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COMMISSION DELEGATED REGULATION (EU) …/...

of XXX

supplementing Regulation (EU) 2019/6 of the European Parliament and of the Council as regards the application of the prohibition of use of certain antimicrobial medicinal products in animals or products of animal origin exported from third countries into the Union

(Text with EEA relevance)

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission.

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

Regulation (EU) 2019/6, replaces the legal framework for veterinary medicinal products established by Directive 2001/82/EC and Regulation (EC) No 726/2004. One of the main objectives of the Regulation is to mitigate the risk of development of antimicrobial resistance, including by strengthening the prudent use of antimicrobial medicinal products. Among others, the Regulation prohibits the use of antimicrobial medicinal products for growth promotion and yield increase, and it forbids the use in animals of medicinal products containing antimicrobials that are reserved for treatment of infections in humans.

The criteria for the designation of antimicrobials reserved for treatment of certain infections in humans are laid down in Commission Delegated Regulation (EU) 2021/1760. The specific list of antimicrobials reserved for human use is contained in Commission Implementing Regulation (EU) 2022/1255.

Article 118(1) of the Regulation (EU) 2019/6 requires third country operators exporting animals or products of animal origin to the Union to respect the prohibition on the use of antimicrobial medicinal products for the purpose of promoting growth or to increase yield, and on the use of antimicrobials that have been reserved for the treatment of certain infections in humans. Article 118(2) of the Regulation (EU) 2019/6 empowers the Commission to adopt delegated acts providing detailed rules on the application of the above-referred prohibitions.

The application of the prohibition of use of certain antimicrobial medicinal products in animals or products of animal origin that are exported from third countries into the Union requires the setting up of an effective enforcement system. As a system permitting controls of animals or products of animal origin imported into the Union does not exist under the Regulation (EU) 2019/6, resort has been made to the Union framework on official controls. Specifically, the Regulation (EU) 2017/625 was amended in 2021 to include the verification of compliance with the prohibition in Article 118(1) of the Regulation (EU) 2019/6 within the scope of the Union framework on official controls.

The purpose of this Delegated Regulation is to supplement Regulation (EU) 2019/6 by establishing detailed rules necessary for the application of the prohibition foreseen in Article 118(1) thereof, including the setting of the conditions to be respected by animals or products of animal origin that are exported from third countries into the Union.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

Member States' experts were consulted within the Expert Group on Veterinary Medicinal Products[1], which met on the subject on 16 February, 4 May and 22 June 2022.

Third countries have been consulted by means of a notification to the World Trade Organisation within the framework of the Agreement on the Application of Sanitary and Phytosanitary Measures.

Finally, before adopting this Delegated Regulation, the Commission has conducted open and transparent public consultations in accordance with the procedures laid down in the Inter-institutional Agreement on Better Law-Making.[2]

[1] Reference E02792 in the Register of Commission Expert Groups and other similar entities.

[2] http://ec.europa.eu/smart-regulation/better_regulation/documents/iia_blm_final_en.pdf.

This Delegated Regulation provides for details on the application of the prohibition of use of certain antimicrobial medicinal products in animals or products of animal origin that are exported from third countries into the Union, which is set out in Article 118(1) of the Regulation (EU) 2019/6. Among others, it provides details on the specific requirements that are to be met by consignments of animals or products of animal origin imported into the Union to be deemed compliant with Article 118(1) of the Regulation (EU) 2019/6.

As the delegated Regulation is designed to enable the application of a prohibition that has been established in a Regulation of the European Parliament and of the Council no impact assessment has been carried out.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

The legal basis for the Delegated Regulation is Article 118(2) of Regulation (EU) 2019/6.

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supplementing Regulation (EU) 2019/6 of the European Parliament and of the Council as regards the application of the prohibition of use of certain antimicrobial medicinal products in animals or products of animal origin exported from third countries into the Union

(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 118(2) thereof,

Whereas:

(1) Antimicrobial resistance is a major threat to public health. When resistance develops to an antimicrobial agent used to treat a specific infection for which there are no alternative treatments and that resistance spreads, it has serious and potentially life-threatening consequences for humans. Human health, animal health and the environment are interlinked. Therefore, one of the objectives of Regulation (EU) 2019/6 is to contain the spread of antimicrobial resistance with concrete measures to promote the prudent and responsible use of antimicrobial medicinal products in animals.

