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INFORMATION NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee/Council
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 - Outcome of the European Parliament's first reading (Strasbourg, 13-16 September 2021)

I. INTRODUCTION

In accordance with the provisions of Article 294 of the TFEU and the Joint declaration on practical arrangements for the codecision procedure[1], a number of informal contacts have taken place between the Council, the European Parliament and the Commission with a view to reaching an agreement on this file at first reading.

In this context, the rapporteur, Pascal CANFIN (Renew, FR), presented a compromise amendment (amendment number 12) to the abovementioned proposal for a Regulation on behalf of the Committee on the Environment, Public Health and Food Safety. This amendment had been agreed during the informal contacts referred to above.

[1] OJ C 145, 30.6.2007, p. 5.

In addition, the Committee on the Environment, Public Health and Food Safety tabled 7 amendments (amendments number 1-7), the EPP group tabled 1 amendment (amendment number 8), individual MEPs tabled 1 amendment (amendment number 10), the Renew group tabled 1 amendment (amendment number 11).

II. VOTE

When it voted on 15 September 2021, the plenary adopted the compromise amendment (amendment number 12) to the abovementioned proposal for a Regulation. No other amendments were adopted. The Commission's proposal as thus amended constitutes the Parliament's first-reading position which is contained in its legislative resolution as set out in the Annex hereto[2].

The Parliament's position reflects what had been previously agreed between the institutions. The Council should therefore be in a position to approve the Parliament's position.

The act would then be adopted in the wording which corresponds to the Parliament's position.

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[2] The version of the Parliament's position in the legislative resolution has been marked up to indicate the changes made by the amendments to the Commission's proposal. Additions to the Commission's text are highlighted in ***bold and italics.*** The symbol " ▌ " indicates deleted text.

P9_TA(2021)0372

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 ***I

European Parliament legislative resolution of 15 September 2021 on the 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 COM(2021)0108 – C9-0094/2021 – 2021/0055(COD))

(Ordinary legislative procedure: first reading)

The European Parliament,

– having regard to the Commission proposal to Parliament and the Council (COM(2021)0108),

– having regard to Article 294(2) and Article 43(2), Article 114 and Article 168(4), point (b) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C9-0094/2021),

– having regard to Article 294(3) of the Treaty on the Functioning of the European Union,

– having regard to the opinion of the European Economic and Social Committee of 9 June 2021[1],

– after consulting the Committee of the Regions,

– having regard to the provisional agreement approved by the committee responsible under Rule 74(4) of its Rules of Procedure and the undertaking given by the Council representative by letter of 8 September 2021 to approve Parliament's position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,

– having regard to Rule 59 of its Rules of Procedure,

– having regard to the report of the Committee on the Environment, Public Health and Food Safety (A9-0195/2021),

1. Adopts its position at first reading hereinafter set out;

2. Calls on the Commission to refer the matter to Parliament again if it replaces, substantially amends or intends to substantially amend its proposal;

[1] OJ C 341, 24.8.2021, p 107.

3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

P9_TC1-COD(2021)0055

Position of the European Parliament adopted at first reading on 15 September 2021 with a view to the adoption of Regulation (EU) 2021/… 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 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*

(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 point (b) of Article 168(4) 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[2],

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure[3],

[2] OJ C 341, 24.8.2021, p. 107.
[3] Position of the European Parliament of 15 September 2021.

Whereas:

(1) Regulation (EU) 2017/625 of the European Parliament and of the Council[4] 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[5] 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 on the use of antimicrobials for growth promotion and yield increase and on the use of antimicrobials reserved for treatment of certain infections in humans.*** Under Article 118(1) of Regulation (EU) 2019/6, operators in third countries are required to respect ***those prohibitions*** when exporting animals and products of animal origin to the Union***. As highlighted 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 Union obligations under international agreements***.

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4 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).

5 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 Commission communication of 29 June 2017 entitled ‘A European One Health Action Plan against antimicrobial resistance (‘AMR’)’, by enhancing the prevention and control of antimicrobial resistance and promoting a more prudent and responsible use of antimicrobials in animals. ▌

(5) In order to ensure the 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***.

(6) In accordance with Article 18(7), point (g), 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 Echinodermata. Echinoderms are generally not filter-feeding 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 that reason, the possibility laid down in Article 18(7), point (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 to those belonging to the 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), (7) and (8) of Regulation (EU) 2017/625 should be aligned accordingly.

(7) Regulation (EC) No 853/2004 of the European Parliament and of the Council[6] excludes from its scope the direct supply, by the producer, of small quantities of meat from poultry and lagomorphs slaughtered on the farm to the final consumer or to local retail establishments directly supplying such meat to the final consumer as fresh meat. Since the date of application of that Regulation, namely 1 January 2006, the exclusion had been extended several times to all meat from poultry and lagomorphs as a transitional measure. The last extension of the transitional period, by Commission Regulation (EU) 2017/185[7], was until 31 December 2020. During the 15 years of the transitional period no significant food safety concerns caused by the activities carried out in accordance with that extension were observed. In addition, the Commission in its communication of 20 May 2020 entitled 'A Farm to Fork Strategy for a fair, healthy and environmentally-friendly food system' underlines the importance of shorter supply chains with a view to enhancing resilience of regional and local food systems. The extension of the derogation to all meat of poultry and lagomorphs should therefore be introduced on a permanent basis. Regulation (EC) No 853/2004 should be amended accordingly.

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6 *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).*

7 *Commission Regulation (EU) 2017/185 of 2 February 2017 laying down transitional measures for the application of certain provisions of Regulations (EC) No 853/2004 and (EC) No 854/2004 of the European Parliament and of the Council (OJ L 29, 3.2.2017, p. 21).*

(8) In accordance with Article 47(1), point (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[8]. However, Article 249 of Regulation (EU) 2016/429 does not concern Commission emergency measures. That error should be corrected and reference should be made to Article 261 of Regulation (EU) 2016/429.

(9) Since the objective of this Regulation, namely to allow for official controls on the use of antimicrobials in animals and products of animal origin entering into the Union, cannot be sufficiently achieved by the Member States but can rather be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.

(10) Regulation (EU) 2017/625 should therefore be amended accordingly.

(11) Since Regulation (EU) 2019/6 applies from 28 January 2022, the corresponding provisions of this Regulation should apply from the same date,

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8 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*; 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).’;

(2) 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) 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;";

(3) 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

In Article 1(3) of Regulation (EC) No 853/2004, point (d) is replaced by the following:

'(d) the direct supply, by the producer, of small quantities of meat from poultry and lagomorphs slaughtered on the farm to the final consumer or to local retail establishments directly supplying such meat to the final consumer;'.

Article 3

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 the entry into force of this Regulation].***

However, Article 1, point (1) shall apply from 28 January 2022.

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

Done at ..., ...

For the European Parliament *For the Council*

The President *The President*