Review of the medicated feed legislation

OVERVIEW

In 2014, the Commission presented a proposal for a regulation on medicated feed with the aim to update and harmonise rules that dated from 1990 and were laid out in a directive. Patchy national implementation was causing difficulties for producers, animal holders and the single market.

Due to the strong correlation between the proposal on medicated feed and the draft regulation on veterinary medicinal products, legislative work on both acts was being coordinated to assure consistency between their provisions. Parliament and Council reached agreement on the text of the proposal in June 2018. The final act was signed in December 2018 and entered into force on 27 January 2019. The new rules apply from 28 January 2022.

Regulation (EU) 2019/4 of 11 December 2018 on the manufacture, placing on the market and use of medicated feed lays down updated rules for the production, use and marketing of medicated feed; these rules apply across the EU. An important aim is to help tackle the issue of antimicrobial resistance, a growing threat to human health worldwide. The regulation introduces stronger requirements for producers and animal keepers, prohibits the preventive use of antibiotics in healthy animals and reiterates that antibiotics should not be used to enhance the performance of animals – a stance that the Parliament has strongly upheld.


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<th>Committee responsible:</th>
<th>Agriculture and Rural Development (AGRI)</th>
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<td>Rapporteur:</td>
<td>Clara Eugenia Aguilera García (S&amp;D, Spain)</td>
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<td>Shadow rapporteurs:</td>
<td>Daniel Buda (EPP, Romania)</td>
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<td>Giulia Moi (EFDD, Italy)</td>
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<td>Procedure completed:</td>
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Ordinary legislative procedure (COD) (Parliament and Council on equal footing – formerly 'co-decision')
Introduction

On 10 September 2014, the Commission adopted a proposal for a regulation on the manufacture, placing on the market and use of medicated feed, and repealing Council Directive 90/167/EEC. It justified the move with the need to modernise the rules dating from 1990 and eliminate the ambiguities in a number of provisions that caused divergence in national implementation. This was creating confusion among operators and obstacles in the single market. The proposal was presented in a package (the animal medicines package) together with another two thematically linked proposals for regulations: on veterinary medicinal products and on medicinal products for human and veterinary use. Parliament and Council reached agreement on the proposal in June 2018, the final act was signed in December 2018. The regulation entered into force on 27 January 2019, repealing the existing directive and harmonising the rules and their implementation across the EU. The new rules apply from 28 January 2022.

Context

Medicated feed is a mixture of a veterinary medicinal product (or products) and feed (or feeds) that is prepared for marketing and intended to be fed to animals without further processing. Medicated feed is mainly used to treat large groups of animals, where individual veterinary treatment would be too difficult or impossible. Its advantage lies in the ease of administration. Medicated feed is generally used for livestock, notably pigs and poultry (of the approximately 800 million farm animals in the EU, some 140 million are pigs and 450 million laying hens). The use of medicated feed for pets is much less frequent and this market is of minor importance, despite the large number of pets in the EU (roughly 200 million, of which 63 million dogs and 72 million cats). Ultimately, the extent to which medicated feed is used depends on factors such as cost-effectiveness, availability of the feed, policy and regulations at national level. All of these vary significantly between Member States.

Medicated feed must be manufactured by approved manufacturers (in feed mills), on the basis of an approved veterinary medicinal product intended for this purpose (premix). It is mostly compound feed manufacturers who produce medicated feed. However, this is only a minor part of the production of compound feed (depending on the Member State, ranging from as low as 0.1% to 9%), and is considered a special service to clients by the feed manufacturers.

By derogation, Member States may permit the preparation of medicated feed (with an authorised premix) on the farm where it is needed, to be mixed by animal holders themselves or by authorised mobile mixers, i.e. operators using a specially equipped lorry.

