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Delegations will find attached document COM(2021) 108 final.

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Brussels, 9.3.2021
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Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Regulation (EU) 2017/625 as regards official controls on animals and products of animal origin exported from third countries to the Union to ensure compliance with the prohibition of certain uses of antimicrobials

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

- **Reasons for and objectives of the proposal**

Regulation (EU) 2019/6¹, which enters into application on 28 January 2022, replaces the legal framework for veterinary medicinal products (“VMPs”) established by Directive 2001/82/EC and Regulation (EC) No 726/2004. Article 118(1) of Regulation (EU) 2019/6 provides that third country operators exporting animals and products of animal origin to the EU will have to respect the prohibition against using antimicrobials for growth promotion and yield increase (Article 107(2)), as well as the ban against using antimicrobials reserved for treatment of certain infections in humans (Article 37(5)).

Article 118(2) of Regulation (EU) 2019/6 empowers the Commission to adopt delegated acts providing detailed rules on the application of the prohibitions referred to in Article 118. Regulation (EU) 2019/6 sets out the legal framework for the authorisation of veterinary medicinal products, whereas Article 118 of that Regulation by contrast applies to animals and products of animal origin. Unlike other legislation that lays down rules for animals and products of animal origin, Regulation (EU) 2019/6 does not contain any basic provisions on import conditions/requirements or on official controls of compliance of imports with these requirements. Import requirements and conditions (such as third country and establishment listing and certificates) for animals and for products of animal origin are laid down in relevant sectorial legislation, such as the Animal Health Law², but may also be laid down on the basis of Regulation (EU) 2017/625 (‘the Official Controls Regulation’)³. For a third country to be included in a list of third countries authorised to export to the Union, it needs, for example, to provide guarantees that the animals and goods concerned comply with the Union’s requirements or with requirements equivalent thereto laid down in the relevant legislation.

However, Article 1(4)(c) of the Official Controls Regulation states that that Regulation does not apply to official controls for the verification of compliance with Directive 2001/82/EC on veterinary medicinal products. When Regulation (EU) 2019/6 enters into application on 28 January 2022, the reference to Directive 2001/82/EC will in effect become a reference to that Regulation.⁴ Article 1(4)(c) of the Official Controls Regulation excludes the entirety of Regulation (EU) 2019/6 from its scope. In the absence of relevant provisions in Regulation (EU) 2019/6 on official controls of compliance of imports with the requirements referred to in

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 L 4, 7.1.2019, p. 43).

² Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health (‘Animal Health Law’) (OJ L 84, 31.3.2016, p. 1).

³ 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 L 95, 7.4.2017, p. 1).

⁴ Article 149 of Regulation (EU) 2019/6.

the preceding paragraph, it would not be possible to implement and enforce Article 118 of Regulation (EU) 2019/6 properly without amending the Official Controls Regulation.

The objective of this amendment is to modify Article 1(4)(c) of the Official Controls Regulation to include an exception to the above exclusion, integrating controls to verify compliance with Article 118 of Regulation (EU) 2019/6 into the scope of the Official Controls Regulation. This would mean that the Union's official control system for animals and products of animal origin could be used to ensure compliance with the prohibitions in Article 118 of Regulation (EU) 2019/6. This would in turn make it possible to implement and enforce Article 118 properly.

Article 123 of Regulation (EU) 2019/6, which was part of the Commission's proposal, provides for controls of compliance with the Regulation by Member State competent authorities. However, these controls only apply to manufacturers and importers of VMPs and active substances (and other persons involved in the placing on the market and use of VMPs and active substances). To ensure that animals and products of animal origin imported into the Union comply with Article 118 of Regulation (EU) 2019/6, it is necessary to provide that controls of compliance with Article 118 are included into the scope of the Official Controls Regulation.

Under its Farm to Fork Strategy, the EU has set the ambitious target of reducing by 50% its overall EU sales of antimicrobials used for farmed animals and in aquaculture by 2030. Building on the One Health approach, Regulation (EU) 2019/6 provides for a wide range of concrete measures that will apply to EU operators in order to enhance the fight against antimicrobial resistance ('AMR') and promote a more prudent and responsible use of antimicrobials in animals. As a leader in the global fight against AMR, the Union also has the responsibility to encourage the reduction of use and consumption of antimicrobials in third countries, in particular linked to imports from third countries, and has the duty to promote its vision of a more sustainable use of antimicrobials to help preserve their efficiency on the international stage. Article 118 of Regulation (EU) 2019/6 is a key element in the fight against AMR.

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

• Legal basis

The legal bases of this proposal are Article 43(2), Article 114 and Article 168(4)(b) of the Treaty on the Functioning of the European Union.

• Subsidiarity (for non-exclusive competence)

Imports of animals and products of animal origin from third countries have been comprehensively regulated at Union level. Therefore, it would not be possible to address the issue at national level.

• Proportionality

Amending the Official Controls Regulation to cover verification of compliance with Article 118(1) of Regulation (EU) 2019/6 is the only effective way of ensuring that Article 118(1) of that Regulation is complied with in relation to imports of animals and products of animal origin from third countries. Regulation (EU) 2019/6 itself does not have the necessary basic

provisions to make this possible. The empowerment in Article 118(2) of Regulation (EU) 2019/6 would not allow the Commission to adopt the necessary rules on official controls for animals and products of animal origin similar to those set out in the Official Controls Regulation. The amendment is indispensable in order to allow the Union's official control system for animals and products of animal origin to apply to verification of compliance with Article 118(1) of Regulation (EU) 2019/6.

