Procedure file

Basic information

COD - Ordinary legislative procedure (ex-codecision procedure) Regulation 2014/0255(COD)	Procedure completed
Medicated feed: manufacture, placing on the market and use Amending Regulation (EC) No 183/2005 2003/0071(COD) Subject 3.10.08 Animal health requirements, veterinary legislation and pharmacy 3.10.08.01 Feedingstuffs, animal nutrition	

Key players

European Parliament	Committee responsible	Rapporteur	Appointed
	AGRI Agriculture and Rural Development		04/12/2014
		S&D AGUILERA Clara	
		Shadow rapporteur	
		epp BUDA Daniel	
		ECR NICHOLSON James	
		FEDERLEY Fredrick	
		SCOTT CATO Molly	
		EFD MOI Giulia	
	Committee for opinion	Rapporteur for opinion	Appointed
	ENVI Environment, Public Health and Food Safety		13/11/2014
		epp LINS Norbert	
	IMCO Internal Market and Consumer Protection	The committee decided not to give an opinion.	
	Committee for opinion on the legal basis	Rapporteur for opinion	Appointed
	JURI Legal Affairs		11/06/2015
		S&D GUTELAND Jytte	
Council of the European Union	Council configuration	Meeting	Date
	Education, Youth, Culture and Sport	3653	26/11/2018
	Agriculture and Fisheries	3437	15/12/2015

European Commission	Commission DG	Commissioner
	Health and Food Safety	ANDRIUKAITIS Vytenis Povilas
European Economic and Social Committee		
European Committee of the Regions		

Key events

10/09/2014	Legislative proposal published	COM(2014)0556	Summary
20/10/2014	Committee referral announced in Parliament, 1st reading		
15/12/2015	Debate in Council	3437	
15/03/2016	Vote in committee, 1st reading		
05/04/2016	Committee report tabled for plenary, 1st reading	A8-0075/2016	Summary
10/07/2018	Approval in committee of the text agreed at 1st reading interinstitutional negotiations	PE626.693 GEDA/A/(2018)007840	
24/10/2018	Debate in Parliament		
25/10/2018	Results of vote in Parliament		
25/10/2018	Decision by Parliament, 1st reading	T8-0422/2018	Summary
26/11/2018	Act adopted by Council after Parliament's 1st reading		
11/12/2018	Final act signed		
11/12/2018	End of procedure in Parliament		
07/01/2019	Final act published in Official Journal		

Technical information

Procedure reference	2014/0255(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
	Amending Regulation (EC) No 183/2005 2003/0071(COD)
Legal basis	Treaty on the Functioning of the EU TFEU 168-p4; Treaty on the Functioning of the EU TFEU 043
Other legal basis	Rules of Procedure EP 159
Mandatory consultation of other institutions	European Economic and Social Committee European Committee of the Regions
Stage reached in procedure	Procedure completed
Committee dossier	AGRI/8/01705

Documentation gateway

Legislative proposal		COM(2014)0556	10/09/2014	EC	Summary
Document attached to the procedure		SWD(2014)0271	10/09/2014	EC	
Document attached to the procedure		SWD(2014)0272	10/09/2014	EC	
Economic and Social Committee: opinion, report		CES5960/2014	21/01/2015	ESC	
Committee draft report		PE549.334	20/05/2015	EP	
Committee opinion	ENVI	PE546.581	18/06/2015	EP	
Amendments tabled in committee		PE560.826	02/07/2015	EP	
Specific opinion	JURI	PE564.927	03/09/2015	EP	
Committee report tabled for plenary, 1st reading/single reading		A8-0075/2016	05/04/2016	EP	Summary
Coreper letter confirming interinstitutional agreement		GEDA/A/(2018)007840	27/06/2018	CSL	
Text adopted by Parliament, 1st reading/single reading		T8-0422/2018	25/10/2018	EP	Summary
Commission response to text adopted in plenary		SP(2018)755	21/11/2018	EC	
Draft final act		00043/2018/LEX	12/12/2018	CSL	
Follow-up document		COM(2023)0078	17/02/2023	EC	

Additional information

Research document	Briefing
European Commission	EUR-Lex

Final act

Regulation 2019/4
OJ L 004 07.01.2019, p. 0001 Summary

Final legislative act with provisions for delegated acts

Medicated feed: manufacture, placing on the market and use

PURPOSE: to ensure a high level of protection of human and animal health, providing adequate information for users and strengthen the effective functioning of the internal market.