(2) The use of antimicrobial medicinal products to promote growth or to increase yield is neither prudent nor responsible. An extensive body of scientific literature has shown that the use of antimicrobials for such purposes can trigger antimicrobial resistance. Therefore, by Regulation (EU) 2019/6, the use of antimicrobial medicinal products for the purpose of promoting growth or to increase yield is prohibited, which includes antimicrobials contained in veterinary medicinal products as well as antimicrobials contained in human medicinal products.

(3) Moreover, Regulation (EU) 2019/6 provides for the procedure to designate certain antimicrobials to be reserved for the treatment of infections in humans. Such antimicrobials are not to be used in antimicrobial medicinal products administered to animals. That measure aims to preserve the efficacy of certain antimicrobials used to treat infections in humans, especially those considered treatments of last resort. Criteria for the designation of antimicrobials reserved for the treatment of certain infections in humans are laid down in Commission Delegated Regulation (EU)

[1] 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 (OJ L4, 7.1.2919, p.43).

2021/1760[2] and the list of antimicrobials reserved for treatment of certain infections in humans is set out in Commission Implementing Regulation (EU) 2022/1255[3].

(4) The international dimension of the development of antimicrobial resistance should also be considered. Specifically, Article 118(1) of Regulation (EU) 2019/6 provides that, in respect of animals or products of animal origin that are exported from third countries into the Union, operators in third countries are not to use antimicrobial medicinal products to promote growth or to increase yield, and are not to use the designated antimicrobials or groups of antimicrobials reserved for treatment of infections in humans.

(5) Medicated feed is one of the routes for the oral administration of medicinal products to animals. Therefore, the prohibition of use of certain antimicrobial medicinal products in respect of animals or products of animal origin that are exported from third countries into the Union should also apply when such antimicrobial medicinal products are administered via medicated feed.

(6) A robust system of controls regarding animals or products of animal origin that are exported from third countries into the Union from third countries is essential to ensure compliance with the requirements laid down in Regulation (EU) 2019/6. No specific system of controls on imports of animals or products of animal origin exists under the Union framework on veterinary medicinal products. The setting up of such dedicated framework of controls would have necessitated significant amount of resources and time. Moreover, it would have led to duplications at the level of the competent authorities and also on the operators concerned. For reasons of effectiveness and reduction of administrative burden, the existing Union framework on official controls is to be used to verify compliance of animals or products of animal origin entering the Union from third countries with Regulation (EU) 2019/6. To this effect, Regulation (EU) 2017/625 has been amended[4]. Therefore, the verification of compliance with the requirements set out in Article 118(1) of Regulation (EU) 2019/6 is to be done in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council.

(7) The consignments of animals or products of animal origin entering the Union that are subject to the prohibition on the use of antimicrobial medicinal products to promote growth or to increase yield and on the use of antimicrobials reserved for treatment of certain infections in humans should be clearly set out. Therefore, this Delegated Regulation should provide detailed rules on the prohibition laid down in Article 118(1) of Regulation (EU) 2019/6.

(8) The vast majority of the consumption of antimicrobials in animals (in volume) relates to food-producing animals. In addition, there is increasing scientific evidence that the use of antimicrobials in food-producing animals has an impact on the development of

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2 Commission Delegated Regulation (EU) 2021/1760 of 26 May 2021 supplementing Regulation (EU) 2019/6 of the European Parliament and of the Council by establishing the criteria for the designation of antimicrobials to be reserved for the treatment of certain infections in humans (OJ L353, 6.10.2021, p.1).

3 Commission Implementing Regulation (EU) 2022/1255 of 19 July 2022 designating antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans, in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council (OJ L 191/58, 20.7.2022, p.58).