Medicine is usually administered to sick animals in order to cure a disease (therapeutic use). Sometimes, to control the spread of a disease, the treatment is extended to other animals in the herd that may be infected (metaphylactic use). The medicine can also be given to avoid the occurrence of the disease in the first place (preventive or prophylactic use). Antimicrobials are among the veterinary drugs used in medicated feed. The use of antibiotics as growth promoters to enhance production has been prohibited in the EU since 2006.

Incorrect use of antimicrobials can lead to antimicrobial resistance. Notably, at low-level exposure, the microorganism can adapt and become resistant to the drug. The risks of resistance may increase when animals are fed ordinary feed contaminated with drugs. This is known as cross-contamination or carry-over to non-target feed (feed not intended to contain a veterinary drug), and can occur during production, transport or storage, or on the farm. Antimicrobial resistance is a serious risk to public and animal health.

Repealing Directive 90/167/EEC

Originally, the conditions for manufacturing, placing on the market and use of medicated feed were laid down in Directive 90/167/EEC (the Medicated Feed Directive).
This directive provided, among other things, that:

- medicated feed had to be manufactured only with authorised premixes;
- the manufacturing premises had to be approved by national authorities;
- medicated feed could be supplied to animal holders only against prescription from a veterinarian;
- the medicated feed manufacturer was responsible for the quality of the products, for the homogeneity of the mix and for preventing contamination of non-target feed;
- the manufacturer had to keep records of the veterinary medicines they used and the feed they produced;
- when medicated feed was used in animals intended for human consumption, these animals could not be slaughtered before the end of the withdrawal period set for the active substances;
- Member States could authorise the manufacture of medicated feed on farms;
- Member States had to ensure that there are no obstacles to intra-EU trade in medicated feed.

The directive did not, however, provide common criteria for:

- the approval of production premises;
- the homogeneity of feed;
- anticipated production;
- the carry-over between medicated feed and non-target feed.

Moreover, it did not address anticipated production (i.e. the manufacturing of medicated feed prior to the issuance of a veterinary prescription and its storage until someone places an order for it) and it was also silent on medicated feed for pets. While requiring that medicated feed had to be manufactured in approved plants, the directive allowed a derogation for preparing such feed directly on the farm, with an authorised premix, giving only a general requirement that medicated feed should be sufficiently homogenous.

According to the European Commission’s impact assessment, some Member States authorise on-farm mixing, while others do not, on the assumption that quality cannot be ensured. Only a few Member States authorise mobile mixers, concerned about insufficient precision of the incorporation of medicine into the feed.

As regards carry-over, the directive stipulated that undesirable interaction between veterinary medicines and feed should be ruled out. Different approaches were taken by the Member States.

**Preparation of the proposal**

The Commission worked on the revision of the medicated feed legislation for several years. In 2009 and 2010, this legislation was the subject of an external evaluation by the Food Chain Evaluation Consortium (FCEC).

Based on this evaluation, as well as on consultations with stakeholders, experts, advisory committees, Member States and citizens, the Commission published an impact assessment of the proposal in September 2014. Of the options analysed, an EU regulation with detailed rules was considered the best way to achieve the set objectives.

The impact assessment identified four main problems that would need to be addressed in the revised legislation:

- residues of veterinary medicines (in particular antibiotics) in ordinary feed, resulting from carry-over during production or from contamination on farms;
- imprecise dosage of veterinary medicines, resulting from poor homogeneity of medicated feed;
barriers to intra-EU trade in medicated feed, resulting from diverging national interpretations;
impossible market access for medicated feed for pets.

EPRS published an initial appraisal of this impact assessment in 2015. Judging it generally reasonable, the appraisal pointed out that the possible impact was not always fully explored (for example costs to farmers and pet owners), that alternatives could have been better balanced and more options included. It also noted that neither the relationship between the proposal and the existing rules, nor the streamlining of legislation that would be achieved, were sufficiently explained.

The changes the new legislation will bring

Regulation (EU) 2019/4 repeals and replaces Directive 90/167/EEC. Most provisions are retained, many of them clarified. The main changes introduced aim to tackle the problems that were identified in the 2010 evaluation and the 2015 impact assessment.

