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**NOTE**

From:	General Secretariat of the Council
To:	Delegations
No. Cion doc.:	6916/21 - COM(2021) 108 final
Subject:	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 – Presidency compromise text

Delegations will find in the Annex suggested rewording from the Presidency on the above proposal, taking into account comments received from delegations (see WK 3894/2021 + ADD1). In case delegations do not agree with the suggested wording or have comments or questions, they are kindly invited to inform the Council Secretariat by 8 April cob, by email to [LIFE.3@consilium.europa.eu](mailto:LIFE.3@consilium.europa.eu).

In the absence of objections by that deadline, the Presidency will engage into contacts with the European Parliament to identify the next steps to proceed for a smooth agreement between the co-legislators.

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)

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 Committee<sup>1</sup>,

Having regard to the opinion of the Committee of the Regions<sup>2</sup>,

Acting in accordance with the ordinary legislative procedure,

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<sup>1</sup> OJ C...,p...

<sup>2</sup> OJ C..., p...

Whereas:

- (1) Regulation (EU) 2017/625 of the European Parliament and of the Council<sup>3</sup> 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 Council<sup>4</sup> lays down rules for, *inter alia*, the control and use of veterinary medicinal products.
- (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. **As set out in Recital (49) of that Regulation, any such requirements on operators in third countries would need to respect Union obligations under relevant international agreements. The inspections and control of compliance of Member State operators with those prohibitions are carried out in accordance with Chapter VIII of that Regulation.**

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<sup>3</sup> 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).

<sup>4</sup> 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).

- (4) Article 118 of Regulation (EU) 2019/6 builds on the One Health Action Plan against antimicrobial resistance (‘AMR’)<sup>5</sup>, 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 Strategy<sup>6</sup>, 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 as well as in the Council Conclusions of 19 October 2020 on that Strategy**<sup>7</sup>.
- (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, **again while respecting Union obligations under international agreements.**
- (5a) Corresponding rules on prohibition of the use of antimicrobials and control thereof in respect of operators in Member States are laid down in Regulation (EU) 2019/6 , providing at least equivalent safeguards as regards antimicrobial resistance.**

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<sup>5</sup> 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](https://ec.europa.eu/health/sites/health/files/antimicrobial_resistance/docs/amr_2017_action-plan.pdf).

<sup>6</sup> 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 .

<sup>7</sup> **Document ST 12099/20.**

- (5b) In accordance with Article 18(7) of Regulation (EU) 2017/625, the Commission is empowered to adopt specific rules for the performance of official controls on criteria and conditions to determine, in relation to Pectinidae, marine gastropods and Holothuroidea, when production and relaying areas are not to be classified. Holothuroidea are a class of the phylum Echinoderms. Echinoderms are generally not filter feeder animals. Consequently, the risk of such animals accumulating micro-organisms related to faecal contamination is remote. In addition, no epidemiological information has been reported which could be linked to risks for public health associated with echinoderms that are not filter feeders. For this reason, the exclusion from the requirement to classify the production areas as laid down in Chapter II of Section VII of Annex III to Regulation (EC) No 853/2004 should be extended to all echinoderms which are not filter feeders. Such echinoderms which are not filter feeders include for instance those belonging to classes Echinoidea and Holothuroidea.**
- (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 Council<sup>8</sup>. 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,

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<sup>8</sup> 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).

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:

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

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\* 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).’;

**(1a) in Article 18(7), point (g) is replaced by the following:**

**‘(g) the criteria and conditions to determine, in relation to Pectinidae, marine gastropods and Echinoderms which are not filter feeders, by way of derogation from paragraph 6, when production and relaying areas are not to be classified’.**

(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*

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