



2021/0055(COD)

19.4.2021

DRAFT 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 (COM2021/0108 – 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 and also 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 Official Controls 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 comply 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 Official Controls 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 EU's common market.

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, control 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 the Official Controls Regulation, which defines the scope of that 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 3

Text proposed by the Commission

Amendment

(3) Under Article 118(1) of Regulation

(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.

(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 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 should be carried out in accordance with Chapter VIII of that Regulation.***

Or. en

Justification

The proposed addition to recital 3 explains that controls of compliance on the use of antimicrobials also for commodities imported from third countries are in line with WTO rules, which stipulate that a WTO member may require imported commodities to meet the same regulatory requirements as producers in their territory.

Amendment 2

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') 5, 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 6, 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

Amendment

(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. This is also reflected in the Commission's Farm to Fork Strategy 6, 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.

by 2030 *as well as in the Council Conclusions of 19 October 2020 on that Strategy*^{1a}.

^{1a} **Document ST 12099/20.**

Or. en

Justification

It is proposed to add a reference to the Council conclusions on this strategy. In an effort to speed up negotiations during the interinstitutional negotiations, the text is taken from a proposal from the Portuguese Presidency to the Council.

Amendment 3

Proposal for a regulation

Article 1 – paragraph 1 – point - 1 (new)

Regulation (EU) 2017/625

Article 1 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

(-1) In Article 1, the following paragraph is inserted:

‘3a. This Regulation shall also apply to official controls performed on animals and products of animal entering the Union from third countries to verify their compliance with the requirements laid down in Article 118 Regulation (EU) 2019/6 of the European Parliament and of the Council.’

Or. en

Justification

It is proposed to provide that the Regulation on official controls, after the entry into force of Regulation 2019/6 on veterinary medicinal products, will also be applicable to checks that animals and products of animal origin imported from third countries comply with the requirements laid down in this Regulation. Authorization to use it is given in Article 118 of Regulation 2019/6 on veterinary medicinal products. This amendment follows the substantive and procedural law of EU law on the use of antimicrobials in relation to the previous proposal.

Amendment 4

Proposal for a regulation

Article 1 – paragraph 1 – point 1

Regulation (EU) 2017/625

Article 1 – paragraph 4 – point c

Text proposed by the Commission

Amendment

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

(1) in Article 1(4), point (c) **is deleted.**

‘(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).’;***

Or. en

Justification

The current wording of Regulation 2017/625 in Article 1 (4) (c) provides that the Regulation on official controls cannot be used to check that animals and products of animal origin from third countries comply with the requirements currently laid down in Directive 2001/6 of the European Parliament and of the Council. 82 / EC on the Community code relating to veterinary medicinal products, which regulates the use of antimicrobials in agriculture and food. This exclusion effectively makes it impossible to carry out checks on imported animals and products of animal origin from third countries to ensure that antimicrobials, the use of which is prohibited in the EU, have not been used in their production. It is proposed to cancel this exclusion. The following amendment will insert a reference to Regulation 2019/6 / EU on veterinary medicinal products with effect from the date of entry into force of this Regulation.