Procedure file

Basic information

COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	2021/0055(COD)
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 Amending Regulation 2017/625 2013/0140(COD) Subject 2.80 Cooperation between administrations 3.10.08 Animal health requirements, veterinary legislation and pharmacy 3.10.08.01 Feedingstuffs, animal nutrition 3.10.10 Foodstuffs, foodstuffs legislation 4.60.04.04 Food safety	Procedure completed

Key players

European Parliament	Committee responsible	Rapporteur	Appointed
	ENVI Environment, Public Health and Food Safety		20/04/2021
		renew europe. CANFIN Pascal	
		Shadow rapporteur	
		epp MORTLER Marlene	
		S&D SCHALDEMOSE Christel	
		ECR WIŚNIEWSKA Jadwiga	
		DAVID Ivan	
	Committee for opinion	Rapporteur for opinion	Appointed
	AGRI Agriculture and Rural Development		26/03/2021
		DAVID Ivan	
Council of the European Union			
European Commission	Commission DG	Commissioner	
	Health and Food Safety	KYRIAKIDES Stella	
European Economic and Social Committee			
European Committee of the Regions			

Key events

09/03/2021	Legislative proposal published	COM(2021)0108	Summary
11/03/2021	Committee referral announced in Parliament, 1st reading		
03/06/2021	Vote in committee, 1st reading		
16/06/2021	Committee report tabled for plenary, 1st reading	A9-0195/2021	
24/06/2021	Decision by Parliament, 1st reading	T9-0312/2021	Summary
24/06/2021	Matter referred back to the committee responsible		
10/09/2021	Approval in committee of the text agreed at 1st reading interinstitutional negotiations	PE696.443 GEDA/A/(2021)004020	
15/09/2021	Results of vote in Parliament		
15/09/2021	Decision by Parliament, 1st reading	T9-0372/2021	Summary
16/09/2021	Act adopted by Council after Parliament's 1st reading		
06/10/2021	Final act signed		
08/10/2021	Final act published in Official Journal		

Technical information

Procedure reference	2021/0055(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
	Amending Regulation 2017/625 2013/0140(COD)
Legal basis	Treaty on the Functioning of the EU TFEU 043-p2; Treaty on the Functioning of the EU TFEU 114; Treaty on the Functioning of the EU TFEU 168-p4
Other legal basis	Rules of Procedure EP 165
Mandatory consultation of other institutions	European Economic and Social Committee European Committee of the Regions
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/9/05573

Documentation gateway

Legislative proposal		COM(2021)0108	09/03/2021	EC	Summary
Committee draft report		PE691.399	26/04/2021	EP	
Amendments tabled in committee		PE692.774	12/05/2021	EP	
Committee opinion	AGRI	PE691.248	21/05/2021	EP	
Committee report tabled for plenary, 1st reading/single reading		A9-0195/2021	16/06/2021	EP	

Text adopted by Parliament, partial vote at 1st reading/single reading		T9-0312/2021	24/06/2021	EP	Summary
Coreper letter confirming interinstitutional agreement		GEDA/A/(2021)004020	08/09/2021	CSL	
Text agreed during interinstitutional negotiations		PE696.443	09/09/2021	EP	
Text adopted by Parliament, 1st reading/single reading		T9-0372/2021	15/09/2021	EP	Summary
Draft final act		00046/2021/LEX	06/10/2021	CSL	
Commission response to text adopted in plenary		SP(2021)637	03/11/2021	EC	

Final act

Regulation 2021/1756
OJ L 357 08.10.2021, p. 0027

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

PURPOSE: to include in existing legislation official controls to verify the compliance of exports of animals and animal products to the EU to ensure compliance with the prohibition of certain uses of antimicrobials.

PROPOSED ACT: Regulation of the European Parliament and of the Council.

ROLE OF THE EUROPEAN PARLIAMENT: the European Parliament decides in accordance with the ordinary legislative procedure and on an equal footing with the Council.

BACKGROUND: Regulation (EU) 2017/625 of the European Parliament and of the Council lays down the rules for the performance of official controls to verify compliance with, inter alia, rules on food and feed safety.

Under Article 118(1) of Regulation (EU) 2019/6 on veterinary medicinal products, 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.

Building on the One Health approach, Regulation (EU) 2019/6 provides for a wide range of concrete measures that will apply to EU operators in order to enhance the fight against antimicrobial resistance (AMR) and promote a more prudent and responsible use of antimicrobials in animals. This objective is also reflected in the Commissions Farm to Fork Strategy, 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.

CONTENT: 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, the Commission proposes to include 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 in the scope of Regulation (EU) 2017/625 which is a key element in the fight against antimicrobial resistance.

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

The Committee on the Environment, Public Health and Food Safety adopted the report by Pascal CANFIN (Renew, FR) 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.