The legislator addressed the problem of barriers to intra-EU trade in medicated feed by choosing the legal form of a regulation. Rules harmonised at EU level should improve clarity and legal certainty and facilitate activity in the single market. The scope of the regulation is extended to non-food producing animals, to include medicated feed for pets. Furthermore, anticipated production is explicitly allowed EU-wide, as are mobile mixers and on-farm manufacturing of medicated feed. To reduce the risk of antimicrobial resistance, rules on carry-over and preventive use of antibiotics are regulated. The limits for carry-over of veterinary medicines into non-target feed are set explicitly. Limits for specific active substances will be established by delegated acts. In the absence of specific values, general limits will apply depending on risk: for antimicrobials, 1 % of the active substance in the last produced batch of medicated feed; 3 % for other active substances. Preventive use of medicated feed containing antimicrobials is prohibited: the supply of such feed is restricted to quantities required for two weeks. Criteria for the homogeneity of medicated will be established by the Commission in implementing acts.

Advisory committees

The European Economic and Social Committee (EESC) adopted its opinion on both proposals for regulations on 21 January 2015. Regarding medicated feed, the committee welcomed the extension of the scope to non-food-producing animals and the allowance for anticipated production. It also seconded the prohibition of routine preventive use of antimicrobials, but believed that such use should be allowed when necessary, in cases identified by Member States. It pointed out that carry-over of the active substance is a reality, and that permitted levels must not be set at a value the industry cannot attain. Furthermore, it considered that medicated feed should also be available for minor species and aquaculture. It recommended establishing concrete criteria for the homogeneity of medicated feed and including provisions on the protection of workers. The EESC also called for greater value to be attached to the role of the veterinarian or skilled professional.

The European Committee of the Regions decided not to issue an opinion.

National parliaments

The deadline for the submission of reasoned opinions on the grounds of subsidiarity was 11 November 2014. Of the 16 national parliaments that made information about their scrutiny of the proposal available, none raised objections as to its compliance with the principle of subsidiarity.

Stakeholder views

The European Feed Manufacturers’ Federation (FEFAC) welcomed the publication of the proposals in September 2014 and the intended harmonisation of rules, but noted that the proposals did not
provide for a consistent framework for all veterinary medicines regardless of their route of administration (for instance, prohibition of preventive use in the proposal on medicated feed but lack of equivalent restrictions for oral powders etc. in the proposal on veterinary medicinal products). It pointed out that, for feed producers, manufacturing medicated feed is a service to farmers and not a commercial objective. FEFAC welcomed a number of provisions such as the possibility for anticipated production, the acknowledgement of an unavoidable carry-over and the introducing of its maximum levels. However, it was concerned that some requirements (such as excessive maximum carry-over levels) could make producers stop manufacturing medicated feed.

FEFAC also welcomed the result and the fact that the competent authorities acknowledge medicated feed as a safe and legitimate route of administration of medicines to sick farm animals subject to veterinary prescription.

The Federation of Veterinarians of Europe (FVE) supported the provision that medicated feed may only be administered on veterinary prescription and suggested strengthening this requirement, in line with the proposal on veterinary medicines. Veterinarians should be the only qualified persons to issue a prescription. All use of medicated feed should be closely monitored. Preventive use of antimicrobials in feed should be allowed only in exceptional circumstances. FVE expressed concern over anticipated production, considering that this goes against the principles of responsible use and should be avoided. It also found that more research is necessary on the use of medicated feed in pets.

The European Farmers and Cooperatives Association (COPA-COGECA) generally welcomed the aim to harmonise the rules and create – through a regulation – a level playing field for operators in the EU. It stressed the importance of the responsible use of antibiotics in the context of antimicrobial resistance. It furthermore stated that routine use of antimicrobials for prevention should not be permitted as a replacement for good hygiene practices, proper feed and appropriate environment; instead, it should be allowed under precise and defined conditions (always limited to the prescription of the veterinarian). The association also felt that the carry-over limit of 1% for antimicrobial substances is disproportionate, not feasible, and should be revised based on scientific risk assessment.

