



2021/0055(COD)

25.5.2021

OPINION

of the Committee on Agriculture and Rural Development

for the Committee on the Environment, Public Health and Food Safety

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))

Rapporteur for opinion: Ivan David

PA_Legam

SHORT JUSTIFICATION

Regulation (EU) 2019/6 of the European Parliament and of the Council on veterinary medicinal products, which will replace the legal framework for veterinary medicinal products laid down by Directive 2001/82/EC and Regulation (EC) No 726/2004, will enter into force on 28 January 2022. Regulation (EC) No 726/2004 and Directive 2001/82/EC currently in force, and Regulation (EU) 2019/6, constitute the substantive part of the comprehensive EU legislation on the use of antimicrobials in agriculture and food.

Article 118 of the Chapter on ‘Supply and Use’ (of veterinary medicinal products) of Regulation (EU) 2019/6 lays down the conditions for importing animals and animal products from third countries. Specifically, paragraph 1 lays down two basic restrictions on operators in third countries, applied simultaneously within the Union:

- a prohibition on the use of antimicrobials to enhance performance (a reference to Article 107(2)), and
- a prohibition on the use on animals of selected antimicrobials, or groups of antimicrobials, which are reserved by EU legislation for the treatment of certain human diseases (a reference to Article 37(5)).

The purpose of those provisions is to maintain the effectiveness of the relevant antimicrobials. The use of such medicines, in the first case globally for non-medical purposes, and in the second in veterinary medicine in general, could result in the development or spread of microbial resistance and thus lead to reduced effectiveness or ineffectiveness of those antimicrobials in treating serious infections, in humans in the first case, as well as, in animals.

Animals which have been treated in breach of the above obligations will be prohibited from being imported into the EU, as will products from such animals.

Article 118(2) of the Regulation further states that the Commission is to adopt delegated acts to supplement the provisions of Article 118 with detailed rules on the application of paragraph 1.

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 or on official controls on compliance with those import requirements.

Since the end of 2019, the issue of official controls in the food chain, including controls on imports of animals and animal products, has been governed by the uniform regulatory framework laid down by 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. Regulation (EU) 2017/625 forms the procedural part of the comprehensive EU legislation on the use of antimicrobials in agriculture and food. This provision lays down the procedural rules for performing controls on compliance with the prohibition on the use of antimicrobials in agriculture and food, including controls on compliance with that prohibition in respect of commodities imported from third countries.

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. As soon as Regulation (EU) 2019/6 enters into force, the reference to the directive will become a reference to that regulation. The current wording of Article 1(4)(c) thus excludes the whole of Regulation (EU) 2019/6 from its scope, thereby effectively preventing effective controls on imported commodities to establish whether or not they contain antimicrobials, or residues thereof, whose use is prohibited in the EU in accordance with Article 118 of the “Veterinary Medicinal Products Regulation”.

In order to ensure the operation of the system for controls on compliance with the rules on the use of antimicrobials in agriculture and foods, including with respect to commodities imported from third countries, it is necessary to harmonise and interconnect the substantive and procedural regulation of this issue in EU law.

In order to create a level playing field for producers within and outside the EU, restrictions and prohibitions on the use of antimicrobials with which producers in EU countries must also apply to commodities imported from third countries. The rules on the presence of antimicrobial residues in animal bodies and animal products imported from third countries are laid down in Article 118 of the “Veterinary Medicinal Products Regulation” as an express obligation on operators importing such commodities from third countries to ensure that only animals and products of animal origin which meet the requirements laid down by EU law for such commodities are imported into the common market of the Union.

The current form of Regulation (EU) 2019/6 does not allow effective control procedures to be established because it was designed as a framework for national legislation on the surveillance of medicines. Furthermore, controls of imported animals and animal products generally falls within the scope of the Official Controls Regulation. In the absence of an amendment to Article 1 of this Regulation, which defines the scope of this Regulation, it would not be possible to control compliance of the above prohibition in accordance with Article 118 of Regulation (EU) 2019/6.

The objective of this amendment is to modify the wording of Article 1 of the Official Controls Regulation to integrate controls to verify compliance with Article 118 of Regulation (EU) 2019/6 into the scope of the Official Controls Regulation.

AMENDMENTS

The Committee on Agriculture and Rural Development calls on the Committee on the Environment, Public Health and Food Safety, as the committee responsible, to take into account the following amendments:

Amendment 1

Proposal for a regulation Recital 1 a (new)

Text proposed by the Commission

Amendment

(1a) Regulation (EC) No 853/2004 of the European Parliament and of the Council ^{1a} lays down specific rules on the hygiene of foodstuffs, including, pursuant to Article 6(1), point (c)(i), thereof, in respect of ‘products of animal origin from outside the Community’;

^{1a} 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 du 30.4.2004, p. 55).