4 Regulation (EU) 2021/1756 of the European Parliament and of the Council of 6 October 2021 amending Regulation (EU) 2017/625 as regards official controls on animals and products of animal origin exported from third countries to the Union in order to ensure compliance with the prohibition of certain uses of antimicrobials and Regulation (EC) No 853/2004 as regards the direct supply of meat from poultry and lagomorphs, (OJ L357, 8.10.2021, p. 27).

antimicrobial resistance. Therefore, addressing antimicrobial resistance requires particular action on the use of antimicrobial medicinal products in food-producing animals or products of animal origin intended for human consumption. In accordance with the principle of proportionality, taking such action will contribute effectively to address the international dimension of the development of antimicrobial resistance while minimising the impacts on trade.

(9) Moreover, it should be clarified that the prohibition of use of certain antimicrobials set out in Article 118(1) of Regulation (EU) 2019/6 concerns food-producing animals or products of animal origin intended for human consumption that are exported from third countries into the Union. To ensure legal certainty, the animals and products of animal origin concerned should be identified by means of references to the Combined Nomenclature codes set out in Council Regulation (EEC) No 2658/87[5].

(10) Consignments of animals or products concerned that are only intended for transit, as well as products concerned intended for the purpose of samples for product analysis and quality testing that are not placed on the market, should not be covered by this Regulation.

(11) Consignments of the animals or products concerned that are exported from third countries into the Union should comply with the same restrictions that apply in the Union in relation to the objectives pursued by Articles 107(2) and 37(5) of Regulation (EU) 2019/6. To that effect, consignments of the animals or products concerned should only be allowed to enter the Union in the case that the third countries or regions thereof, from which those animals or products originate, can ensure compliance with the prohibition on the use of antimicrobial medicinal products for the purpose of promoting growth or to increase yield, and on the use of antimicrobials that have been reserved for the treatment of certain infections in humans.

(12) Third countries -or regions- thereof that meet those requirements are to be included in a list that is to be drawn up by the Commission, by means of implementing acts, in accordance with Article 127 of Regulation (EU) 2017/625 of the European Parliament and of the Council[6]. Third countries or regions thereof are to be included on that list on the basis of available evidence and guarantees that the concerned animals or products originating in them comply with the Union's prohibition on the use of antimicrobial medicinal products for the purpose of promoting growth or to increase yield, and on use of antimicrobials that have been reserved for the treatment of certain infections in humans.

(13) Consignments of animals or products concerned entering the Union from third countries listed in accordance with Article 127 of Regulation (EU) 2017/625 should also be accompanied by an official certificate confirming compliance with the Union's

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5 Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff (OJ L 256, 7.9.1987, p. 1).

6 Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L95, 7.4.2017, p.1).

prohibition on the use of antimicrobial medicinal products for the purpose of promoting growth or to increase yield, and on use of antimicrobials that have been reserved for the treatment of certain infections in humans.

(14) The Commission should adopt specific requirements on the official certificates required, by means of implementing acts, in accordance with Regulation (EU) 2017/625.

(15) The conditions for entry into the Union of consignments of animals or products concerned will be known to third country operators as from the date of publication of this Regulation. However, the practical application of the framework laid down in this Regulation will necessitate the adoption of further implementing measures. For reasons of predictability and legal certainty and with a view to allow stakeholders concerned sufficient time to comply with the Union requirements, the conditions for the entry into the Union of consignments of animals or products set out in this Regulation should be deferred.

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter and scope

1. This Regulation lays down detailed rules on the application of the prohibition of use, in animals or products of animal origin that are exported from third countries into the Union, of antimicrobial medicinal products for growth promotion and yield increase, and antimicrobials reserved for treatment of certain infections in humans.

2. This Regulation applies to live food-producing animals for which Combined Nomenclature codes ('CN codes') have been laid down in Part Two, Chapter 1, of Annex I to Regulation (EEC) No 2658/87.

   This Regulation also applies to products of animal origin intended for human consumption, for which CN codes have been laid down in Part Two, Chapters 2 to 5, 15 and 16, of Annex I to Regulation (EEC) No 2658/87, and for which Harmonised System subheadings have been laid down under headings 3501, 3502 and 3504.

3. This Regulation does not apply to the following:

   (a) gelatine and raw materials for the production thereof referred to in Section XIV, Chapter I, point 1, of Annex III to Regulation (EC) No 853/2004 of the European Parliament and of the Council[7];

   (b) collagen and raw materials for the production thereof referred to in Section XV, Chapter I, point 1, of Annex III to Regulation (EC) No 853/2004;

   (c) highly refined products referred to in Section XVI, Chapter I, point 1, of Annex III to Regulation (EC) No 853/2004;

   (d) wild animals and products derived therefrom;

   (e) insects, frogs, snails and reptiles, including products derived therefrom;

   (f) composite products;

[7] Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55).

