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'I' ITEM NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee
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 – Mandate

1. On 9 March 2021, the Commission submitted to the Council the above proposal. The proposal was presented to the Working Party of Chief Veterinary Officers in the informal videoconference of its members on 10 March 2021.
2. On 18 March 2021, the Presidency launched an informal consultation of delegations on the Commission proposal, inviting them to send their possible comments by 25 March 2021. The Presidency also suggested to include in a Recital a reference to the need to respect the Union's international obligations which had been discussed at the informal videoconference referred to above¹.

¹ WK 3894/2021.

3. According to the comment received from delegations by the given deadline, all delegations agreed on the Commission proposal and on the addition of a reference to the Union's international obligations. In addition, some of them asked to include in the proposal a further amendment concerning the requirements to classify production and relaying areas of bivalve molluscs, echinoderms, tunicates and marine gastropods.
4. On 30 March 2021, the Presidency presented to delegations compromise text in those lines².
5. The precise wording of the Presidency compromise text was subsequently fine-tuned three times and examined by the Working Party of Veterinary experts at its informal videoconference on 23 April 2021.
6. On 25 May 2021, the Presidency informed delegations that as no comments were received regarding the Presidency compromise text in document 7465/3/21 REV 3, that text was considered as supported at Working Party level³.
7. In the meantime, informal contacts with the European Parliament had led to a situation where all amendments included in that text were also acceptable to the European Parliament. As a consequence, on 3 June 2021 the ENVI Committee adopted amendments which are substantially the same as in the Presidency compromise text set out in the Annex to this note⁴.
8. The Permanent Representatives Committee is therefore invited:
 - to confirm the agreement reached by the Working Party,
 - to mandate the Chair of the Permanent Representatives Committee to send a letter to the Chair of the ENVI Committee of the European Parliament indicating that should the European Parliament at its first reading adopt the text as set out in the annex to this note, the Council would accept the voted text of the European Parliament.

² 7465/21.

³ WK 6929/2021.

⁴ Same as in document 7465/3/21 REV 3.

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 Committee¹,

Having regard to the opinion of the Committee of the Regions²,

Acting in accordance with the ordinary legislative procedure,

¹ OJ C...,p...

² OJ C..., p...

Whereas:

- (1) Regulation (EU) 2017/625 of the European Parliament and of the Council³ 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 Council⁴ lays down rules for, *inter alia*, the control and use of veterinary medicinal products, with a particular focus on antimicrobial resistance.
- (3) In accordance with Regulation (EU) 2019/6, a more prudent and responsible use of antimicrobials in animals is ensured, *inter alia*, by way of the prohibitions 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. Under Article 118(1) thereof, third country operators exporting animals and products of animal origin to the Union are required to respect those prohibitions. As set out in Recital (49) of that Regulation, it is important to consider the international dimension of the development of antimicrobial resistance by taking non-discriminatory and proportionate measures, while respecting the Union's international obligations.

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 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’)⁵, by enhancing the prevention and control of AMR and promoting a more prudent and responsible use of antimicrobials in animals.
- (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 the Union’s international obligations.
- (5a) In accordance with Article 18(7) of Regulation (EU) 2017/625, the Commission is 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 link public health risks to Echinoderms that are not filter feeders. For this reason, the possibility laid down in Article 18(7)(g) of Regulation (EU) 2017/625 to derogate from the requirement to classify the production and relaying areas should be extended to all echinoderms which are not filter feeders, for example those belonging to class Echinoidea, and not be limited to Holothuroidea. For the same reason, it should be clarified that the conditions for the classification and monitoring of classified production and relaying areas to be laid down by the Commission apply to live bivalve molluscs, echinoderms, tunicates and marine gastropods, except those marine gastropods and echinoderms that are not filter feeders. The terminology used in Article 18(6) to (8) of Regulation (EU) 2017/625 should be aligned accordingly.

⁵ 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

- (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 Council⁶. 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, the relevant provision of 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:
- ‘(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).’;

⁶ 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).

(1a) Article 18 is amended as follows:

(a) paragraph 6 is replaced by the following:

‘6. For the purposes of official controls referred to in paragraph 1 performed in relation to live bivalve molluscs, echinoderms, tunicates and marine gastropods, the competent authorities shall classify production and relaying areas.’

(b) in paragraph 7, point (g) is replaced by the following:

‘(g) criteria and conditions to determine, by way of derogation from paragraph 6, when production and relaying areas are not to be classified in relation to:

(i) Pectinidae, and

(ii) the following, where they are not filter feeders: echinoderms and marine gastropods;’

(c) in paragraph 8, point (b) is replaced by the following:

‘(b) the conditions for the classification and monitoring of classified production and relaying areas for live bivalve molluscs, echinoderms, tunicates and marine gastropods;’

(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 the date of its entry into force.

However, point (1) of Article 1 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