Amendment 2

Proposal for a regulation

Recital 3

Text proposed by the Commission

(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.

Amendment

(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 **Union standards and** 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.

Amendment 3

Proposal for a regulation

Recital 4

Text proposed by the Commission

(4) Article 118 of Regulation (EU) 2019/6 builds on the One Health Action Plan against antimicrobial resistance (‘AMR’)⁹, by enhancing the prevention

Amendment

(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.

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. ***Even as the use of antimicrobials in Europe has decreased, the work should continue and the fight against misuse and overuse of antimicrobials should be upheld across the whole world. There is therefore a need for a consistent global approach against AMR that establishes, when possible, reduction targets for countries, taking countries' starting positions and specific prerequisites into account.***

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 .

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 .

Amendment 4

Proposal for a regulation Recital 5

Text proposed by the Commission

(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

Amendment

(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.

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. ***The 2017 RONAFA report calls for more preventative measures in the combat against AMR. Higher animal welfare standards and better implementation of animal welfare legislation, together with the use of preventative tools such as vaccines and the use of innovative animal health technologies such as diagnostics, can reduce the need for antimicrobials.***

Amendment 5

Proposal for a regulation

Article 1 a (new)

Regulation (EC) No 853/2004

Article 1 – paragraph 3 – point d

Present text

(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 ***as fresh meat***;

Amendment

Article 1a

Regulation (EC) No 853/2004 is amended as follows:

In Article 1(3), 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;”.

PROCEDURE – COMMITTEE ASKED FOR OPINION

Title	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
References	COM(2021)0108 – C9-0094/2021 – 2021/0055(COD)
Committee responsible Date announced in plenary	ENVI 11.3.2021
Opinion by Date announced in plenary	AGRI 11.3.2021
Rapporteur for the opinion Date appointed	Ivan David 26.3.2021
Discussed in committee	21.5.2021
Date adopted	21.5.2021
Result of final vote	+: 44 –: 1 0: 1
Members present for the final vote	Mazaly Aguilar, Clara Aguilera, Atidzhe Alieva-Veli, Álvaro Amaro, Eric Andrieu, Attila Ara-Kovács, Carmen Avram, Mara Bizzotto, Daniel Buda, Isabel Carvalhais, Asger Christensen, Angelo Ciocca, Ivan David, Paolo De Castro, Jérémy Decerle, Salvatore De Meo, Herbert Dorfmann, Dino Giarrusso, Francisco Guerreiro, Martin Häusling, Martin Hlaváček, Krzysztof Jurgiel, Jarosław Kalinowski, Elsi Katainen, Gilles Lebreton, Chris MacManus, Colm Markey, Marlene Mortler, Ulrike Müller, Maria Noichl, Juozas Olekas, Pina Picierno, Maxette Pirbakas, Eugenia Rodríguez Palop, Bronis Ropé, Bert-Jan Ruissen, Anne Sander, Petri Sarvamaa, Simone Schmiedtbauer, Annie Schreijer-Pierik, Veronika Vrecionová, Sarah Wiener, Juan Ignacio Zoido Álvarez
Substitutes present for the final vote	Anja Hazekamp, Michaela Šojdřová, Thomas Waitz

FINAL VOTE BY ROLL CALL IN COMMITTEE ASKED FOR OPINION

44	+
ECR	Mazaly Aguilar, Krzysztof Jurgiel, Bert-Jan Ruissen, Veronika Vrecionová
ID	Mara Bizzotto, Angelo Ciocca, Ivan David, Gilles Lebreton, Maxette Pirbakas
PPE	Álvaro Amaro, Daniel Buda, Salvatore De Meo, Herbert Dorfmann, Jarosław Kalinowski, Colm Markey, Marlene Mortler, Anne Sander, Petri Sarvamaa, Simone Schmiedtbauer, Annie Schreijer-Pierik, Michaela Šojdrová, Juan Ignacio Zoido Álvarez
Renew	Atidzhe Alieva-Veli, Asger Christensen, Jérémy Decerle, Martin Hlaváček, Elsi Katainen, Ulrike Müller
S&D	Clara Aguilera, Eric Andrieu, Attila Ara-Kovács, Carmen Avram, Isabel Carvalhais, Paolo De Castro, Maria Noichl, Juozas Olekas, Pina Picierno
The Left	Chris MacManus, Eugenia Rodríguez Palop
Verts/ALE	Francisco Guerreiro, Martin Häusling, Bronis Ropé, Thomas Waitz, Sarah Wiener

1	-
The Left	Anja Hazekamp

1	0
NI	Dino Giarrusso

Key to symbols:

+ : in favour

- : against

0 : abstention