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: livestock production occupies a very important place in the agriculture of the Union. There are 13.7 million animal holdings in the EU. The value of livestock farming output in the EU is EUR 157 billion.

In addition, the protection of animal health constitutes one of the general objectives of EU food law.

The rules concerning medicated feed have significant influence on the keeping and on the rearing of animals, including non-food producing animals, and on the production of products of animal origin.

Council Directive 90/167/EEC constitutes the Unions regulatory framework for the manufacture, placing on the market and use of medicated feed.

Experience with the application of Directive 90/167/EEC has shown that further measures should be taken to strengthen the effective functioning of the Internal Market and to explicitly give and improve the possibility to treat non-food producing animals by medicated feed.

IMPACT ASSESSMENT: the impact assessment identified the following main axes along which the system has to change in order to answer the stakeholders concerns: residues of veterinary medicines in feed, imprecise dosage of veterinary medicines, impossible market access to medicated feed for pets and barriers to intra EU trade of medicated feed. The impact assessment concluded that an EU Regulation with detailed rules would have the most positive impacts and would provide for the best way forward to achieve the objectives for the EU.

The impact assessment concluded that an EU Regulation with detailed rules would have the most positive impacts and would provide for the best way forward to achieve the objectives for the EU.

CONTENT: the proposed Regulation seeks to update the current legislation on medicated feed by repealing Directive 90/167/EEC which sets out the conditions under which medicated animal feed may be manufactured, placed on the market and used within the EU.

The main elements of the proposed Regulation include:

Scope: the scope of the proposed Regulation covers the manufacture, placing on the market and use of medicated feed for use in pets and in food-producing animals within the Union. It does not apply to veterinary medicinal products used as the medicinal component of medicated feed (previously called "medicated premixes"), which are dealt with under the veterinary medicinal products legislation.

Manufacture, composition, placing on the market and use of medicated feed: the proposal:

- ensure that the general manufacture requirements laid down in Regulation (EC) No 183/2005 apply;
- stipulates that medicated feed may only be manufactured from veterinary medicinal products authorised under the veterinary medicinal products legislation;
- sets rules for the approval of feed business operators and rules they need to comply with in order to manufacture medicated feed;
- lays down rules for the homogenous incorporation of the veterinary medicinal products into the medicated feed and requirements in order to avoid carry-over of active substances from veterinary medicinal products into non target feed.

Labelling: the proposal provides that as regards labelling, the general provisions laid down in Regulation (EC) No 767/2009 on the placing on the market and use of feed should apply and that it be subject to specific labelling requirements in order to provide the user with the information necessary to correctly administer the medicated feed. It should also ensure that:

- specific rules for the prescription, the validity of the prescription, the use of medicated feed containing antimicrobials in food-producing animals and the quantities required for the treatment of animals with medicated feed are laid down;
- manufacturers, distributors and users of medicated feed are keep daily records for the effective tracing of medicated feed;
- for veterinary medicinal products authorised at national level, the Regulation sets Intra-Union rules for trade of medicated feed in order to prevent distortions in competition.

DELEGATED ACT: the proposal contains provisions empowering the Commission to adopt delegated acts in accordance with Article 290 of the Treaty on the Functioning of the European Union.

Medicated feed: manufacture, placing on the market and use

The Committee on Agriculture and Rural Development adopted a report by Clara Eugenia AGUILERA GARCÍA (S&D, ES) on the proposal for a regulation of the European Parliament and of the Council on the manufacture, placing on the market and use of medicated feed and repealing Council Directive 90/167/EEC.

The committee recommended that the European Parliaments position adopted at first reading following the ordinary legislative procedure should amend the Commission proposal as follows:

Legal basis: the proposal should be based on Article 43(2) whereby the ordinary legislative procedure is used for legislation necessary for the pursuit of the objectives of the common agricultural policy.