Members support the aim of the proposal to amend the regulation on official controls to cover verification of compliance with the rules on prudent use of antimicrobials is the only effective way of ensuring that the rules are complied with in relation to imports of animals and products of animal origin from third countries.

The committee responsible recommended that the European Parliament's position adopted at first reading under the ordinary legislative procedure should amend the proposal as follows:

Cross-border dimension of the antimicrobial resistance problem

Members proposed to underline in a recital that in accordance with Regulation (EU) 2019/6, a more prudent and responsible use of antimicrobials in animals is ensured, inter alia, by prohibiting the use of antimicrobials for growth promotion and yield increase and on the use of antimicrobials reserved for treatment of certain infections in humans.

The report suggested that the proposal should refer to recital 49 of Regulation (EU) 2019/6 which stresses the importance of taking into account the international dimension of the development of antimicrobial resistance by taking non-discriminatory and proportionate measures, while respecting Union obligations under international agreements.

Specific rules on official controls

Members considered that the possibility provided for in Article 18(7)(g) of Regulation (EU) 2017/625 to derogate from the obligation to classify production and relaying areas should be extended to all echinoderms that are not filter-feeders, for example those belonging to class Echinoidea.

For this reason, it is also proposed to specify that the conditions for the classification and control of classified production and relaying areas to be defined by the Commission apply to live bivalve molluscs, echinoderms, tunicates and marine gastropods, with the exception of marine gastropods and echinoderms that are not filter-feeders.

The Regulation would apply from the date of its entry into force. However, point (1) of Article 1 would apply from 28 January 2022, the date on which the Regulation on veterinary medicinal products would start to apply.

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

The European Parliament adopted by 687 votes to 2, with 2 abstentions, amendments to 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.

The matter has been referred back to the committee responsible for inter-institutional negotiations.

The proposal under discussion is to amend the Regulation on official controls to cover verification of compliance with the rules on the prudent use of antimicrobials, which is the only effective way of ensuring that imports of animals and animal products from third countries comply with these rules.

The main amendments adopted in plenary concern the following points:

Cross-border dimension of the problem of antimicrobial resistance

Members propose to underline in a recital that 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.

An amendment suggests that the proposal should refer to recital 49 of Regulation (EU) 2019/6 which stresses the importance of considering the international dimension of the development of antimicrobial resistance by taking non-discriminatory and proportionate measures, while respecting Union obligations under international agreements.

Specific rules for the performance of official controls

Given that no epidemiological information has been provided that could establish a link between public health risks and echinoderms that are not filter-feeders, Members consider that 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 to those belonging to the class Echinoidea, and not be limited to Holothuroidea.

For this reason, Members also propose to clarify 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.

Specific hygiene rules for food of animal origin

An amendment adds that Regulation (EC) No 853/2004 should not apply to 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 supplying such meat directly to the final consumer.

Entry into force

The Regulation would apply from the date of its entry into force. However, Article 1(1) would apply from 28 January 2022, the date on which the Regulation on veterinary medicinal products would start to apply.

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

The European Parliament adopted by 685 votes to 3, with 7 abstentions, a legislative resolution 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.

The proposed Regulation aims to amend the Regulation on official controls to cover the verification of compliance with the rules on the use of antimicrobials in animals and products of animal origin entering the EU.

The European Parliament's position adopted at first reading under the ordinary legislative procedure amends the Commission's proposal as follows

Cross-border dimension of the antimicrobial resistance problem

The amended text underlines, in a recital, that in accordance with Regulation (EU) 2019/6, a more prudent and responsible use of antimicrobials in animals is ensured, inter alia, by prohibiting the use of antimicrobials to promote growth and increase yield and by prohibiting the use of antimicrobials reserved for the treatment of certain infections in humans.

The amending Regulation refers to recital 49 of Regulation (EU) 2019/6 which stresses the importance of taking into account the international dimension of the development of antimicrobial resistance by taking non-discriminatory and proportionate measures, while respecting the obligations of the Union under international agreements.

Specific rules for the performance of official controls

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.

The regulation therefore specifies that the conditions for the classification and control of classified production and relaying areas to be defined by the Commission should apply to live bivalve molluscs, echinoderms, tunicates and marine gastropods, except those marine gastropods and echinoderms that are not filter feeders.

Specific hygiene rules for food of animal origin

Regulation (EC) No 853/2004 of the European Parliament and of the Council 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. 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 underlined the importance of shorter supply chains with a view to enhancing resilience of regional and local food systems.

The amended text therefore introduces a permanent derogation by stipulating that Regulation (EC) No 853/2004 should not apply to the direct supply of small quantities of meat from poultry and lagomorphs slaughtered on the farm by the producer to the final consumer or to local retail establishments supplying such meat directly to the final consumer.

Entry into force

The Regulation should apply from the date of its entry into force. However, Article 1(1) should apply from 28 January 2022, the date on which the Regulation on veterinary medicinal products should start to apply.