and the exposure of the environment.

(17) The characteristics of the drinking water used to administer veterinary medicinal products via drinking water can impact the solubility and stability of those veterinary medicinal products. Therefore, the animal keeper should take appropriate measures to ensure that the drinking water used is appropriate for the oral administration of the veterinary medicinal product.

(18) Biocidal products, feed additives or other substances used simultaneously with veterinary medicinal products administered via drinking water or liquid feed might interact with the veterinary medicinal products or impact their uptake or their efficacy and safety. Those products should not be used simultaneously with veterinary medicinal products if interactions or incompatibilities have been documented in the marketing authorisation of the veterinary medicinal products. Where no data or information on those interactions or incompatibilities is available, it should be reflected in the product information.

(19) Article 106(1) of Regulation (EU) 2019/6 requires that veterinary medicinal products are used in accordance with the terms of the marketing authorisation. Therefore, existing marketing authorisations should be amended, where relevant, to ensure

consistency with the requirements of this Regulation. That should ensure the proper prescription by veterinarians and administration and dosing of the veterinary medicinal products by the animal keeper.

(20) Local husbandry and farming practices might be divergent among Member States. Therefore, Members States should have the possibility to provide further guidance at national level adapted to the animal species and production systems in their territory. Such guidance should contribute to the effective and safe use of veterinary medicinal products authorised and prescribed for oral administration by means of mixing in drinking water, mixing into different types of feed or adding onto the surface of feed.

(21) In order not to compromise the availability of the veterinary medicinal products concerned, it is necessary to provide for transitional measures to allow marketing authorisation holders, the competent authorities or, where the veterinary medicinal product is authorised under the centralised marketing authorisation procedure, the Commission, sufficient time to amend existing marketing authorisations with a view to ensuring consistency with the provisions of this Regulation.

(22) The entry into application of this Regulation should be deferred in order to provide veterinarians and in particular animal keepers with sufficient time to adapt to the new requirements laid down by this Regulation,

HAS ADOPTED THIS REGULATION:

Article 1
Scope

1. This Regulation applies to authorised and prescribed veterinary medicinal products administered orally in drinking water, mixed into feed, or administered on the surface of feed immediately prior to feeding and administered by the animal keeper to food-producing animals.

2. This Regulation does not apply to the use of medicated feed manufactured in accordance with Regulation (EU) 2019/4.

Article 2
Definitions

For the purposes of this Regulation, the following definitions apply:

(a) ‘feed’ means feed as defined in Article 3, point 4 of Regulation (EC) No 178/2002 of the European Parliament and of the Council[4];

(b) ‘non-target feed’ means non-targeted feed as defined in Article 3(2), point (c), of Regulation (EU) 2019/4;

(c) ‘biocidal product’ means biocidal product as defined in Article 3(1), point (a), of Regulation (EU) 528/2012 of the European Parliament and of the Council[5];

(d) ‘liquid feed’ means any feed material or compound feed in a liquid or semi-liquid form, including milk or diluted milk replacers and ready to use for oral animal feeding;

[4] OJ L 31, 1.2.2002, p. 1, ELI: http://data.europa.eu/eli/reg/2002/178/oj.
[5] OJ L 167, 27.6.2012, p. 1, ELI: http://data.europa.eu/eli/reg/2012/528/oj.

(e) ‘solid feed’ means all types of feed other than liquid feed;

Article 3
Decision on treatment

When deciding whether to treat food-producing animals with a veterinary medicinal product by oral route of administration, the veterinarian shall take account of the following:

1. the diagnosis;
2. the availability of appropriate veterinary medicinal products;
3. ensuring individual treatment of animals whenever possible, except for immunological veterinary medicines;
4. the animal species, production system and the number of animals to be treated;
5. the properties of the veterinary medicinal product;
6. the relevant characteristics of the feed or drinking water;
7. the presence of biocidal products, feed additives or other substances in the feed or drinking water that might impact the uptake or the efficacy or safety of the veterinary medicinal product, including by interaction or incompatibility of the veterinary medicinal product, and in particular the requirements set out in article 4;
8. the state of the facilities and equipment for oral administration of veterinary medicinal products on the farm, such as the mixing and dosing equipment, type of feeding or drinking equipment and storage premises, as well as the maintenance conditions of those facilities and equipment;
9. the expertise and skills of the animal keeper or staff on the farm to ensure the correct storage, preparation, administration and disposal of veterinary medicinal products for oral administration, including the ability to use the necessary equipment or dosing devices.

Article 4
Simultaneous use of veterinary medicinal products and other categories of products

1. Biocidal products, feed additives or other substances used in drinking water shall not be used simultaneously with a veterinary medicinal product where there is evidence of negative interactions or incompatibilities between those products and the veterinary medicinal product when added to drinking water.
2. Veterinary medicinal products containing an anticoccidial or antihistomonal active substance shall not be used in feed containing the same substance as a feed additive authorised as a coccidiostat or a histomonostat with a maximum content.
3. For active substances other than anticoccidial or antihistomonal substances, where the active substance in the veterinary medicinal product is the same as a substance in a feed additive contained in the feed, the total content of that active substance in the feed once the veterinary medicinal product has been mixed into it or added onto its surface shall not exceed the maximum content set out in the prescription.

Article 5
Information and instructions on disposal

1. The veterinarian shall inform the animal keeper that the inappropriate disposal of

feed or drinking water containing veterinary medicinal products prescribed for oral administration may pose a threat to the environment and, where relevant, may contribute to the development and spread of antimicrobial or antiparasitic resistance.