Scope: this Regulation shall apply to:

- the manufacture, storage and transport of medicated feed and intermediate products intended for both food-producing and non-food producing animals;
- the placing on the market, including import from third countries, and use of medicated feed and intermediate products intended for both food-producing and non-food producing animals.

This Regulation shall not apply to finished veterinary medicinal products to be orally administered that have been approved for use via feed as oral powders (via 'top dressing') or in drinking water. The Commission shall, by 12 months after the date of entry into force of this Regulation, propose a specific legislative proposal on the administration of veterinary medicinal products for use via feed or in drinking water.

Definitions: the report proposes:

- to amend the definition of ´premix for medicated feedingstuffs´, as the medicated premix is the veterinary medicinal product, which is an appropriate pharmaceutical form primarily authorised to be used incorporated in medicated feedingstuffs in conditions fully in compliance with the conditions of the marketing authorisation;
- to introduce the definitions of 'antimicrobials'and 'antibiotics' / 'antibacterials', as well as the definitions of 'preventive treatment (prophylaxis), 'control treatment (metaphylaxis) and 'curative (therapeutic) treatment' as laid down in the Veterinary Medicinal Products proposal;
- to define non-target feed as an ordinary feed containing no veterinary medicinal products;
- to define mobile mixer and on-farm mixer;
- to define 'cross-contamination' to mean a contamination resulting from a carry-over or from the transfer in feed of any unintended substance.

General obligations: Members added a provisions stipulating that distributors who supply medicated feed solely for non-food producing animals, which is manufactured and distributed in sealed bags and supplied under prescription directly to the animal holders, shall be exempt from the obligations of feed business operators.

Justification

The exemption proposed facilitates wholesale and retail (veterinary and pharmacist) distribution solely of medicated feed for pets without imposing unnecessary administrative burdens.

Composition: the feed used for the production of medicated feed shall comply with all relevant provisions of Union legislation concerning animal feedingstuffs.

Homogeneous distribution: it is stated that feed business operators manufacturing medicated feed shall ensure the homogeneous distribution (instead of homogeneous incorporation) of the veterinary medicinal product or the intermediate product in the feed.

Carry-over: according to the amended text, feed business operators shall manufacture, store, transport and place on the market medicated feed and intermediate products shall apply measures to avoid carry-over in accordance with the ALARA (As Low As Reasonably Achievable) principle, in order to avoid risk for animal health, human health or the environment.

The Commission proposes to establish a general 1% carry-over limit for all active substances containing antimicrobials, until such time as specific limits are set for each active substance individually. Members proposed that a 3% general limit for all active substances is more appropriate until specific limits - established by the European Feed and Safety Authority (EFSA) and based on scientific evidence - are fixed for each active substance.

The Commission shall, by means of implementing acts, establish a detailed schedule listing, in order of priority, the different active substances for which specific carry-over limits must be adopted. EFSA and the European Medicines Agency (EMA) shall be consulted as the list is being compiled. By two years after the date of entry into force of this Regulation, the Commission shall submit a report to the European Parliament and to the Council indicating the specific carry-over limits adopted.

Packaging: medicated feed and intermediate products shall be placed on the market only in properly labelled and sealed packages, including sack packaging, or containers. Appropriate derogations should be provided for those instances where the application of that requirement is not necessary to protect human or animal health or consumer interests, and would represent an excessive administrative and technical burden.

Trade with third countries: Members proposed that imports, from third countries, of food producing animals which have been administered medicated feed containing antimicrobial veterinary medicinal products in order to prevent disease shall be prohibited. Similarly, imports of foodstuffs derived from those animals shall be prohibited.

Prescriptions: the supply of medicated feed to animal holders shall be subject to the presentation and, in case of manufacturing by on-farm mixers, the possession of a veterinary prescription issued by a veterinarian or another professional person qualified to do so in accordance with applicable national law, following a proper assessment of the health status of the animals concerned.