3. RESULTS OF EX-POST EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

From a Better Regulation perspective, a roadmap, stakeholder consultation or impact assessment are not necessary, as the proposal is a technical measure, necessary to ensure implementation of Article 118 of Regulation (EU) 2019/6. The proposal, when adopted, will allow for official controls in accordance with the Official Controls Regulation and thus not introduce any significant burden on economic operators and on Member States. The proposal needs to be adopted ahead of the entry into application of Regulation (EU) 2019/6 in January 2022 and in good time to allow for the preparation of implementing acts specifying the modalities for official controls in relation to Article 118 of Regulation (EU) 2019/6 before that date.

4. BUDGETARY IMPLICATIONS

The proposal has no implications on the Union budget.

5. OTHER ELEMENTS

- **Detailed explanation of the specific provisions of the proposal**

Article 1(4)(c)

The modification of Article 1(4)(c) of the Official Controls Regulation is a technical amendment to allow verification of compliance with Article 118(1) of Regulation (EU) 2019/6 to be covered by the Official Controls Regulation. It would allow the Union's official control system for animals and products of animal origin to be used to ensure compliance with the prohibitions in Article 118(1) of Regulation (EU) 2019/6.

The Commission has to adopt a delegated act in accordance with Article 118(2) of Regulation (EU) 2019/6 which should set out the substantive rules that need to be met for imports of animals and products of animal origin entering the Union from third countries in order for them to comply with Article 118(1). The amendment of Article 1(4)(c) of the Official Controls Regulation would include Article 118(1), which applies to the imports of animals and products of animal origin, in the scope of the Official Controls Regulation and allow the Commission to subsequently adopt the necessary implementing act(s).

Article 47(1)(e)

The aim of this provision is to correct a manifest error in the Official Controls Regulation with respect to a reference to Regulation (EU) 2016/429.

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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), Article 114 and Article 168(4)(b) 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 Committee⁵,

Having regard to the opinion of the Committee of the Regions⁶,

Acting in accordance with the ordinary legislative procedure,

Whereas:

- (1) Regulation (EU) 2017/625 of the European Parliament and of the Council⁷ lays down the rules for the performance of official controls to verify compliance with, *inter alia*, rules on food and feed safety.
- (2) Regulation (EU) 2019/6 of the European Parliament and of the Council⁸ lays down rules for, *inter alia*, the control and use of veterinary medicinal products.

⁵ OJ C...,p...

⁶ OJ C..., p...

⁷ 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 L 95, 7.4.2017, p. 1).

- (3) Under Article 118(1) of Regulation (EU) 2019/6, third country operators exporting animals and products of animal origin to the Union are required to respect the prohibition of the use of antimicrobials for growth promotion and yield increase, as well as the prohibition of the use of antimicrobials reserved for treatment of certain infections in humans in order to preserve the efficacy of those antimicrobials.
- (4) Article 118 of Regulation (EU) 2019/6 builds on the One Health Action Plan against antimicrobial resistance ('AMR')⁹, by enhancing the prevention and control of AMR and promoting a more prudent and responsible use of antimicrobials in animals. This is also reflected in the Commission's Farm to Fork Strategy¹⁰, in which the Commission has set the ambitious target of reducing by 50% overall EU sales of antimicrobials used for farmed animals and in aquaculture by 2030.
- (5) In order to ensure an effective implementation of the prohibition of the use of antimicrobials for growth promotion and yield increase and of the use of antimicrobials reserved for treatment of certain infections in humans, official controls for the verification of compliance of animals and products of animal origin exported to the Union with Article 118(1) of Regulation (EU) 2019/6 should be included in the scope of Regulation (EU) 2017/625.
- (6) In accordance with Article 47(1)(e) of Regulation (EU) 2017/625, competent authorities are to perform official controls at the border control post of first arrival into the Union on each consignment of animals and goods subject to, *inter alia*, the emergency measures provided for in acts adopted in accordance with Article 249 of Regulation (EU) 2016/429 of the European Parliament and of the Council¹¹. However, Article 249 of Regulation (EU) 2016/429 does not concern Commission emergency measures. Accordingly, this error should be corrected and reference should be made to Article 261 of Regulation (EU) 2016/429.
- (7) Regulation (EU) 2017/625 should therefore be amended accordingly.
- (8) Since Regulation (EU) 2019/6 applies from 28 January 2022, this Regulation should apply from the same date,

HAVE ADOPTED THIS REGULATION:

Article 1

Regulation (EU) 2017/625 is amended as follows:

- (1) in Article 1(4), point (c) is replaced by the following:

⁸ 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 L 4, 7.1.2019, p. 43).

⁹ European Commission, A European One Health Action Plan against Antimicrobial Resistance (AMR), June 2017, https://ec.europa.eu/health/sites/health/files/antimicrobial_resistance/docs/amr_2017_action-plan.pdf.

¹⁰ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions of 20 May 2020, A Farm to Fork Strategy for a fair, healthy and environmentally-friendly food system, COM (2020) 381 final .

¹¹ Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law') (OJ L 84, 31.3.2016, p. 1).

‘(c) Regulation (EU) 2019/6 of the European Parliament and of the Council*;
however, this Regulation shall apply to official controls for the verification of
compliance with Article 118(1) of that Regulation.’

* 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 L 4, 7.1.2019, p. 43).’;

(2) in Article 47(1), point (e) is replaced by the following:

‘(e) animals and goods which are subject to an emergency measure provided for in
acts adopted in accordance with Article 53 of Regulation (EC) No 178/2002,
Article 261 of Regulation (EU) 2016/429, or Articles 28(1), 30(1), 40(3), 41(3),
49(1), 53(3) and 54(3) of Regulation (EU) 2016/2031 requiring consignments of
those animals or goods, identified by means of their codes from the Combined
Nomenclature, to be subject to official controls at their entry into the Union;’

Article 2

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 28 January 2022.

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

Done at Brussels,

For the European Parliament
The President

For the Council
The President