The Federation of European Companion Animal Veterinary Associations (FECAVA) did not support the new legislation. It pointed out that it can be difficult to ensure the correct dose of medicine when treating pets with medicated feed. Antimicrobials should never be included in medicated feed, as this can contribute to antimicrobial resistance. FECAVA stressed that further research is needed on the benefits and risks of medicated feed for pets and that there should be separate legislation for companion animals.

The European Consumer Organisation (BEUC) welcomed the aim to tackle antibiotics in medicated feed by setting a carry-over limit of 1% and prohibiting preventive use. BEUC believed, however, that a total ban on antibiotics in feed should be considered.

After the co-legislators reached final agreement on the text, stakeholders’ reactions were overall positive. AnimalHealthEurope welcomed the new rules, which, in its opinion, put the industry in a much better position to ensure availability of animal health products throughout Europe and to improve animal health management and animal welfare. The new rules are seen as a good tool to address antimicrobial resistance, while at the same time supporting innovation and reducing the administrative burden for the animal health sector. It also appreciated the provisions for companion animals that will help owners by offering new ways to treat chronic diseases.

**Legislative process**

The Commission proposal was published and submitted to the Parliament and the Council on 10 September 2014. In Parliament, it was attributed to the Committee on Agriculture and Rural Development (AGRI) as the committee responsible, with the Committee on Environment, Public
Health and Food Safety (ENVI) as committee for opinion. Clara Eugenia Aguilera García (S&D, Spain) was appointed rapporteur.

The ENVI opinion was adopted on 17 June 2015. It welcomed the intended harmonisation of rules and the extension of the scope to non-food-producing animals. The fight against antimicrobial resistance was considered a crucial point. The committee considered that use of antimicrobials in medicated feed needs to be reduced and the prophylactic use of medicated feed containing antimicrobials prohibited. Carry-over limits should be set on the basis of a scientific risk assessment conducted by the European Food Safety Authority (EFSA). Medicated feed should only be administered after examination, diagnosis and prescription by a veterinarian or another qualified professional, in accordance with applicable national law.

The AGRI committee asked the Committee on Legal Affairs (JURI) for an opinion on the legal basis of the proposal. Where the Commission’s proposal was based on Article 43 of the Treaty on the Functioning of the European Union (TFEU), the rapporteur preferred to reference only paragraph 2 of this article, which empowers the Parliament and Council to establish the common organisation of agricultural markets and other provisions necessary for the pursuit of the objectives of the common agricultural policy. According to the JURI opinion, of the two paragraphs (2 and 3) of Article 43 that could serve as the legal basis, paragraph 2 covers all aspects of the common agriculture policy included in the proposal, therefore this change would be appropriate.

In the Council, the proposal was attributed to the Working Party on Agricultural Questions (Feeding stuffs). A progress report was published on 7 December 2015, according to which, in the text redrafted by the presidency, special attention was given to measures to fight antimicrobial resistance: specific prescription for medicated feed; obligatory measures to avoid carry-over; and a maximum level of active substances in non-target feed.

The working party decided that, despite the different pace of work on the two proposals, they should continue to be treated as a package in order to ensure consistency.

During the Agriculture and Fisheries Council of 15 December 2015, many delegations stressed the importance of the joint adoption of both acts and noted that fighting antimicrobial resistance was an essential element of both proposals. Some highlighted the need to prohibit online sales of veterinary medicines requiring a prescription, and to ensure consistency between internal rules and import rules. Following this discussion, the examination of the medicated feed proposal by the Council preparatory bodies was put on hold until sufficient progress was achieved on the proposal on veterinary medicinal products.