Members called for prescriptions for medicated feed containing veterinary medicinal products which have anabolic, anti-inflammatory, anti-infectious (other than anthelmintic), anti-cancer, hormonal or psychotropic properties or substances only to be issued by a veterinarian after a clinical examination and diagnosis.

For medicated feed containing antibiotics, a physical examination and diagnosis shall be carried out for every prescription issued.

The duration of the treatment shall follow the valid summary of product characteristics (SPC) of the authorised veterinary medicinal product incorporated into the medicated feed and should not exceed three weeks in the case of medicated feed with incorporated veterinary medicinal products containing active substances with the potential to select resistance.

Significant and imminent health risks may be grounds for the limited and non-routine prophylactic use of vaccines and anti-parasitical treatments.

Use in food-producing animals: the Commission proposal sets limits for the quantities of medicated feed that suppliers are allowed to provide to farmers (one months supply or 2 weeks for antimicrobials).

Members considered that setting time limits of this type in an EU regulation is inappropriate. They suggested the quantities required for a treatment shall be determined in accordance with the summary of product characteristics included in the marketing authorisation of the veterinary medicinal product included in the prescription.

Use of medicated feed containing antimicrobials: Members stated that the prophylactic use of medicated feed containing antibiotics shall not be allowed unless such use is permitted under the veterinary medicinal products. The use of antibiotics to enhance the performance of food-producing animals shall be prohibited.

Prophylaxis with antibiotics shall not be applied routinely nor to compensate for poor hygiene or for inadequate husbandry conditions. However, such prophylaxis may be permitted in very exceptional cases before a disease is diagnosed or clinical signs of disease are present on the basis of the epidemiological and clinical knowledge of the veterinarian.

Annexes: in annex IV, the report proposes changes to the permitted tolerances of deviations from the amount of an active substance indicated on the label, in order to adapt them to the proportions used in the manufacture of medicated feed.

Medicated feed: manufacture, placing on the market and use

The European Parliament adopted by 583 votes to 31 with 6 abstentions a legislative resolution on the for a Regulation of the European Parliament and of the Council on the manufacture, placing on the market and use of medicated feed and repealing Council Directive 90/167/EEC.

The European Parliaments position adopted at first reading under the ordinary legislative procedure amended the Commission proposal as follows:

Purpose: the proposed Regulation shall establish new rules on more responsible ways to produce, sell and use medicated feed to tackle the spread of antimicrobial resistance. It shall apply to: (i) the manufacture, storage and transport of medicated feed and intermediate products; (ii) the placing on the market, including import from third countries, and the use of medicated feed and intermediate products; (iii) the export to

third countries of medicated feed and intermediate products.

Composition: the feed business operator manufacturing the medicated feed or intermediate product shall ensure that the medicated feed or intermediate product is manufactured in compliance with the relevant conditions laid down in the veterinary prescription for medicated feed or, in the summary of the product characteristics, related to the veterinary medicinal products to be incorporated in the fee.

Those conditions shall include particular provisions regarding known interactions between the veterinary medicinal products and the feed that may impair the safety or the efficacy of the medicated feed or intermediate product.

Operators shall also take measures to avoid cross-contamination, i. e. contamination of a non-target feed with an active substance originating from the previous use of the facilities or equipment.

The Commission shall be empowered to adopt delegated acts in order to supplement this Regulation by establishing specific maximum levels of cross-contamination for active substances in non-target feed. Those delegated acts shall be based on a scientific risk assessment carried out by EFSA.

Approval of establishments: the competent authority shall approve establishments only where an on-site visit, prior to start-up of the relevant activity, has demonstrated that the system put in place for the manufacture, storage, transport or placing on the market of medicated feed or intermediate products meets the specific requirements.

Feed business operators dealing with some lower risk activities, such as certain types of transport, storage and retail, should be exempted from the approval obligation, however this should not exempt them from the registration obligation.

Prudent use of antibiotics: the amended text emphasises that medical treatments, especially with antimicrobials, should never replace good husbandry, bio-security and management practices.

The new rules shall ban prophylactic (preventive) use of medicated feed or its use for improving animal performance, except in some cases for medicated feed containing antiparasitic and immunological veterinary drugs. Metaphylactic use, i.e. treating the whole group of animals when one is infected, will be allowed only when the risk of spread of infection is high and there is no appropriate alternative.

The use of medicated feed containing some antiparasitics shall be based on the knowledge of the parasite infestation status in the animal or group of animals.

Prescription: in order to ensure the safe use of medicated feed, its supply and use shall be subject to presentation of a valid veterinary prescription for medicated feed which has been issued by a veterinarian after examination or any other proper assessment of the health status of the animals to be treated.

Advertising: the new rules shall prohibit the advertising of medicated feed and intermediate products. That prohibition shall not apply to advertising made exclusively to veterinarians. The advertising shall not include information in any form which could be misleading or lead to incorrect use of the medicated feed. In addition, medicated feed shall not be distributed for promotional purposes except for small quantities of samples.

Imports into the EU: operators importing medicated feed or intermediate products into the EU shall ensure that the use of veterinary medicinal products used for the manufacture of such medicated feed or intermediate products is authorised.

Medicated feed: manufacture, placing on the market and use

PURPOSE: adopt new rules on medicated feed with a view to ensuring a high level of protection for human and animal health, providing adequate information for users and strengthening the effective functioning of the internal market.

LEGISLATIVE ACT: Regulation (EU) 2019/4 of the European Parliament and of the Council on the manufacture, placing on the market and use of medicated feed, amending Regulation (EC) No 183/2005 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC.

CONTENT: the Regulation establishes new rules on more responsible ways to produce, sell and use medicated feeds for animals in order to combat the spread of antimicrobial resistance. It will apply to (i) the manufacture, storage and transport of medicated feed and intermediate products; (ii) the placing on the market, including import from third countries, and the use of medicated feed; (iii) the export to third countries of medicated feed.

The new rules clarify, in particular, the following points:

Approval of establishments

Feed business operators manufacturing, storing, transporting or placing on the market medicated feed or intermediate products shall ensure that establishments under their control are approved by the competent authority.

The competent authority shall approve establishments only where an on-site visit, prior to start-up of the relevant activity, has demonstrated that the system put in place for the manufacture, storage, transport or placing on the market of medicated feed or intermediate products meets the specific requirements of the Regulation.

Feed business operators dealing with some lower risk activities, such as certain types of transport, storage and retail, will be exempted from the approval obligation, but this does not exempt them from the registration obligation.

Cross-contamination

Cross-contamination may occur during manufacture, processing, storage or transport of feed where the same production and processing equipment, including for mobile mixing, storage facilities or means of transport are used for feed with different components.

The Regulation sets out harmonised requirements to prevent cross-contamination of non-target feed with active substances. The Commission may establish, by means of delegated acts, specific maximum levels of cross-contamination for active substances in non-target feed on the basis of a scientific risk assessment performed by the European Food Safety Authority (EFSA) and in cooperation with the European

Medicines Agency.

Prescription and use

The new rules specify how to prescribe and use medicated feed containing antimicrobial agents for food producing animals.

The supply of medicated feed to animal keepers shall be subject to the presentation and, in case of manufacturing by on-farm mixers, the possession of a veterinary prescription for medicated feed. A veterinary prescription for medicated feed shall be issued only after a clinical examination or any other proper assessment of the health status of the animal or group of animals by a veterinarian and only for a diagnosed disease.

Prophylaxis or use of medicated feed to enhance the performance of animals will not be allowed, except, in certain cases, as regards medicated feed containing antiparasitics and immunological veterinary medicinal products.

The use of medicated feed containing antimicrobials for metaphylaxis will only be allowed when the risk of spread of an infection or of an infectious disease is high. The use of medicated feed containing some antiparasitics should be based on the knowledge of the parasite infestation status in the animal or group of animals.

Advertising

The advertising of medicated feed and intermediate products is prohibited. That prohibition shall not apply to advertising made exclusively to veterinarians. The advertising shall not include information in any form that could be misleading or lead to incorrect use of the medicated feed. Medicated feed shall not be distributed for promotional purposes except for small quantities of samples.

ENTRY INTO FORCE: 27.1.2019.

APPLICATION: from 28.1.2022.