(g) animals or products of animal origin not intended for human consumption, unless the destination of the animals or products has not been decided at entry into the Union;

(h) animals or products of animal origin intended for human consumption only for transit through the Union without being placed on the market;

(i) products of animal origin intended for human consumption for the purpose of samples for product analysis and quality testing without being placed on the market.

Article 2

Definitions

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

(1) 'antimicrobial medicinal product' means a medicinal product that contains or consists of one or more antimicrobials;

(2) 'medicinal product' means a medicinal product that is administered to animals, including when it is administered in medicated feed as defined in Article 3(2), point (a), of Regulation (EU) 2019/4 of the European Parliament and of the Council[8];

(3) 'food-producing animal' means food producing animal as defined in Article 2, point (b), of Regulation (EC) No 470/2009 of the European Parliament and of the Council.[9]

(4) 'consignment' means consignment as defined in Article 3, point (37), of Regulation (EU) 2017/625 of the European Parliament and of the Council;

(5) 'transit' means transit as defined in Article 3, point (44), of Regulation (EU) 2017/625 of the European Parliament and of the Counci.

Article 3

Restrictions on the use of certain antimicrobial medicinal products in animals or products derived therefrom entering the Union

Animals or products referred to in Article 1(2) that are exported from third countries into the Union shall not have been administered, or originate from animals that have been administered any of the following:

(a) an antimicrobial medicinal product used for the purpose of promoting growth or to increase yield;

(b) an antimicrobial medicinal product containing an antimicrobial that is included in the list of antimicrobials reserved for treatment of certain infections in humans laid down in Implementing Regulation (EU) No 2022/1255.

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8 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 (OJ L4, 7.1.2019, p.1).

9 Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L52, 16.6.2009, p.11).

Article 4

Conditions for the entry into the Union

1. Consignments of the animals or products referred to in Article 1(2*)* shall only enter the Union where the following conditions are met:

   (a) they originate from a third country or region thereof included in the list of countries referred to in Article 5, and

   (b) they are accompanied by an official certificate referred to in Article 6 attesting that the consignment complies with the requirements in Article 3.

2. By way of derogation from paragraph 1, point (a), consignments of the animals or products referred to in Article 1(2) may enter the Union from third countries that are not included in the list referred to in Article 5(1), where such third countries ensure that the consignments entering the Union originate from a Member State or from a third country included in the list.

Article 5

List of approved third countries

1. The list referred to in Article 4(1), point (a), is to be established by means of an implementing act adopted by the Commission in accordance with Article 127 of Regulation (EU) 2017/625. If appropriate, that list may be combined with other lists developed under Article 127 of Regulation (EU) 2017/625.

2. The Commission shall decide on the inclusion of third countries in the list in accordance with the requirements laid down in Article 127(3), points (a) to (d), and points (f) and (g), of Regulation (EU) 2017/625, on the basis of available evidence and guarantees that the requirements laid down in Article 3 are complied with, including information received on the procedures in place to guarantee the traceability and origin of animals or products referred to Article 1(2).

3. In accordance with Article 127(4) of Regulation (EU) 2017/625, the Commission shall delete the reference to a third country or a region of a third country from the list if the conditions for inclusion in the list cease to be met.

Article 6

Certification of compliance

1. Specific requirements on the official certificates referred in point (b) of Article 4(1) are to be laid down by the Commission, by means of implementing acts, in accordance with the examination procedure referred to in Article 126(3) of Regulation (EU) 2017/625.

2. The official certificates may include details required in accordance with other Union legislation on public and animal health matters.

Article 7

Controls

Controls to verify compliance of consignments of the animals or products referred to in Article 1(2) with Article 3 shall be carried out in accordance with Regulation (EU) 2017/625.

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Article 8

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*.

The conditions for entry into the Union of consignments of animals or products set out in this delegated act shall apply as from 24 months after the date of application of the implementing act referred to in Article 6(1).

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

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN

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