In Parliament, the AGRI committee report was adopted on 15 March 2016. Amendments to the proposal concerned, among others, the following issues:

- **Scope.** Where food-producing animals are mentioned in the text, references to non-food-producing animals were inserted to reflect that the legislation applies to both groups. A new article was added, stating that the regulation will not apply to finished veterinary medicinal products administered through top dressing or in drinking water, and that the Commission should draw up a separate legislative proposal regulating the administration of veterinary medicines products through these routes.

- **Carry-over.** Instead of requiring that carry-over should be avoided, it should be kept as low as reasonable. The Commission should establish a list of active substances for which specific limits must be adopted. The proposed general limits (1 % for antimicrobials and 3 % for other active substances) should be amended to 3 %, regardless of the active substance. A 1 % limit was found to be too stringent and not viable.

- **Antimicrobials.** Prophylactic use of antimicrobials should be prohibited; antimicrobials should be used in exceptional cases only. This use should also be regulated under the veterinary medicines proposal. A provision allowing
metaphylactic use was added. The point about prohibiting the use of antibiotics as growth promoters was rewritten, so as to correctly reflect the fact that such a ban already applies and to stress that it should be strictly adhered to.

- The possibility for other qualified professionals to issue prescriptions, in accordance with national law, was clarified by adding this reference in the text.

With the adoption of the report, the AGRI committee also voted on opening interinstitutional negotiations. It was decided that negotiations would start after the beginning of the trilogues on the proposal on veterinary medicinal products (which, following a partial vote in plenary in March 2016 on amendments, had been referred back to the ENVI committee). Due to the slower pace of advancement on this piece of legislation, trilogues on medicated feed only began on 6 March 2018. On 19 June 2018, the co-legislators came to an agreement on a final compromise text, which was confirmed by the Council's Committee of Permanent Representatives (Coreper) on 27 June.


Parliament insisted that medicinal treatments should never replace good husbandry, bio-security and management practices, highlighting that prevention is better than cure and calling for prudent use of antimicrobials, as expressed in the ‘One Health’ concept, endorsed by the WHO and the World Organisation for Animal Health.

In addition, antibiotics must under no circumstances be used to enhance the performance of animals, and medicated feed containing antibiotics should always be prescribed by a veterinarian, following a proper physical examination of the health status of the animal or group of animals and only for a diagnosed disease.

According to the new rules, preventive use of medicated feed containing antibiotics is banned. Metaphylactic use, that is, the treatment of a whole group of animals when only one is infected, will be allowed i) when it is not possible to confirm the presence of a diagnosed disease (only applicable to parasite infection); ii) and when there is no appropriate alternative and the risk of spreading the infection is high.

Parliament strongly insisted on the extension of the new rules to all animal medicines administered orally, whether through feed or drinking water, including ‘top dressing’, and advised the Commission to consult the European Medicines Agency and establish appropriate rules. The final aim is the fight against antimicrobial resistance. The Parliament also called on the Commission to consult with the EFSA before commencing work on defining science-based specific maximum levels for cross-contaminations of various active medicinal substances.

Last but not least, Parliament was keen to remind that inappropriate disposal of medical feed poses risk to the environment and contributes to antimicrobial resistance.

As part of its implementation, the regulation requires the European Commission to adopt delegated and implementing acts. A list of these acts and documents regarding the progress of the work on this legislation is published on a dedicated Commission webpage.
EP SUPPORTING ANALYSIS

- **Medicated feed: manufacture, placing on the market and use**, European Parliament, Legislative Observatory (OEIL).
- **Veterinary medicinal products**, European Parliament, Legislative Observatory (OEIL).

ENDNOTES

1. European Feed Manufacturers' Federation (FEFAC), 2013.
2. FEDIAF Facts and Figures 2014.
6. This section aims to provide a flavour of the debate and is not intended to be an exhaustive account of all different views on the proposal. Additional information can be found in related publications listed under ‘EP supporting analysis’.

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