2. The veterinarian shall provide the animal keeper with instructions for the safe disposal of unused veterinary medicinal products prescribed and give advice on how to minimise the exposure of the environment to feed or water containing the veterinary medicinal products.

Article 6

Prescription of antimicrobial and antiparasitic veterinary medicinal products

1. The veterinarian shall not prescribe more than one antibiotic veterinary medicinal product to be administered orally in the same course of treatment.

2. The veterinarian shall only prescribe veterinary medicinal products containing antimicrobial or antiparasitic active substances administered by means of mixing into solid feed or administered on the surface of solid feed immediately prior to feeding, for the treatment of individually fed animals or a small group of animals where the intake of the veterinary medicinal product by individual animals can be effectively controlled.

3. By way of derogation from paragraph 2, where medicated feed produced in accordance with Regulation (EU) 2019/4 is not available or where a veterinarian considers animal treatment is necessary to commence before the delivery of the medicated feed, the veterinarian may prescribe group treatments with antimicrobial or antiparasitic veterinary medicinal products to be mixed into solid feed for food producing aquatic species.

4. By way of further derogation from paragraph 2, a Member State may restrict on its territory the prescription and oral administration of veterinary medicinal products containing antimicrobial or antiparasitic active substances administered by means of mixing into solid feed or administered on the surface of solid feed immediately prior to feeding, to individually fed animals only. Such restriction shall be duly justified on grounds of sufficient availability of veterinary medicinal products, access to medicated feed produced in accordance with Regulation (EU) 2019/4 and/or local husbandry and farming practices.

5. The Member State shall inform the Commission on any measure it has adopted on the basis of paragraph 4.

Article 7

Handling and use of veterinary medicinal products by animal keepers

1. The animal keeper is responsible for:

   (a) providing the veterinarian with the relevant information concerning Article 3, points (6), (7), (8) and (9);

   (b) using veterinary medicinal products subject to veterinary prescription for oral administration in feed or drinking water only in accordance with the veterinary prescription;

   (c) the proper storage, preparation and administration of veterinary medicinal products in feed or drinking water, including:

(i) the proper dosage of the veterinary medicinal products in accordance with the veterinary prescription and ensure the uptake of the appropriate amount of feed and water by all target animals;

(ii) the proper, homogeneous dilution of the veterinary medicinal products in the liquid feed or the drinking water;

(d) ensuring that any person administering veterinary medicinal products under their supervision, has the relevant expertise and skills or has been trained with regards to the responsibilities set out in point (c).

2. The animal keeper shall take the necessary measures to:

(a) avoid contamination of non-targeted feed or drinking water from feed or drinking water containing veterinary medicinal products;

(b) ensure the safe disposal of unused veterinary medicinal products and avoid the exposure of the environment to feed or drinking water containing veterinary medicinal products according to the product information and to the instructions of the veterinarian;

(c) ensure that the water used for the administration of veterinary medicinal products via drinking water or liquid feed is appropriate for the oral administration of the veterinary medicinal product.

Article 8
Equipment

1. The animal keeper is responsible for ensuring that the equipment used for preparing and mixing veterinary medicinal products for oral administration in drinking water, milk, milk replacers or other forms of liquid feed:

(a) corresponds to the range of weights or volumes being mixed;

(b) allows the preparation of homogeneous dilutions;

(c) is designed, built and placed in such a way that:

(i) medication is supplied to the target animals only;

(ii) contamination of untreated drinking water or feed is avoided;

(iii) treatment of drinking water with biocidal products and use of feed additives via drinking water, may be decreased or stopped, if necessary, before and during the treatment with the veterinary medicinal product to ensure the safety and efficacy of the treatment.

2. The animal keeper shall ensure that all scales and metering devices used correspond to the range of weights or volumes to be measured and are calibrated in accordance with the manufacturer's instructions.

3. The animal keeper is responsible for ensuring that the equipment, watering systems or dosing devices used for the oral administration of veterinary medicinal products in feed or drinking water are properly used, maintained and cleaned after being used for the administration of veterinary medicinal products in feed or drinking water.

Article 9

Product information

1. The product information of an antimicrobial or antiparasitic veterinary medicinal product to be administered to a terrestrial food-producing animal species by means of mixing into solid feed or administered on the surface of solid feed immediately prior to feeding shall clearly indicate that the product is to be administered only for the treatment of individually fed animals or a small group of animals where the intake of veterinary medicinal products by individual animals can be effectively controlled.

2. The product information of a veterinary medicinal product to be administered orally by means of mixing into drinking water or liquid feed shall provide appropriate guidance on known interactions and incompatibilities between the veterinary medicinal product and biocidal products, feed additives or other substances used in drinking water. Where no data or information on potential interactions or incompatibilities is available, the product information shall include a warning indicating that no such information is available.

3. Where relevant, marketing authorisation holders of veterinary medicinal products authorised before *[OP: please insert the date of application of this Regulation]* shall amend their existing marketing authorisations or product information, as appropriate, in accordance with paragraphs 1 and 2 at the latest by 28 January 2027.

Article 10
Guidelines on good practice

Member States may develop national guidelines on good practice to facilitate the application of Chapters II and III, taking into account the different food-producing animal species and production systems in their territories.

Article 11
Entry into force and application

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from [*OP: please insert date: 18 months after the date of entry into force of this Regulation*].

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN